平成 18 年度　文部科学省大学知的財産本部整備事業

21 世紀型産官学連携手法の構築に係るモデルプログラムについて

大学におけるマテリアルトランスファーの現状と問題点

調査研究報告書

平成 19 年 3 月

国立大学法人 奈良先端科学技術大学院大学

はじめに

奈良先端科学技術大学院大学は、平成 18 年度文部科学省「大学知的財産本部整備事業」21 世紀型産官学連携手法の構築に係るモデルプログラムについて、の受託業務として「大学におけるマテリアルトランスファーの現状と問題点についての調査研究」を実施した。

本調査研究は、科学技術・学術審議会・研究基盤部会産学官推進委員会において検討が進められている「国際的な産官学連携の強化」について、国の役割として、国際的産官学連携を進める上での共通的な課題について調査研究を行い、情報発信していくことが重要であると共に、ライフサイエンス分野における特有の知的財産問題について議論していくことが必要であるとの指摘を踏まえ上記事業の一環として委託されたものである。

奈良先端技術大学院大学では、法人化前より多くのマテリアル提供を行い、その中でも民間企業に対する有償のマテリアルトランスファー契約（以下、MTA）を約 10 件行っている。その経験から、MTA においてマテリアルを用いた新規知的財産の取り扱い、研究結果の発表、マテリアルの改変、ライセンスの Grant、保証条項、免責条項など多くの問題があることを認識している。

そこで本調査においては、マテリアルトランスファーにおいて多くの経験と歴史を有している米国での調査を行い、MTA の類型化、問題点、管理体制を明らかにすると共に、MTA 問題点に対する解決策の調査を行い、さらに同時に有償バイオマテリアルの主な受け手である国内製薬メーカーに対する聞き取り調査を行いアカデミア MTA についての企業の立場からの意見を求めた。

本調査の実施にあたっては本学産官学連携推進本部特任教授を中心に調査チームを組織し米国アカデミア（7 大学・施設）への現地調査を行うと共に、国内企業・法人（製薬メーカー5 社および農水省独立行政法人）へのヒアリングを行った。さらに学外協力として元オレゴン健康科学大 Sandra Shotwell 氏に米国アカデミアにおける現状と問題点について調査を依頼した。

これらの調査結果・報告は第二章、第三章、第四章にそれぞれまとめられている通りであるが、第一章に総括したごとく、国内大学におけるマテリアルトランスファーの現状についてはいくつかの問題点が指摘される。しかしながらそれら MTA 上の問題点を克服改善する努力を通じて、今後おこるトラブルを未然に回避し、産学連携のさらなる促進を図ることが可能であると考える。

最後に本調査に協力をいただいた国内外の大学・企業の方々にあらためて謝意を表したい。

「大学におけるマテリアルトランスファーの現状と問題点に関する調査研究」研究代表者
奈良先端科学技術大学院大学　先端科学技術研究調査センター　教授

久保　浩三

目 次

Appendices 目次

調査チームメンバー

奈良先端科学技術大学院大学「大学におけるマテリアルトランスファーの現状と問題点に関する調査研究」
調査チームメンバー一覧

統括

久保　浩三	先端科学技術研究調査センター　教授・弁理士

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谷　直樹	知的財産本部　特任教授

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学外協力

Dr. Sandra Shotwell	元オレゴン健康科学大教授

第一章　本調査研究について

Ⅰ. 調査概要

■調査タイトル

大学におけるマテリアルトランスファーの現状と問題点

■調査目的

国際的な産官学連携の強化を図るためにライフサイエンス分野における特有の知的財産問題について議論・認識を深める、その一環としてアカデミアにおけるマテリアルトランスファーを取り上げ、現状・問題点を明らかにすると共に将来への展望を構築する。

■調査対象

- 国内製薬企業(大手・中堅製薬メーカー5 社)
- 米国アカデミア(NIH および 6 大学; メリーランド大学、エモリー大学、アリゾナ大学、UCSF、スタンフォード大学、ワシントン大学)

■調査項目

(国内企業)

- 企業より国内アカデミアへの譲渡状況
- 国内アカデミアよりのマテリアル受け入れ状況
- 海外アカデミアよりのサンプル受け入れ
- 基本的な問題点

(米国アカデミア)

- 各大学の MTA 担当組織について
- MTA 件数について
- MTA 分類
  アカデミア/非アカデミアの内訳、地域別、対価、バイオプロダクツの種類
- マテリアルに関する取り扱い規定およびポリシー
  成文化ルールの有無、マテリアルの帰属、対価の分配、処理フローチャート
- マテリアル移転契約
  MTA 雛型、対価決定方法、MTA 交渉担当者、契約書決裁
- マテリアル移転契約交渉時の論点となる交渉項目

■調査方法

ヒアリング調査および Dr. Shotwell によるレポート作成(別途記載)

■調査期間

2006 年 11 月～2007 年 3 月

■学外協力者; Dr. Shotwell(Alta Biomedical Group)によるレポート

- 調査目的; 米国アカデミアにおけるバイオマテリアルトランスファーの歴史と現状
- 調査対象: 米国アカデミアにおける MTA および BML(BIOMATERIAL LICENSES)
- 調査方法; 大学関係者への電話インタビューおよび WEB 検索
- 調査期間; 2007 年 1 月～2 月

Ⅱ. 調査報告　総括

1. 国内製薬メーカーからみたアカデミア・マテリアルトランスファー

国内アカデミアにおけるバイオマテリアルトランスファーの現状および問題点について企業の側からの見方を探るため、東京・関西に本社を有する大手・中堅製薬企業 5 社に聞き取り調査を行った。

研究開発に関わる領域は新薬メーカーにとって最高度の企業機密に関わる事項であることや時間的な制約（1 回あたり概ね 1 時間程度）から、網羅的な調査は避け、国内アカデミアにおけるマテリアルトランスファーの現状と問題点について実務担当者を中心に忌憚の無い意見を求めるということを主眼にインタビューを行った。

詳細は第 2 章にまとめたとおりであるが、特に大学にとって関心の深い国内アカデミアよりのマテリアル受け入れについては、各社とも積極的でない、あるいは止むを得ない場合を除いてできる限り回避したいとするのが（特に担当部門において）現時点でのいわば本音であるとみなされる。件数においては 1 社を除いて年間 10 件以下、国内アカデミアとのマテリアル受け入れは殆どないとする製薬メーカーも複数社存在していた。

その理由として多くの担当者があげたのが大学におけるバイオ知的財産処理の未熟さ、マテリアルトランスファーの基本となるべき、マテリアルについての権利・所有関係があいまいなままに交渉が進められるケースにしばしば遭遇することがあげられた。

さらにマテリアル対価の設定についても医薬品開発の現実的業務に殆ど無知なことから非常識に高額な要求がなされること、あるいは GLP 管理について信頼がおけないこと、さらに企業よりのサンプル供給のケースで依然しばしばみられる特に公表にかかわる遵守意識の希薄さなども企業が大学とのマテリアルトランスファーに消極的となる要因を形成しているように思われる。

一方、これに比較して数はあまり多くないが海外（米国）アカデミアとのマテリアル受け入れにおいては経済条件よりも権利関係・Legal 条項の処理などでメーカーの国際法務部門も動員した極めてハードな交渉になるケースがあるとのことで、第三章、第四章での米国アカデミアにおける MTA・BML（Bio Material License）の現状分析・聞き取り調査の結果を裏付けると共に、バイオ関係における国内大学知財部門とのギャップをも浮き彫りにしているといえよう。

しかしながら、一方において多くのメーカー担当者はライフサイエンス領域における国内の大学の基礎研究のレベルそのものについては否定的な見解はなく、むしろ高く評価している。

従って、今後大学知財本部がバイオ関係の専門知識あるいは交渉経験をもつ人材により支援充実されていけば、国内アカデミアよりのメーカーへのバイオマテリアル供与が活発化していくことは十分可能であると思われる。

2. 米国アカデミア現地調査

2007 年 1 月下旬、2 週間にわたってMTA 調査チームは米国アカデミアにおけるマテリアルトランスファーの現況についての現地調査を行うため、米国各地の大学・施設を訪問した。

訪問した大学・施設は 国立衛生研究所（NIH）の他、州立大学であるメリーランド大学、アリゾナ大学UCSF、ワシントン大学、私立大学であるスタンフォード大学、エモリー大学である。

訪問先選定にあたっては、本調査において協力を依頼した Dr. S. Shotwell（元 NIH 知的財産移転部門主幹）の尽力により、いずれもアカデミアにおけるマテリアルトランスファーについて多くの実績を有する施設・大学および熟練の担当者と面談することが可能となった。米国アカデミアにおけるライフサイエンス領域の研究資金の大半が連邦政府（NIH）によって供給されているという現状を反映して、州立・私立大学を問わず、NIH のマテリアルトランスファー・リサーチツールに対するガイドライン・方針に強く規制されていることが、これらの大学に共通した色彩を与えている。

その聞き取り調査結果の詳細は、訪問時入手した資料と共に第三章にまとめた。

今回の調査に当たっては、当日のインタビューを効率的実施し、かつ俯瞰的に調査結果をまとめるため、訪問先選定と同様に Dr. S. Shotwell の協力を得て共通質問シートを作成、事前に送付した。

今回調査を行った各大学はほぼ共通して知的財産移転部門（OTT； Office of Technology Transfer）に特許 IP 部門とは別に約 20 名程度の人員を擁し、その中にマテリアルトランスファー（MTA）を扱う専門のセクション（3 名から 5 名）を設けている。これは、現実的に年間数百件に及ぶ MTA を扱うために、それだけの人員が必要であると同時に、特化した技術的な修練もそこで行われているということになる。

マテリアルトランスファー（MTA）の件数は、各大学とも IN、OUT とも年間各 150 件から数百件程度を扱っているのが通常となっている。IN については、製薬メーカー・ベンチャーよりの受け入れが受け入れ総数の半分程度を占めているが、OUT については企業への MTA による供与は 10％程度と少ない。これは企業への供与は経済的対価をフレキシブルに設定できる BML（Biomaterial License）を用いることが多いことによるようである。

なお、企業との BML を含めたマテリアルトランスファーの総数は今回調査の対象とはしなかったため、かつ担当者が MTA 部門とは別部門であるため、正確な数は不明であるがインタビュー時の印象よりは各大学とも年間数十件程度に達すると思われる。

対価については、マテリアルトランスファーに限っては無償もしくは製作費実費程度で供給されている。これは対企業の場合も同様で大学の公共的使命および各大学への研究資金の大半を供給している NIH の姿勢（企業・大学を問わずバイオサイエンスにおける非排他的なサンプル供給を促進させる）を反映しているものであろう。

一方では BML のケースにおいてはそのサンプルの商業的価値に応じた対価が個々のケースにおいて UPFRONT、Royalty などと組み合わせながら、定められ、大学への収入確保という面もそこでは配慮されているようである。

制度的な側面においては今回インタビューを行った各大学とも MTA 書式、サンプルに関わる研究者への Q&A より始まるフローチャート、署名者の規定など、十分に整備され、ほとんど問題とする点は残されていない。

MTA 書式については、NIH の指導のもとに整備された UBMTA（Uniform Biological Material Transfer Agreement）、Simple Letter Agreement が基本フォームとして各大学とも使用、企業にもその趣旨が徹底されているため、大学よりのサンプル提供における制度的な面においては企業・大学の間においてその混乱はないようにみられる。

しかしながら企業よりのサンプル受け入れについては、近年の製薬産業におけるベンチャー企業の比重の増加に伴い、より自らの利益の確保を絶対的に行わねばならないベンチャーの責務と大学における独立した研究を確保したいという大学側の姿勢とあわせ、対立は鋭角化し、その交渉は複雑かつ困難なものとなっており、大学側もそのマテリアルの研究への必要性に応じ、場合によっては Academic Freedom という大原則の一部修正・妥協にも応じざるを得ない実情がうかがわれた。

以上、米国アカデミアにおけるマテリアルトランスファーの現状は、MTA で処理されるべき非商業的移転については、大学より企業へのサンプル移転、大学−大学間の移転など総体としてはスムーズに処理されていると思われる。また商業的研究のためのマテリアル移転においても、概ね円滑な関係が確立されていよう。

一方、大きな問題点はバイオサイエンスにおいて既存の製薬メーカーに代わって研究開発面で比重を増加させているベンチャーとのマテリアルトランスファー（受け入れ）にあり、これはまだ包括的な解決策の提起には至っていないと考えられる。

3. Dr. Shotwell らによる米国アカデミアにおけるマテリアルトランスファーの現状分析

調査チームの米国現地調査をさらに補完し全体への俯瞰を与えるものとしてDr. Shotwellらによる報告書(第四章)がある(Dr. Shotwell は NIH においてマテリアルトランスファーの政策立案に深くかかわり、UBMTA を企画立案した経歴を有している)。

本報告書は分析レポートと資料部分に分かれている。資料部には UBMTA をはじめとする各種大学における MTA 書式および BML が多数収載されており国際的産官学連携を今後推進するにあたってそれ自体として十分な価値を有していよう。

また分析レポート後半では、マテリアルトランスファー契約(特に INCOMING)において企業との対立点をいかに解決していくかを中心に条項別に分析されており実務的ガイダンスとなるものと考える。

一方、分析レポート前半においては、1980 年におけるバイドール法の成立が米国アカデミアにおけるマテリアルトランスファーについて決定的な転回点となったことを基軸にその歴史的経過をふまえた現状分析が述べられている。

特に注目すべき視点としてバイドール法の成立およびその後の諸制度の整備が大学よりのバイオマテリアルの移転にあたって、契約および交渉の必要性を飛躍的に増大させたこと、バイドール法の予想外の転帰あるいは弊害として大学を介するリサーチツール・バイオマテリアルの自由な流通が劇的に減少してバイオサイエンスへの悪影響が懸念されるに至ったこと、米国において大学への研究資金の大半を供給する NIH がその状況を憂慮、90 年代後半以降それらを回避する措置を次々ととり、特にバイオサイエンスにおけるリサーチツールについては非排他的な流通・拡散を強く促していることなどが述べられている。

本報告書の概念的理解の一助とするため、以下項を改めてShotwellらのレポートにもとづき、米国におけるマテリアルトランスファーの歴史的背景ならびにその契約形式的側面(MTA および BML)についての分析の一部を概観する。

4. マテリアルトランスファーの歴史的経緯と契約形式（MTA および BML）

4-1. マテリアルトランスファーの歴史的経緯

バイドール法以前

第二次大戦後、米国連邦政府は軍事およびヒューマンヘルスの分野での研究開発活動に対する支援を強化した。種々の政府機関ならびに政府よりの受託機関（主に大学）がその種々のプロジェクトについての資金を受領している。2002 年には非軍事的 R&D への支出は 233 億ドル（2 兆 8 千億円）に達した。しかしながら 1950 年代までは政府は資金援助をした研究から得られる成果・発明について統一した政策を有していなかった。26 に及ぶ政府官庁がそれぞれ独自の特許及びライセンスに関わる方針を有していたのである。したがってもし企業が政府資金によってなされた発明を応用・発展させたいと意図した場合、その 26 にも及ぶ政策・方針のどれによってその発明がカバーされているのかを調査・決定しなければならなかったのである。このような官僚的な障害は連邦政府により支援された研究からの発明を利用しようという企業の意欲を大いに阻害するものであった。

1960 年代になると米国議会はこの弊害に気づき、米国産業が外国産業と成功裏に競争していくためには、連邦政府により支援された研究からの発明をより企業にとって利用しやすくするための政策の検討を開始した。以下のような政策が立案された。研究開発に資金を供給したそれぞれの政府機関にその研究開発活動から得られた発明の所有権を与えると同時に非独占的なライセンスによってそれらの発明を商業化のために利用可能としようというものである。連邦政府資金によってその発明を実際になした研究グループはその発明を使用するための非独占的かつロイヤルティーフリーのライセンス（non-exclusive royalty-free license; NERF license）を与えられることとなった。大学よりのさらに権利を与えられるべきであるという要請に応える形で、HHS（Health and Human Services）及び NSF（the National Science Foundation）は機関間の特許合意を締結するに至る。この合意により、承認された特許方針・政策を有する大学は政府資金援助による研究から得られる成果・特許についての所有権を有することとなった。このような改善にもかかわらず、バイドール法通過以前においては、3 万件もの政府所有特許のうち、わずか 5%が企業にライセンスされたにすぎなかった。

バイドール法

1980 年、連邦議会は後にバイドール法あるいは単にバイドール（Bayh-Dole）として広く知られることになる法律 Public Law No.96-517 を通過・成立させた（ちなみに Bayh-Dole という名称は本議案を提出した二人の上院議員 Birch Bayh と Robert Dole による）。本法律は政府資金により援助された発明が企業化される率の低さを改善し、かつそれらの発明を製品化するための大学と企業との間の協力・連携を活発化させようという議会の努力が現実化されたものである。この法律は技術移転の枠組みを提供したものであり、ここでいう技術移転とは大学より企業への技術（政府資金による研究の成果としての発明・発見）の移転（ライセンスあるいはその他の形態による分布拡散）を指している。もとより企業はそれらの発明を

製品化するための努力を行うことになる。単純化していえば、バイドール法は税金によって支払われた政府支援の研究をさらに納税者の利益となる製品として結果させようというものである。

バイドール法の最も重要な側面は、大学にその研究者によって政府資金研究によりなされた発明・発見に所有権を与えたことにある。その根拠・理由は資金を与えられた者にその発明の所有権を付与すれば、大学はより積極的にその発明を特許化し商業化しようという意欲にかられるであろうし、言葉を変えていえばより公共の利益に貢献しうるということを生じると予想されるためである。所有権の獲得は、その保持者に対してその特許化された技術を公共あるいは企業に移転すべき機会を奨励する契機となり、その対価として特許保持者は研究開発に対する評価と、さらにその特許を用いて企業が市場化したときに金銭的なリターンを獲得することができるようになったのである。

連邦政府資金による研究より生じた発明を所有する権利を得たことに対する代償としてバイドール法は大学が幾つかのの責任を負うべきことを規定している。すなわち大学が連邦政府資金による研究から生じた発明を所有することを決定した場合、主要に負うべき責任・義務としては、

- 発明について特許保護を求めることならびに実際的にその発明の商業化の努力を行うこと
- 発明が生じた研究資金を支援した連邦政府機関に対してその商業化努力の報告を行うこと
- 例外的なケースを除いて、その発明を他の団体・法人へ譲渡できないこと
- 発明をライセンスする場合、米国の企業に第一優先権をあたえること、米国企業についてはより小規模の会社が望ましいこと
- いかなるライセンスにおいても連邦政府に対して Worldwide な非独占権を留保すること
- ライセンスによるロイヤルティー収入は発明者および教育・研究目的の使用に分割されるべきこと

などが規定されている。またバイドール法の実際の運用については“Code of Federal Regulations”にその詳細な解説が記載されている。

バイドール法と MTA 契約の増加

バイドール法は本法における発明（invention）を以下のように定義している。

- 特許取得が可能な、あるいは法のもとで保護可能な発明もしくは発見、あるいは法の下で保護可能な植物の新品種、これらの発明が連邦政府支出の資金による研究遂行中になされたものであること。

この定義により、大学は連邦政府により資金支援された研究から生じた有体マテリアルについてその特許すべき諸性質とともにその所有権を確保するに至った。

大学がマテリアルを所有する場合、大学はそのマテリアルについてどのようなことが起こるかについて関心を持つべき多くの理由を有していることになる。例えばそのマテリアルの商業的価値を追求することを欲するかもしれないし、またマテリアルが誰かに危害を生じた場合に起こりうる訴訟から保護される必要がある。

これらのことから、大学はマテリアルの使用と流通をコントロールする必要がでてくる。このことはマテリアルトランスファー契約（MTA）として知られる契約によってなされる。

技術移転の分野が成長し拡大していくにつれて、大学は技術移転を有力な収入確保の手段としてみるようになり、また研究の成果として得られた有体物の潜在的な価値を防御することがさらに強調されるようになった。このことは結果として毎年締結される MTA の数がおおきく増加することを招き、さらにそれを締結するために必要な交渉も同様に激増していくこととなった。

4-2. マテリアルトランスファーの契約形式；MTA 及び BML

MTA とは何か

研究目的のマテリアルの共有は、特にバイオサイエンスにおいては新知見の発見と進歩にとって最も重要な要素の一つである。歴史的に企業は自らの研究者によって創出されたマテリアルの外部使用について、厳しい制限を課するのが常である。一方、近年に至るまで、アカデミアの研究者によって作り出されたマテリアルについては、自由な流通がその常であり、何らかの制限が課されるのは極めて例外的なケースであった。

しかしながら大学への発明所有権の移転により、米国と同様わが国においても全くの制限なしの流通は急速に減少している。最近ではアカデミア間の移転であろうとも、MTA を伴わないケースはまれになりつつあると考えられる。

MTA は法的な拘束性を有し、一方から他方への有体物の移転を統御する契約である。

本契約は、ある特定の組織より別の組織への移転されるある特定のマテリアルについてその移転に際しての条件と使用方法について規定するものである。通常移転されるマテリアルは、動物モデル（トランスジェニックあるいはノックアウトマウス）、細胞ライン、バクテリア、プラスミド、ファージ、核酸、蛋白、医薬品、化学物質さらにその他の有用な反応試薬などがある。マテリアルは特許で保護されている場合もあればそうでない場合もある。そうでない場合は、特許申請中のケースと全く特許で保護されていないケースがある。

それぞれの MTA の詳細な条件はマテリアルの提供者と受領者の間で交渉される。典型的なあるいは雛型の MTA を用意しようという努力は常になされているが、どのマテリアルトランスファーにも適用可能な共通の MTA というものは存在していない。しかしながら特にアカデミア間においては多くの場合、いわゆるモデル MTA に基づいて交渉が開始される。ただ残念なことに、このような限定されたアカデミア間のケースにおいても、1 年あるいは 2 年という短期の間に重要な変更を必要とする点が生じる。したがって結果として大半の場合、MTA はケースバイケースとして処理されるということになる。すべてにおいて共通して使用される MTA というのは存在していないにもかかわらず、大半の MTA は共通して以下のような事項についての規定を有している。

1. 移転されるマテリアルの正確な定義
2. 移転されるマテリアルについてそれぞれが持つ興味と権利
3. 受領者がどのようにマテリアルを使用するか
4. 受領者のマテリアル使用についての制限（MTA 下で移転されるマテリアルはほとんど常に内部研究

目的のみの使用に限られ、またヒトへの使用は禁止される）
5. 秘密保持の義務
6. 受領者のマテリアルを用いた研究成果の公表についての権利
7. それぞれが有すべき、研究成果、新規マテリアル、当該のマテリアルを用いた新規発明についての権利と利益
8. 受領者より供与者へ支払われるべきマテリアルトランスファーに伴うコスト（例えば受領者はマテリアル移転の移送費、製作実費を通常負担する）
9. 各種既定法に対するそれぞれの責任
10. 保証の回避ならびに免責、受領者がマテリアルを使用することから生じる製造物責任について
11. 準拠法
12. 余剰サンプルの処理方法

何故 MTA を用いるのか

MTA はマテリアルの供与者に対してそのマテリアルがどこで、いつ、どのように使われるかについてコントロールする権限を与える。また受領者がそのマテリアルを使用することから生じる法的な製造者責任を軽減させる。さらにマテリアルの供与者は MTA を用いることによって受領者がそのマテリアルを用いて行った研究成果に対するアクセスを得ることができる。MTA が受領者としての大学に与える最も主要な利点の一つはマテリアルを用いて行った研究成果を公表することを保証することにある。また、しばしばMTA は受領者が研究成果を所有することを防衛する。

バイオマテリアルライセンスとは何か

バイオマテリアルライセンス（BML）と MTA は多くの共通点を有しているが、一方では明確な差異点を有している。共通点としては、両契約形式とも交渉に基づき締結される一方から他方への有体物の移転を規定する契約であり共通の規定事項としてマテリアルの定義、所有権、マテリアル使用による生成物についての所有権、支払われるべきコスト、法的規制に対するそれぞれの遵法義務、準拠法などがあげられる。

一方、MTA とBML の最も顕著な相異は、BML が MTA においては受領者に対して非商業的な研究への使用のみが許可されるのに対し、BML においては受領者あるいはライセンシーに対してより広い権利が供与されるということにある。また BML においては、受領者はしばしばそのマテリアルについて商業的な利用を追究する権利を供与される。とりわけライセンシーはバイオマテリアルあるいはそのバイオマテリアルを使用して創出された新しいバイオマテリアルについて使用・利用・販売・製造する権利を供与されうる、また BML によりライセンシーはライセンサーの保有する特許の使用権も得ることができる。

一般的に BML はライセンシーにそのバイオマテリアルを商業的に使用する権利を供与することから、ライセンサーには一定の額の経済的対価が支払われるのが通常である。

経済的対価の支払は通常は金額の支払でなされるが、その額についてはライセンサーとライセンシー

の間の交渉で決定される。一般にその対価の支払については 2 種類の形式がある。

- 全額一時支払い（Fully Paid-Up License）；契約締結後直ちにライセンシーはライセンサーに取り決めを行った一定の額の一時金を支払い以降契約終了までいかなる金額の支払いも要しない。
- 締結時一時金の支払いと契約期間中のロイヤルティーの支払い；契約締結時直ちに一時金を支払うと共に契約期間中、マテリアルあるいはマテリアルを使用して創出された製品の売り上げに応じた一定額がライセンシーからライセンサーに支払われる。このような場合、一時金の額は Fully Paid-Up License の場合に比べて少ない。

どのような場合に BML を用いるのか

一般的にいって、大学が他の大学にマテリアルを移転する場合は常に MTA を用いる。マテリアルを企業に移転・供与する場合に大学は MTA を用いるのか BML を用いるのかを選択する。それはマテリアルの属性とまた企業がそのマテリアルをどのような意図で使用するかによる。企業が大学にマテリアルを供与する場合は常に MTA を用いる。これは大学は非営利機関であり、サンプルを商業的に使用することができないためである。

4-3. リサーチツール　その円滑な使用にむけて

バイドール法の予期せざる結果の一つとして、連邦政府資金を用いた研究において創出された研究成果物の自由かつ無償の流通が顕著に減少したことがあげられる。その障害となったのは主にMTAである。すなわち MTA を用いた結果として、マテリアルの受け渡しに非常な時間を要するようになっただけでなく、場合によってはマテリアルの移転そのものが阻害されるケースも出るようになった。このような状況を改善するため、NIH は UBMTA と略称される統一的な雛型書式を創出した（UBMTA；Uniform Biological Materials Transfer Agreements；本調査報告書 Appendices 1 および 2）、NIH は本書式が基準書式として広汎に用いられるべき MTA となりマテリアル移転を簡素化することを期待したのである。300 以上の施設が UBMTA の使用に基本的に同意したが、実際には本 MTA がそのまま用いられることはごく小数例にとどまり、いずれかの条項・語句に一部改変が加えられるのが常であり、必ずしもその目的が達成されたとはいえなかった。このような現状を憂慮し、NIH 責任者は技術移転にかかわる研究者および専門家を糾合し、問題点の所在と必要な勧告・指針の調査研究を開始した。

1998 年 6 月、調査グループは報告書を提出した。その報告書に述べられた勧告の一つが NIH は、施設間での連邦政府資金より創出されたリサーチツールの移転を円滑にすべく合理的なMTAならびにライセンス条件を記述したガイドラインを起案し公表すべきであるというものである。1999 年 5 月に NIH はリサーチツールガイドライン（案）を公表した。本ガイドラインには NIH より資金を給付される各施設に対して NIH が望むべき基準が述べられている。ガイドラインは 1999 年 12 月 23 日に最終化された。

このガイドラインは以下の 4 つの原則を有していた。

（1） 科学者は自由に科学者同士共同すべきでありかつ時宜を得たタイミングで研究結果を公表しな

ければならないこと。

(2) リサーチツールの制限的なライセンスおよび排他的な特許出願は避けられるべきこと

(3) リサーチツール移転に際して書類上の処理およびいたずらな引き延ばしは可能な限り避けられるべきこと

(4) NIH 資金を用いて行われた研究より生まれたユニークな価値を有するリサーチ成果物はすべてリサーチコミュニティーに使用可能とされるべきであること。

しかしながら、NIH ガイドラインの公表は研究成果物移転をめぐる種々の不満を沈静化させることはできなかった、NIH ガイドラインが有用なものであり本当に適用可能なものであるかについて繰り返し議論が行われた。2001 年 10 月に NAS(the National Academics of Science)は NCI(National Cancer Institute)、NSF(National Science Foundation)、Sloan 財団(the Sloan Foundations)の支援賛同のもと“公表された研究データとマテリアルの共有について; 生物科学における著者の責任”と題する調査委員会を発足させた。この委員会の任務はライフサイエンスにおけるデータ及びマテリアルの共有についての報告者の責任を規定するための調査研究を行うものであった。本報告において公表された研究データとマテリアルを共有することについて統一的な基準を策定すべきこと、なぜならこのような基準の策定と流布こそが科学の進歩前進を促すものであることが強調されている。

このような研究マテリアル共有に関する問題は米国のみならず欧州においても議論されている。2002 年 1 月に OECD は世界規模のリサーチツールの WEB が科学の進歩に大きく貢献するものであること、またリサーチツールに対するアクセスに制限を加えることは大きく科学の進展を損なうものであることとする報告をまとめている。

5. まとめ

以上のようなわたしたちの調査は製薬メーカーおよび米国アカデミアといういわば外部の眼に依拠したもので、もとより一定の限界を有している。同時に進められた国内大学におけるマテリアルトランスファーの現状についての網羅的な調査結果と結合して、包括的な展望は語られるべきであると考える。

ただ、そのような限定下においてわたしたちの調査から、なお、提起すべきものがあるとすれば、大学の公共的使命さらにバイオサイエンスの成果が究極的には、国民大衆の福祉・健康に奉仕すべきものであるという視点からは、研究目的として使用されるバイオマテリアル・リサーチツールの非排他的な流通を促す大胆な施策（MTA 共通書式の整備、バイオ専門スタッフの充実など）が必要と考えられる。

一方、マテリアルの商業的移転・研究使用については画然と区別されるべきで、大学への正当な対価（経済的条件）を保証する BML の整備と国際的スタッフの充実が図られるべきであることもまた重要なことと思われる

さらに今後創薬の分野においては既存の製薬メーカーを凌駕する研究を展開するに至った欧米バイオベンチャー企業との対応についても十分な国際的経験の共通化とスタッフの充実が急務と考えられる。

第二章　国内企業調査

Ⅰ. はじめに　国内製薬企業への聞き取り調査について

奈良先端科学技術大学院大学・MTA 調査チームは、2006 年 12 月より 2 月にかけて国内アカデミアにおけるバイオマテリアルトランスファーの現状および問題点について企業の側からの見方を探るため、製薬企業 5 社に聞き取り調査を行った。

マテリアルトランスファーと深く関わる研究開発の領域は新薬開発を使命とする製薬企業にとって、もとより最高度の企業機密事項であるが、一方では投資家に対する公正な情報提供という観点から、企業自身による積極的な disclosure や社外の第三者たとえば、証券アナリスト等による情報分析が活発に進められている分野でもある。

今回の調査にあたっては東京・関西に拠点を有する製薬大手・中堅企業に対して、ほぼ無作為的にインタビューを申し込んだが、一部を除いて誠実な対応を受けることができた。厚く感謝したい。

本聞き取り調査をまとめるにあたっては、研究開発の具体的なプロジェクト名を避けることはもちろん、企業名を特定できるような内容も極力排除したが、なんらかの類推が可能であるとしたら、それは一に編者の責任によるものである。

主に時間的な制約から、網羅的な調査をおこなうことはできなかったが、今回の聞き取り調査によって、国内アカデミアのマテリアルトランスファーの現状を、バイオ産業の側よりいわば逆照射するという試みは一定程度達することができたと考えている。

調査に応じていただいた方々は研究本部・研究企画部門でマテリアルトランスファーの主として交渉・契約に携わる部門に属するケースが最も多かったが、ライセンス・事業開発部門あるいは法務部門に属するケースもある。

聞き取り調査を行うにあたって、調査チームの問題意識を明らかにするためもあり質問事項のガイドラインとして共通の質問事項を章末に送付したが、むしろ率直に国内アカデミアにおけるマテリアルトランスファーの現状について意見を聞きたいとの主旨・意図から必ずしも、これら個々の項目に沿っての回答を求めたわけではないことを付記しておきたい。

Ⅱ. 国内企業聞き取り調査のまとめ

各事項ごとの回答まとめ、さらに各企業ごとの調査概要は本章後半部にまとめたとおりであるが、全体的な特徴あるいは事項毎の特記事項は以下の通りである。

●企業より国内アカデミアへの譲渡状況および譲渡ポリシーについて

メーカー各社によって対応に大きな差がみられたのが特徴である。特に製薬メーカーがライブラリー中に有する化合物あるいは市販品については、開発・販売に支障が無い限り（あるいは少々あっても）要請の有る限り対応するとするメーカーから、これらは企業KNOW-HOWの一部であり提供は行わないのを原則とするメーカーまで大きな幅があった。

これらは、各メーカーのポリシーでありあえて云々すべきものでもないと思われるが、積極的にサンプルを提供するメーカーにおいても提供側への事前通知なしの大学側のデータ発表などについて担当者は少なからぬ不安・不信を有しているように窺われたことは記しておきたい。

化学合成品以外の抗体、細胞、Knock Out マウスなどのいわゆるバイオロジカルサンプルについては、単独の MTA での提供は殆どなく共同研究の枠組みの中での提供がその殆どである。

●国内アカデミアよりのマテリアル受け入れ状況およびそのポリシーについて

国内アカデミアより年間 25 件程度を受け入れている 1 社を除いて MTA の下にサンプルを受け入れる件数はどのメーカーとも年間 10 件以下である。その殆どが遺伝子、Cell Line などのバイオロジカルマテリアル。共同研究などで受け入れる件数をいれてもその件数は多くない、メーカーによっては数年間ゼロというケースもあり、聞き取り調査全体のトーンからも企業が国内大学からのマテリアル受け入れ・購入に必ずしも積極的でないことは事実であろう。

これの要因としていくつかの理由が担当者よりあげられた。

医薬品開発の特質として、大学がその特徴として多く有する特殊な評価系は膨大な開発データの一部をなすもので、1 薬理データが必須コンポーネントであることは可能性としては大きくなく、いつでも代替可能であること。

従って、大学がメーカーからみて、サンプル譲渡にあたって不当な条件（対価、リーチスルー、ロイヤルティーなど）を要求された場合は研究者に断念を要請することも可能であること。

大学での GLP 管理について全幅の信頼がおけないこと、例えば実験動物については感染リスクがある

ことから大学よりの受け入れは全面禁止としている。

研究者個人と大学の関係、第三者との関係など、マテリアルについての権利関係が必ずしも明確でないまま交渉が開始され、交渉途中でそれらが露呈することがあり、契約締結に多大の労力を必要とすること、また研究者の移動に伴う権利関係の処理についても大学・機関で取り扱いが相違すること。

●海外アカデミアよりのサンプル受け入れについて

海外、その殆どが米国であるが、権利関係の主張が明確かつシビアであるのが特徴、特に 経済条件の議論・交渉よりも legal 条項あるいは知的財産権の処理でハードな交渉になり、研究部門だけでは対応が難しいケースも存在しているようである。

●その他あるいは全般

各メーカー担当者のコメントとして国内の大学の研究レベルそのものについては否定する意見は無く、むしろ高く評価されている。

ただ、それを MTA という形態に要約したとき、大学側の知財処理における種々の未成熟な面が露呈し、メーカーとして積極的な受け入れに躊躇しているというのが担当者のコメントである。

その未熟さは、メーカー担当者によれば一方では医薬品開発の実態から遊離した MTA の経済条件についての過大な要求・条件となってあらわれ、一方ではマテリアル権利関係のあいまいさや契約規定の遵守が必ずしも徹底されないことなどに表現される。

これらの問題点については大学知財本部が研究者との関係で定着していくにつれ解決されるのではないかとメーカーよりは期待されている。

Ⅲ. 製薬企業 5 社および農水省系独立行政法人への聞き取り調査（項目別まとめ）

●マテリアル譲渡状況（OUTGOING MTA）について

アカデミアへの提供

A 社

- 年間 5, 6 件、国内の大学がメイン。特殊な cell line。

B 社

- アカデミア・大学への提供は発表済みの化合物を中心に年間 300-400 件に上る。無償で、雛型契約を用い、定型的に処理。
- 大学・Academia との間でマテリアルだけのやりとりは例が少ない。
- 米国との場合はリサーチツール的なもののやりとりは大半がベンチャー。

C 社

- 国内の大学は共同研究の枠組みの中で Material のやりとりも処理するケースが大半。
- 国内外のアカデミアとの試料のやり取りは OUT が大半。
- 件数は OUT が共同研究における試料のやり取りを含め年間 100 数十件、内海外が約 20 件。
- 海外は欧州・米国のほかに、子会社の存在するアジア（韓国・台湾）など。
- OUT の場合　種類は抗体、遺伝子、化合物 etc　種々、ほとんど全てが無償。

D 社

- 特に国公立に対しては無償。
- アカデミアへの提供、年間 10 件未満。

E 社

- 国内が大半、細胞、Knock out マウス、病態モデルマウス、化合物など基本的には無償。

農水省系独立行政法人

- 大学・理研などの公的研究機関へ月 1-2 件。

●マテリアル受け入れ状況（INCOMING MTA）について

A 社

- 受け入れ　年間 50 件程度、国内外の区別ではおおむね 50：50。海外の場合、米国が大半。
- 種類は特殊な評価系を IN するというケースが約 8 割、それ以外は上流遺伝子などであるが、ゲノム創薬の退潮傾向にともないその数は減少している。
- 実験動物については感染リスクなどを考慮して大学よりの直接の受け入れは行わない。
- 対価については有償・無償、いずれのケースもあるが、有償のほうが多い。
- 単価の算出は難しいが、評価/cell line のケースで 1 件あたり数十万円から、100 万円、200 万円くらいまで。
- 公的機関よりの MTA 件数は年間 5 件程度、研究者からの要望に基づくものが大半。

B 社

- IN（受け入れ）については全てが有償、逆に有償なものについて契約を行うというほうが正確（無償提供はトラブルを懸念する）、契約金額は数百万円程度を上限とする、基準はあるようでない。
- 大学・Academia との間でマテリアルだけのやりとりは例が少ない。
- 米国との場合はリサーチツール的なもののやりとりは大半がベンチャー。

C 社

- 国内の大学は共同研究の枠組みの中で Material のやりとりも処理するケースが大半。
- IN の件数は海外アカデミアとの間で年間数件、国内大学との間にはほとんどない。

D 社

- 海外からの受け入れは抗体などの他に特殊な KNOCK OUT マウスなどのケースがある。

E 社

- MTA 単独でのマテリアル受け入れは殆どない、細胞・遺伝子など年間 1-2 件程度、共同研究・ライセンス契約などに伴い試料受け入れが発生するケースが大半。

農水省系独立行政法人

- 公的研究機関より月 1-2 件、海外 2 ヶ月に 1 件程度。

●マテリアル譲渡（OUTGOING）のポリシーについて

A 社

- 開発化合物・評価系にしろ、これらは企業 KNOW-HOW の一部であり、提供しないのが原則。ただ、大学・アカデミアとの付き合いの中で特殊な cell line を提供することはありうる。
- 第三者分譲については、厳しく禁止している。

B 社

- 公表済みの化合物について無償で、雛型契約を用い、定型的に処理。
- 委託研究のケースに伴いサンプルを提供するが、その他にも会社の方針として REQUEST があればよほどの支障がある場合を除いて提供。

D 社

- 特に国内アカデミアに対しては、いわば社会還元のつもりで提供している。

E 社

- 要請があった場合ケースバイケースで判断するが、開発進行中のプロジェクトに関るマテリアルは提供しないのが原則、提供可能な場合は定型的に処理。

農水省系独立行政法人

- OUT の場合、MTA 契約については改変不可が基本。

●マテリアル受け入れ（INCOMING）のポリシーについて

A 社

- 開発候補品の評価について、その一部の協力を仰ぐというのが基本で特殊な評価系を IN するというケースが大半。

B 社

- IN については代替不能なもの、あるいは特許取得しているものに限定。
- 国内大学とのケースでは契約の処理にいらぬ労力を費やされるため、できれば避けたいというのが本音。

C 社

- リサーチサイドで他に代替手段がなく、どうしてもというものに限られる。
- 海外との場合は研究者からの REQUEST によるものが多い。

D 社

- 国内との大学からの IN がほとんどないのはレベルの問題というよりも、統一的な仕組みが確立されていないことによる。サンプル提供にあたっての多数の経験から、MTA の体制・仕組み・契約交渉体制が確立されているとはとても考えられず、交渉の煩雑さを忌避するためによる所が多い。

E 社

- MTA 単独での受け入れが殆どないのは、Basic テーマを単独として取り上げ展開・Validation させる余裕がないこと・大学の知的財産権の主張がわずらわしい、リーチスルー権に対する懸念などから、購買可能な代替手段を勧めていることなどによる。

●マテリアル譲渡契約（OUTGOING MTA）の交渉事項について

D 社

- 契約主体は旧来の個人から大学法人に切り替わっている。
- 大学のフォーマットを持ち出されるケースもかなりある。以前は文部科学省よりの雛型ということで改変不可、硬直的な対応も多く、結局提供できなかったケースもあった。
- 独立行政法人化したということで、Flexibility を有している大学も増加している。
- 歴史のある大学はやはり対応も洗練されている。ただ大学によっては対応があいかわらず硬直的なところもあり（特に医学部）、また企業に比べて担当者の対応のバラツキが大きい。
- また、一般に大学よりのフォーマットは大部分で企業からの MTA が一般に 1-2 頁程度であるのに比して、余りにも不必要な条項が多すぎるという印象。文部科学省・大学知的財産本部などに医薬品開発の知識を有する人材がほとんどいないようでそのあたりに起因しているのか。

E 社

- 従来簡単な送付状・受領状で処理してきたが、大学の独立行政法人化・知財機構の整備に伴い、企業の利害への抵触・侵害が懸念されるため法務部門と協力して MTA 締結に切り替えている。
- 契約そのものは 1 ページ程度のシンプルなもので、それ自身で交渉が紛糾することはない。

農水省系独立行政法人

- 有償での対価の算出。今までの研究投資額と提供試料に対する価値評価を考慮して妥当な額を決定。

●マテリアル受け入れ契約（INCOMING MTA）の交渉事項について

A 社

- 大学よりの IN について　ゲノム創薬のムーブメントはほぼ終息したとみているが、大学サイドは以前それにこだわったアプローチ、契約態度で過大な要求・条件など　メーカーとの間でずれが目立つ。
- 医薬品開発においてある評価系のデータは開発を進める上での膨大なデータの１つに過ぎない、いつでも可変可能ということが大学・アカデミアで十分実感として理解できていないようだ。
- 過去、評価系からの成果についても Royalty を要求されるケースがしばしばあったが、特許庁 3 極合意・米国での判例などから全て拒絶、固執する場合は代替の評価系を用いるよう研究サイドを説得している。
- 実験ツールの対価については使用特許の対価としての UPFRONT の支払いのほかに、year by year に使用料を支払っていくケースもある。
- 米国アカデミアとの交渉については、米国は知的財産については特殊な国であるということをまず認識する必要がある。MTA についても NIH ガイドライン、バイドール法に基づく規制などを熟知していなければならない。

B 社

- 海外（米国）と国内の相違について、
  - 米国：非常に権利関係の主張がシビアである
  - 国内；特徴的なのは帰属が不明確であること、法人化前の個人所有であったことが未だにひきずっている印象。
- 特に研究者が移動・退職などしている場合の帰属関係の確定が極めて困難、さらに改変を加えている場合など当事者自身も判断不明で大学によっても取り扱いが違う。
- また大学の成果と称していても、競合企業との共同プロジェクトの結果であることが判明したりするケースもあり。
- リサーチツールについては買いきり的な条件で契約を行うことが原則。
- ツールよりの成果についても報酬を求められるケースもあるが拒否が絶対原則で粘り強く説得を行う。買いきりとはいっても期間限定で使用料を払うなどのケースは認容している。

C 社

- 国内大学とのやりとりで最も困るのが権利関係があいまい、かつ複雑なこと、研究者自身は完全に自らの所有であるとしていても、モノのオリジナルな所有権は別のところにあったり、あるいは研究者の移動に伴って、幾つもの機関にまたがっているケースも多い。
- 国内大学とのケースでは上記の処理にいらぬ労力を費やされるため、できれば避けたいというのが本音。リサーチサイドで他に代替手段がなく、どうしてもというものに限られる。

D 社

- アメリカとの大学の交渉では経済条件の議論・交渉よりも、legal/IP 的なところで厳しいやり取りになるケースが多く、ポイントを得た指摘も多い。
- 研究本部だけでなく本社法務部の応援を仰ぐこともある。これは試料受け入れの場合に顕著で、特に米国特有の政府規制の問題の扱いには神経を使う。

●その他

A 社

- 対アカデミアの交渉当事者は initial contact は研究者間のケースが大半であるが、その後の交渉主体は知財本部・TLO。
- アンブレラ特許・あるいはリーチスルーについては 3 極合意により原則認められなくなり、解決済みと認識している。
- リサーチツールをどこまで権利保護をするのかについては、見解が極端から極端まで大きくわかれて混乱しているというのが実情。
- 公共の福祉、新治療手段の開発という観点から特許保護は制限されるべき。
- あるいは有害であるという観点から、労働の正当な成果であり最大限保護されるべきという考え方まで大きく振れている。
- そもそも現行特許法が 19C 的なもの主体という観点から抜けきれておらず、情報価値の評価という点で整合性がとれていない。
- 一方、大学の研究そのものについては、米国の発展から見て今後ますます利用価値があると考えている。
- ただ、大学の研究からストレートに創薬開発ができるわけではないことをもっとアカデミアは認識すべき。どうしてもベンチャーというステップが必要で、それに向けての規制整備、ベンチャーキャピタルの充実、知的財産の取り扱いの習熟などにもっと大学は目を向けるべき。

B 社

- 率直に言って国内アカデミアとの IN MTA は可能な限り避けている、他に購入できる類似 cell、評価系などがあればそれに切り替えるように研究者には勧めている。

＜希望・要望＞

B 社

- 研究者が個人としてやっているのか大学としてやっているのか、当人自身もあいまいで、受け手として困惑する。
- 大学本部が HEAD QUARTER としての指導性を強く発揮してほしい。
- 研究者の移動に伴うケースなど大学−大学の取り決めも標準化・整備すべき。

C 社

- 大学との提携で問題なのは実験データが申請資料としては使うに耐えられないこと、GLP 的な観点

からは問題外で、結局メーカーで再実施の必要がでてくる。
- リサーチツール特許は、企業にとっては喉に刺さった魚の骨のようなもので Critical なものでもないが、かといって放置しておくこともできないといった厄介なもの。

＜大学よりの実験動物の受け入れについて＞

D 社
- 感染面での不安から直接の搬入は絶対に行わない。
- 実験動物業者に委託してクリーン化を行い、さらに研究所に搬入後も一定期間は隔離して観察を行う。

＜大学との MTA でのケースでの問題点・要望＞

D 社
- 公表にあたっての事前連絡についてなど、大学側に順法意識が欠けるケースがしばしば見られる。始めから MTA の規定を守る気持ちがない確信犯的な場合もある。
- 企業として気になるケースは、
  - 製品に対するネガティブデータ
  - IP データの取り扱い
- ネガティブデータについては GLP 的な観点からみてサンプルの品質保証のチェックが不十分、n 数の問題、データの取捨選択のしい的な取り扱いなど疑問点が多い。特にネガティブデータについてはマスコミも飛びつきやすく、影響も大きいだけにモラル的な向上を是非要請したい。

E 社
- 大学知的財産本部の整備により共同研究などが透明化したことは高く評価。大学の独立行政法人化以後、バイオ分野においても知的財産のビジネス化に大学は積極的であるがビジネスのイメージが企業とは全く違うことが多い。
- 医薬品開発が膨大なデータの集積であり、大学研究成果はごくその一部であり、代替可能であるということへの認識が乏しい。
- 現時点では、新薬メーカーにとっての大学の利用価値は、臨床研究など特殊な場における特殊な知識・技術にその大半がある。基礎的研究は知的財産化しても消化不良に陥るだけ。プラットフォーム技術として積極的に公開利用を図るべき。
- 工学系とライフサイエンスではその知財の意味が全く違うことを認識すべき。

Ⅲ. 製薬企業5社および農水省系独立行政法人への聞き取り調査（個別聞き取り要約）

1. 製薬企業 A 社

東京に本社を有する大手製薬メーカー、研究本部にて研究試料移転管理・契約（臨床サンプルは除く）を担当する責任者に聴取した。

●マテリアル譲渡状況（OUTGOING MTA）について

- A 社よりのアカデミアへの提供； 年間 5, 6 件、国内の大学がメイン。特殊な cell line。

●マテリアル受け入れ状況（INCOMING MTA）

- A 社への受け入れ 年間 50 件程度、国内外の区別ではおおむね 50 ： 50、海外の場合、米国が大半。
- 種類は特殊な評価系を IN するというケースが約 8 割、それ以外は上流遺伝子などであるが、ゲノム創薬の退潮傾向にともないその数は減少している。
- 実験動物については感染リスクなどを考慮して大学よりの直接の受け入れは行わない。

- 対価については、有償・無償いずれのケースもあるが、有償のほうが多い。単価の算出は難しいが、評価/cell line のケースで 1 件あたり数十万円から、100 万円、200 万円くらいまで。

●マテリアル譲渡（OUTGOING）のポリシーについて

- 開発化合物・評価系にしろ、これらは企業 KNOW-HOW の一部であり、提供しないのが原則。
- ただ、大学・アカデミアとの付き合いの中で特殊な cell line を提供することはありうる。
- 第三者分譲については、厳しく禁止している。

●マテリアル受け入れ（INCOMING）のポリシーについて

- 開発候補品の評価について、その一部の協力を仰ぐというのが基本で特殊な評価系を IN するというケースが大半。

●マテリアル受け入れ契約（INCOMING MTA）の交渉事項について

- 大学よりの IN について ゲノム創薬のムーブメントはほぼ終息したとみているが、大学サイドは以前そ

れにこだわったアプローチ、契約態度で過大な要求・条件など、メーカーとの間でずれが目立つ。

- 医薬品開発において、ある評価系のデータは開発を進める上での膨大なデータの 1 つに過ぎない、いつでも可変可能ということが大学・アカデミアで十分実感として理解できていないようだ。

- 過去、評価系からの成果についても Royalty を要求されるケースがしばしばあったが、特許庁 3 極合意・米国での判例などから全て拒絶、固執する場合は代替の評価系を用いるよう研究サイドを説得している。

- 実験ツールの対価については使用特許の対価としての UPFRONT の支払いのほかに、year by year に使用料を支払っていくケースもある。

- 米国アカデミアとの交渉については、米国は知的財産については特殊な国であるということをまず認識する必要がある。MTA についても NIH ガイドライン、バイドール法に基づく規制などを熟知していなければならない。

●その他

- 対アカデミアの交渉当事者は initial contact は研究者間のケースが大半であるが、その後の交渉主体は知財本部・TLO。

- アンブレラ特許・あるいはリーチスルーについては 3 極合意により原則認められなくなり、解決済みと認識している。

- リサーチツールをどこまで権利保護をするのかについては、見解が極端から極端まで大きくわかれて混乱しているというのが実情。
- 公共の福祉、新治療手段の開発という観点から特許保護は制限されるべき、あるいは有害であるという観点から、労働の正当な成果であり最大限保護されるべきという考え方まで大きく振れている。

- そもそも現行特許法が 19C 的なもの主体という観点から抜けきれておらず、情報価値の評価という点で整合性がとれていない。
- 一方、大学の研究そのものについては、米国の発展から見て今後ますます利用価値があると考えている。

- ただ、大学の研究からストレートに創薬開発ができるわけではないことをもっとアカデミアは認識すべき。どうしてもベンチャーというステップが必要で、それに向けての規制整備、ベンチャーキャピタルの充実、知的財産の取り扱いの習熟などにもっと大学は目を向けるべき。

2. 製薬企業 B 社

東京に本社を有する大手製薬メーカー、研究本部にて研究試料管理・契約（臨床サンプルは除く）担当者ならびに法務担当者に聴取した。

●マテリアル譲渡状況（OUTGOING MTA）について

- B 社よりアカデミア・大学への提供は発表済みの化合物を中心に年間 300-400 件に上る。無償で、雛型契約を用い、定型的に処理。

●マテリアル受け入れ状況（INCOMING MTA）

- 公的機関よりの MTA 件数は年間 5 件程度、研究者からの要望に基づくものが大半。

- IN（受け入れ）については全てが有償、逆に有償なものについて契約を行うというほうが正確（無償提供はトラブルを懸念する）、契約金額は数百万円程度を上限とする、基準はあるようでない。

●マテリアル譲渡（OUTGOING）のポリシーについて

- 公表済みの化合物について無償で、雛型契約を用い、定型的に処理。

●マテリアル受け入れ（INCOMING）のポリシーについて

- IN については代替不能なもの、あるいは特許取得しているものに限定。

●マテリアル受け入れ契約（INCOMING MTA）の交渉事項について

- 海外（米国）と国内の相違については
  - 米国；非常に権利関係の主張がシビアである。
  - 国内；特徴的なのは帰属が不明確であること、法人化前の個人所有であったことが未だにひきずっている印象。
- 特に研究者が移動・退職などしている場合の帰属関係の確定が極めて困難、さらに改変を加えている場合など当事者自身も判断不明で大学によっても取り扱いが違う。

- また大学の成果と称していても、競合企業との共同プロジェクトの結果であることが判明したりするケースもあり。

・ リサーチツールについては買いきり的な条件で契約を行うことが原則。ツールよりの成果についても報酬を求められるケースもあるが拒否が絶対原則で粘り強く説得を行う。買いきりとはいっても期間限定で使用料を払うなどのケースは認容している。

●その他

・ 率直に言って国内アカデミアとの IN MTA は可能な限り避けている、他に購入できる類似 cell、評価系などがあればそれに切り替えるように研究者には勧めている。

＜希望・要望＞

・ 研究者が個人としてやっているのか大学としてやっているのか、当人自身もあいまいで、受け手として困惑する。

・ 大学本部が HEAD QUARTER としての指導性を強く発揮してほしい。

・ 研究者の移動に伴うケースなど大学−大学の取り決めも標準化・整備すべき。

3. 製薬企業 C 社

大阪に本社を有する大手製薬メーカー、ライセンス部にてベンチャー・Academia との契約・交渉を担当する責任者に聴取した。

●MTA 本体は、研究本部研究企画が主管

●マテリアル譲渡状況（OUTGOING　MTA）およびマテリアル受入状況（INCOMING MTA）について

- 大学・Academia との間でマテリアルだけのやりとりは例が少ない。
- 米国との場合はリサーチツール的なもののやりとりは大半がベンチャー。
- 国内の大学は共同研究の枠組みの中で Material のやりとりも処理するケースが大半。

●マテリアル受け入れ（INCOMING）のポリシー・交渉事項について

- 国内大学とのやりとりで最も困るのが権利関係があいまい、かつ複雑なこと、研究者自身は完全に自らの所有であるとしていても、モノのオリジナルな所有権は別のところにあったり、あるいは研究者の移動に伴って、幾つもの機関にまたがっているケースも多い。
- 国内大学とのケースでは上記の処理にいらぬ労力を費やされるため、できれば避けたいというのが本音。リサーチサイドで他に代替手段がなく、どうしてもというものに限られる。

●その他

- 大学との提携で問題なのは実験データが申請資料としては使うに耐えられないこと、GLP 的な観点からは問題外で、結局メーカーで再実施の必要がでてくる。
- リサーチツール特許は、企業にとっては喉に刺さった魚の骨のようなもので Critical なものでもないが、かといって放置しておくこともできないといった厄介なもの。

4. 製薬企業 D 社

東京・大阪に本社を有する大手製薬メーカー。研究本部にて臨床用サンプルを含め、研究試料移転管理・契約を担当する責任者に聴取した。

●マテリアル譲渡状況（OUTGOING MTA）について

- 国内外のアカデミアとの試料のやり取りは OUT が大半。
- 件数は OUT が共同研究における試料のやり取りを含め年間 100 数十件、うち海外が約 20 件。
- 海外は欧州・米国のほかに、子会社の存在するアジア（韓国・台湾）など。
- OUT の場合、種類は抗体、遺伝子、化合物 etc 種々、ほとんど全てが無償、特に国公立に対しては無償。

●マテリアル受け入れ状況（INCOMING MTA）

- IN の件数は海外アカデミアとの間で年間数件、国内大学との間にはほとんどない。
- 海外からの受け入れは抗体などの他に特殊な KNOCK OUT マウスなどのケースがある。

●マテリアル譲渡（OUTGOING）のポリシーについて

- 委託研究のケースに伴いサンプルを提供するが、その他にも会社の方針として REQUEST があればよほどの支障がある場合を除いて提供。
- 特に国内アカデミアに対しては、いわば社会還元のつもりで提供している。

●マテリアル受け入れ（INCOMING）のポリシーについて

- 海外との場合は研究者からの REQUEST によるものが多い。
- 国内との大学からの IN がほとんどないのはレベルの問題というよりも、統一的な仕組みが確立されていないことによる。サンプル提供にあたっての多数の経験から、MTA の体制・仕組み・契約交渉体制が確立されているとはとても考えられず、交渉の煩雑さを忌避するためによる所が多い。
- 結果として共同研究の枠組みの中で試料を受領する場合に限定される。

●マテリアル譲渡契約（OUTGOING MTA）の交渉事項について

- 契約主体は旧来の個人から大学法人に切り替わっている。

- 大学のフォーマットを持ち出されるケースもかなりある。以前は文部科学省よりの雛型ということで改変不可、硬直的な対応も多く、結局提供できなかったケースもあった。
- 独立行政法人化したということで、Flexibility を有している大学も増加している。
- 歴史のある大学はやはり対応も洗練されている。ただ大学によっては対応があいかわらず硬直的なところもあり（特に医学部）、また企業に比べて担当者の対応のバラツキが大きい。
- また、大学よりのフォーマットは企業からの MTA が一般に 1-2 頁程度であるのに比して、余りにも不必要な条項が多すぎるという印象。文部科学省・大学知的財産本部などに医薬品開発の知識を有する人材がほとんどいないようでそのあたりに起因しているのか。

●マテリアル受け入れ契約（INCOMING MTA）の交渉事項について

- アメリカの大学との交渉では経済条件の議論・交渉よりも、legal/IP 的なところで厳しいやり取りになるケースが多く、ポイントを得た指摘も多い。
- 研究本部だけでなく本社法務部の応援を仰ぐこともある。これは試料受け入れの場合に顕著で特に米国特有の政府規制の問題の扱いには神経を使う。

●その他

＜大学よりの実験動物の受け入れについて＞
- 感染面での不安から直接の搬入は絶対に行わない。
- 実験動物業者に委託してクリーン化を行い、さらに研究所に搬入後も一定期間は隔離して観察を行う。

＜大学との MTA ケースでの問題点・要望＞
- 公表にあたっての事前連絡についてなど、大学側に順法意識が欠けるケースがしばしば見られる。
- 始めから MTA の規定を守る気持ちがない確信犯的な場合もある。
- 企業として気になるケースは、
  - 製品に対するネガティブデータ
  - IP データの取り扱い

- ネガティブデータについては GLP 的な観点からみてサンプルの品質保証のチェックが不十分、n 数の問題、データの取捨選択のしい的な取扱いなど疑問点が多い。特にネガティブデータについてはマスコミも飛びつきやすく、影響も大きいだけにモラル的な向上を是非要請したい。

5. 製薬企業 E 社

関西に本社を有する中堅製薬メーカー、本社部門において研究企画・研究試料契約を担当する責任者に聴取。

●マテリアル譲渡状況（OUTGOING MTA）について

- D 社よりアカデミアへの提供、年間 10 件未満。国内が大半、細胞、Knock out マウス、病態モデルマウス、化合物など基本的には無償。

●マテリアル受け入れ状況（INCOMING MTA）について

- MTA 単独でのマテリアル受け入れは殆どない、細胞・遺伝子など年間 1-2 件程度、共同研究・ライセンス契約などに伴い試料受け入れが発生するケースが大半。

●マテリアル譲渡（OUTGOING）のポリシーについて

要請があった場合ケースバイケースで判断するが、開発進行中のプロジェクトに関るマテリアルは提供しないのが原則、提供可能な場合は定型的に処理。

●サンプル受け入れ（INCOMING）のポリシーについて

- MTA 単独での受け入れが殆どないのは、Basic テーマを単独として取り上げ展開・Validation させる余裕がないこと・大学の知的財産権の主張がわずらわしい、リーチスルー権に対する懸念など、購買可能な代替手段を勧めていることなどによる。

●マテリアル譲渡契約（OUTGOING MTA）の交渉事項について

- 従来簡単な送付状・受領状で処理してきたが、大学の独立行政法人化・知財機構の整備に伴い、企業の利害への抵触・侵害が懸念されるため法務部門と協力して MTA 締結に切り替えている。契約そのものは 1 ページ程度のシンプルなもので、それ自身で交渉が紛糾することはない。

●その他

- 大学知的財産本部の整備により共同研究などが透明化したことは高く評価。
- 大学の独立行政法人化以後、バイオ分野においても知的財産のビジネス化に大学は積極的である

がビジネスのイメージが企業とは全く違うことが多い。

- 医薬品開発が膨大なデータの集積であり、大学研究成果はごくその 1 部であり、代替可能であるということへの認識が乏しい。
- 現時点では、新薬メーカーにとっての大学の利用価値は、臨床研究など特殊な場における特殊な知識・技術にその大半がある。基礎的研究は知的財産化しても消化不良に陥るだけ、プラットフォーム技術として積極的に公開利用を図るべき。
- 工学系とライフサイエンスではその知財の意味が全く違うことを認識すべき。

〈補〉 農水省系独立行政法人

●マテリアル譲渡状況（OUTGOING MTA）について

・ 大学・理研などの公的研究機関、月 1-2 件。

＜最近の事例＞
・ MTA を含むライセンス契約では、欧州農業化学メーカーとの事例あり。
・ 特許の取り扱い、免責規定、品質保証、損害補償など極めてシビアな問題が多くあったため、弁護士を雇用して対応。

●マテリアル受け入れ状況（INCOMING MTA）

・ 公的研究機関より、月 1-2 件、海外 2 ヶ月に 1 件程度。

●マテリアル譲渡（OUTGOING）のポリシーについて

・ OUT の場合、MTA 契約については改変不可が基本、同様な原則（改変不可）を持つ理研との場合、共有特許の取り扱いが相違し、対応に苦慮したが、別途覚書を締結することで対応。

●マテリアル契約交渉事項について

・ 有償での対価の算出。今までの研究投資額と提供試料に対する価値評価を考慮して妥当な額を決定。

＜参考＞

共通質問レジュメ

MTA INTERVIEW FORM（企業用）

●OUTGOING（企業→大学）

- マテリアル譲渡を許可するケース、拒否するケースの区分は
- マテリアルの譲渡件数
- マテリアルトランスファーの分類
  - 相手； 国内大学、公的機関　海外大学・公的機関
  - 種類： 菌株、実験動物・植物、動物・植物細胞、高分子、低分子
  - 有償・無償の区別（取り扱いを違える場合はその線引き）
- 大学・公的機関に対する定型契約の有無
- 担当部門は； 研究本部・法務・ライセンス
- 交渉（OUT）内容（国内・海外）についての論点となる以下の事項についてのコメント
  - 新たな特許の扱い
  - 品質保証
  - 研究の詳細を求めるのか
  - 秘密保持の定義
  - マテリアル改良について
  - 試験研究内容の公表
- 過去の経験の内で最も dispute が起こるポイントは
  （例えば 公表;期間の目処、事前チェック、事前承認・了解）
- 現実の運用について： 学会発表を拒絶する場合があるか
- 上記交渉内容で、国内・海外の違いは
- 契約規定の遵守について

●INCOMING（大学・公的機関→企業への受け入れ）の場合

- マテリアルの受け入れ件数の推移
- 件数分類： 国内大学・公的機関より、海外大学・公的機関より
- 種類： 菌株、実験動物・植物、動物・植物細胞、高分子、低分子
- 担当部門は： 研究本部あるいは法務部門
- 交渉内容（特に海外・国内の違い）
  - 新たな特許の扱い
  - 品質保証
  - 研究の詳細を求めるのか
  - 秘密保持の定義
  - マテリアル derivative/
  - 改良について
  - 試験研究内容の公表
- 契約交渉内容・実態： 期間、独立法人化後の交渉傾向について
- 交渉がデッドロックに乗り上げるケースは、そのポイントは

第三章　米国アカデミア現地調査

Ⅰ．米国アカデミアへの聞き取り調査について（はじめに）

2007年1月下旬、奈良先端科学技術大学院大学・MTA調査チームは、米国アカデミアにおけるマテリアルトランスファーの現況について現地聞き取り調査を行った。

訪問・聞き取り調査を行った大学・施設は以下の7大学・施設である。

- 国立衛生研究所（NIH）（メリーランド州ベセスダ）
- メリーランド大学（メリーランド州ボルティモア）
- エモリー大学（ジョージア州アトランタ）
- アリゾナ大学（アリゾナ州ツーソン）
- UCSF（カリフォルニア州サンフランシスコ）
- スタンフォード大学（カリフォルニア州パロアルト）
- ワシントン大学（ワシントン州シアトル）

6大学のうち私立大学であるエモリー大学・スタンフォード大学以外は全て州立大学である。

これらの大学・施設は米国ライフサイエンス・産学連携の領域においていずれも著名な実績を有しているが、選択にあたっては本調査に協力を依頼した元オレゴン健康科学大教授 Sandra Shotwell 氏による。とくにマテリアルトランスファーについて十分な経験・実績を有する担当者とインタビューが可能な大学・施設の候補リストをもとに、調査チームで検討、スケジュール的な要素も加味して決定したものである。

なお、今回の調査において協力を依頼した元オレゴン健康科学大教授・コンサルティング事務所 Alta Biomedical 主宰 Sandra Shotwell 氏は20年以上にわたる米国アカデミアでの知的財産移転・ライセンス業務における実績・経験を有し、特にNIHにおいてTechnology License Branchの創設にかかわり、米国アカデミアにおいて、MTA雛型として広く用いられているUBMTA（Uniform Biological Material Tarnsfer Agreements）の作成を領導したことでAUTM（the Association of University Technology Managers）内で著名な存在である。

各大学・施設へ訪問・聞き取り調査を実施するにあたって共通の質問シートを事前に作成・送付した(原文;英文)。参考資料として添付。

共通質問事項

A. マテリアル出入状況についての一般的質問
1. OUTGOING MTA(譲渡)について
1-1. 1 年間の OUT MTA の件数
1-2. 分類
Academia/非アカデミア(企業)、地域別(北米・欧州・日本など)
対価、移転マテリアルの種類　バイオプロダクツ・化学合成物質など
バイオプロダクツの分類; 微生物、培養細胞、実験動物、実験植物、抗体、遺伝子
2. INCOMING MTA(受け入れ)
2-1. 1 年間の INCOMING MTA の件数
2-2. 分類
Academia/非アカデミア(企業)、地域別(北米・欧州・日本など)
対価、移転マテリアルの種類　バイオプロダクツ・化学合成物質など
バイオプロダクツの分類;微生物、培養細胞、実験動物、実験植物、抗体、遺伝子

B. マテリアルに関する取り扱い規定あるいはポリシーについて
1. 成分化したルールを有しているか
2. マテリアル(OUT)の帰属について
3. 対価の分配
4. マテリアルの流れ・事務処理についてのフローチャート

C. マテリアル移転契約について
1. MTA の雛型は有しているか
2. 有償・無償、有償の場合の対価決定はどのように行っているか
3. MTA 交渉の責任部署
4. 契約書決裁(サイナー)は誰が行っているか

D. マテリアル移転契約交渉の論点となる交渉項目について
1. 譲渡契約(OUT MTA)交渉において下記の項目のうち、最も論点となるのは
a. マテリアルを用いた新規知的財産の取り扱いについて
b. マテリアルの品質管理について
c. 対価(ロイヤルティー・一時金)について
d. 研究目的
e. 研究結果の譲渡主体への報告について
f. 研究結果の発表について
g. 秘密保持について
h. マテリアルの改変(progeny, duplicates, derivatives など)
i. 新規知的財産あるいは改変物の譲渡主体の使用権について
j. 米国政府の権利について
k. ライセンスの Grant について
l. 保証条項(Warranties)について
m. 免責条項(Indemnification)およびその他のリーガル条項について
n. その他
2. 受け入れ契約(IN MTA)交渉において下記の項目のうち、最も論点となるのは
a. マテリアルを用いた新規知的財産の取り扱いについて
b. 対価(ロイヤルティー・一時金)について
c. 米国政府の権利について
d. マテリアルの定義について
e. マテリアル・データの所有権
f. ライセンスの Grant について
g. 既存契約との相反について
h. アカデミックフリーダム・発表権について
i. 秘密保持について
j. 保証条項(Warranties)について
k. 免責条項(Indemnification)およびその他のリーガル条項について
l. その他

E. 以下のガイドラインあるいは規制の影響について
a. バイドール法
b. NIH ガイドライン
c. カルタヘナ議定書
d. 生物多様性条約
e. 各地域の規制
f. その他

各事項ごとの回答詳細ならびに個別大学・施設ごとの聞き取り調査概要は本章後半部に記述の通りであるが、全体の概略は以下の通りである。

●各大学の MTA 担当組織について

各大学ともおおむね 20 名前後の知的財産移転部門（OTT； Office of Technology Transfer）を擁し、そのなかで MTA 担当の Section を設け、5 名内外の専門のスタッフをそれにあてているというのが今回調査した大学・施設の標準的な組織形態である（エモリー大学、ワシントン大学の組織図を参考資料として添付）。

●MTA 件数について

譲渡（OUTGOING）、受け入れ（INCOMING）あわせて NIH 各施設で年間 200-600 件、NIH の場合はその殆どが OUTGOING となっている。

調査した各大学においては、OUT・IN 総数で年間 150 件程度から数百件、最も多い大学（UCSF）で約 1,500 件となっている。

IN/OUT の内訳、OUT が 50 件から 300 件程度、IN が 100 から 300 件程度、各大学において IN・OUT の比率は概ね同数程度から IN が OUT の 2 倍程度にまで分布している。

●MTA 分類

◇アカデミア/非アカデミア（企業）の内訳について

OUTGOING については、アカデミアが大半（80%-90%）を占めるという大学・施設が多い。これは対企業へのマテリアル譲渡件数が少ないということを必ずしも意味せず、対企業マテリアル供給については MTA ではなく、UPFRONT・Royalty の設定を行えるライセンス契約で処理する大学が多いためと説明される。

INCOMING については臨床試験用のサンプル受け入れケースなどを除いても、企業からの受け入れサンプルが全件数の 20%から 50%と各大学ともかなりの比率を占め、ベンチャー企業あるいは製薬企業からのマテリアルが各大学での研究遂行に必須な役割を占めていることを窺わせている。

◇地域別

地域別にはOUT/INとも北米地域が過半を占めているが、特にOUTの場合、大学によっては欧州・アジアもかなりの比率をしめており、米国がバイオ研究の圧倒的な中心であることを反映している。

◇対価

OUTGOING;

調査を行った殆どの大学では、Academia/非アカデミアに対してともに無償もしくは製作実費程度で提供している。これは、マテリアル提供は大学の公共的使命であり、それは対企業にも原則として適用されるべきであるというNIHの姿勢が反映されているものである(後述するように各大学とも研究資金の過半以上をNIHよりの財政に依存していることも関係している)。一方では、商業的応用が推定されるものに対しては、極力ライセンス契約で処理されていることも見逃せない。また各大学のインタビューからはマテリアル譲渡も有力な収入財源としている大学も全米には一定数存在しているものと推定される。

INCOMING;

殆どの大学が対企業をふくめて無償あるいは実費程度での提供を求めているのは大学の財政・研究実態から推して当然のことと思われる。

◇バイオプロダクツの種類

OUT、IN とも抗体、DNA、プラスミド、微生物、細胞、実験動物など多岐にわたるが、一部の大学においてはhuman tissueの取り扱いが大きくクローズアップされている。これはinformed consentの取得など個人情報に係ることで細心の取り扱いが必要なためで、他のマテリアルとは別の取り扱い規定を作って処理されている。また政治的な問題も関連して、human embryo cellについてもOUT/INとも厳重に管理されている。

●マテリアルに関する取り扱い規定およびポリシーについて

◇成文化ルールの有無

各大学とも全て成文化した規則を整備している、準拠は NIH ガイドラインを始めとする連邦法、連邦ガイドライン、州法など。

◇マテリアルの帰属について

大学の設備を使用・構成員である限り大学・機関に所属。

◇対価の分配（OUTGOING）

各大学とも一定のルールに従い研究者・研究室・大学財団・学部などに配分。また OTT（Office of Technology Transfer）部門が一定費用（10%-20%）を控除しているケースが多い。

◇事務処理フローチャート

各大学においてフローチャートを作成している。さらにその前段階として研究者への Q&A フォーマートを作成している大学も多い。入手した各大学の例（メリーランド大学、エモリー大学、UCSF、スタンフォード大学、ワシントン大学）を参考資料として本章末に添付した。

●マテリアル移転契約について

◇MTA の雛型について

各大学とも NIH ガイドラインに基づいて作成された、SLA（Simple Letter Agreement）および UBMTA を用いると共に、若干それに州法などに基づき各大学の修正・改変を加えた独自の雛型も使用している。第 4 章付表に UBMTA、SLA および大学雛型の例を添付している。

◇対価決定について

いずれのケースも製作実費を上限とすることから大きな論議は行われていない。

◇MTT 交渉責任者

各大学とも OTT 部門が担当しているが、雛型 MTA を用いるサンプル譲渡のケースは研究者に一任されている大学もあり。

◇サイナー（契約書決裁）

OTT 部門責任者が原則であるが、OUTGOING で雛型 MTA に完全に準拠する場合は各学科責任者・研究責任者としているケースもあり。また、OTT 責任者のサインと同時に研究責任者を witness としてサインを要請している大学もある。

●マテリアル移転契約交渉の論点となる交渉項目について

◇譲渡契約（OUT GOING）について

各大学とも OUT GOING については、州法にもとづく準拠法などの問題を除いて、それほど大きな論点はないとするところが殆どであった。これは、対 Academia の場合はもとより対企業の場合においても NIH

ガイドラインおよびそれに基づく SLA、UBMTA などが徹底され、対価も実費程度であることが大きく寄与しているためと考えられる。

ただ、大学よりのマテリアルに第三者の権利関係が関与しているかどうかについては、OTT 部門として慎重に検討するとの回答を数大学より聴取している。

◇受け入れ契約（INCOMING）について

各大学とも Academia、non-Academia を問わず慎重な検討を行っており、交渉の際の論議も複雑かつ困難な状況となるケースも多くあるようである。

各大学とも今後の大学における研究をサンプル受け入れによって制限されたくない、またマテリアルを用いた研究を大学の独立した研究資産として確保すべきであるという強い共通の認識として有していることがその背景にある。

従って、アカデミックフリーダム・発表権の確保に加え、マテリアルを用いた新規知的財産の取り扱いについても鋭く論議が交錯している状況がうかがわれた。特にバイオサイエンスの分野において近年その存在を増しているベンチャー系製薬企業からはリーチスルー、Material の定義の拡大などについて過大な要求（大学にとって）をされるケースがあり、交渉不成立となるケースもかなりあると推察される。

また、州立大学においては、州法遵守の観点より免責、準拠法、保障条項などいわゆる Legal 条項についてもその対応が制約されており、特に海外の Academia・企業との場合契約締結への大きな障害となるケースもあるようである。

●その他

- 米国大学のバイオ研究領域については NIH による資金がその過半以上、大学によっては 90％近くに達する大学もある。従って知的財産移転・マテリアル移転の分野においても NIH の政策・方針が貫徹されるのはある意味で当然と考えられる。

- NIH は基本方針として投入された国家予算をいかに社会に還元するかに最大の重点をおいており、NIH のマテリアル移転に関するガイドラインも全てその観点から構成されている。このことは各大学にも周知徹底されている。本章末にそのガイドラインを資料として添付する。

- ただしこのことは企業との関係において硬直的な対応をとることを必ずしも意味せず、中心の視点が一貫していれば、個々のケースについては各大学にて柔軟に対応されている状況がインタビューより

もうかがわれた。

- いずれにせよ、大学は MTA を大学にとって産業への最初のドア（ワシントン大学）と位置づけ、MTA 担当に相当の人材を配置してその充実を図っている。

Ⅱ. 米国 7 大学・施設への聞き取り調査（項目別まとめ）

●Technology Transfer Group の組織・分担について

NIH;

- NIH は主に疾患別に区分される NCI など 27 の施設から成り立っている。
- それぞれの施設に Technology Transfer Group が存在すると同時に NIH 中央にも Technology Transfer Office（NIHOTT）が機能している。
- MTA に関しては、各施設の TTD が主として Academia 間の MTA を取り扱い、対企業との MTA の交渉は施設 TTG と連携して、NIHOTT が中心になって行う。
- また、特許出願・ライセンス交渉は NIHOTT の責任となる。
- NIAID（アレルギー・感染症）の TTG は 40 名程度の陣容を擁している。

エモリー大学;

- Technology Transfer Office には 17 名のスタッフを有しており、内 MTA セクションには 3 名が専従している。

アリゾナ大学;

- Technology Office が設立されたのは、2001 年と比較的新しいが、大学としては本部門を重点的に整備していく方針。
- TT office は FTE が約 10 名、IN Bound 担当と OUT Bound 担当に分かれている。

UCSF;

- OTT G はサンフランシスコ市内に、6 年前にオフィスを設け（それまではバークレイに集中していた）弁護士 4 人。博士 6 から 8 名を有する。UCSF OTT G は IN BOUND MTA/OUT BOUND MTA を取り扱う G を分けており、それぞれ 2-3 名が従事。

スタンフォード大学;

- 技術移転 G は 1970 年代に設立され、30 年の歴史を有している。現在人員が 29 名、その半数が Industrial Contract G に所属。Research Agreement、MTA などを扱う MTA は 4 名で処理する。
- 1 年間で 650 件の Research Agreement を OTL は締結、その内訳は、
  - Sponsored Research Agreement 150 件
  - Consortium Agreement 50 件
  - 0$ collaboration（相互無償の共同研究契約） 30 件
  - MTA 450 件

ワシントン大学;

- ワシントン大学・OTT（Office of Technology Transfer）部門は約 50 名の人員で構成、MTA については 4 名の FTE が担当、いずれも 5 年-10 年の経験を有している。
- 2006 年の実績は、
  - 発明受理 310 件
  - 締結した Commercialization Agreement 153 件
  - US 特許出願 151 件
  - 締結した MTA 600 件
  - 締結した CDA 171 件
  - Start Up Companies 10 件

●各質問事項に対する回答

A マテリアル出入状況についての一般的質問

1. OUTGOING MTA（譲渡）について

1-1. 1 年間の OUT MTA の件数

NIH; MTA 総数（殆どが OUT）

アレルギー・感染症 G（NIAID）	約 150 件/年（OUT が 80-90%、IN が 10-20%）
糖尿病 G（NIDDK）	約 600 件/年（殆どが OUT）
肺疾患・高血圧 G（NIHLB）	約 300-400 件（殆どが OUT）
癌 G（NCI）	約 600 件

メリーランド大学; 50-80 件/年（過去 3 年の平均、申し込みの内 80%が締結）

エモリー大学; 2004 年 74 件、2005 年 134 件、2006 年 101 件

アリゾナ大学; 2004 年 46 件、2005 年 43 件、2006 年 45 件（2000 年 9 件）

UCSF; 契約件数は年間 total で 1,000 件程度

スタンフォード大学; （OUT 及び IN）MTA 450 件

ワシントン大学; 年間 298 件（2006 年）

1-2. 分類

◇Academia/非アカデミア（企業）

NIH/NIAID; MTA 149 件（うち企業対象 17 件）

メリーランド大学; 大半が大学。企業よりの申し入れに対してはライセンス契約で処理が原則。

エモリー大学; 2006 年 101 件中、非アカデミア 4 件

アリゾナ大学; アカデミア : 非アカデミア 50% : 50%

UCSF; 20%程度が For Profit（企業）へのサンプル提供で、100-200 ケース/年

ワシントン大学； Non-Profit（Academia） 282 件、For-Profit（企業） 16 件

◇地域別（北米・欧州・日本など）

メリーランド大学； Academia について米国以外の地域からの申し込みも多い。企業では米国以外からは少ない。

エモリー大学； 2006 年、北米 65%、欧州 27%、アジア 8%

アリゾナ大学； 50%以上が北米

◇対価

NIH； Academia については無償原則、対企業については研究目的などを審査して有償とするかどうかを決定。

メリーランド大学； 一般に運送経費のみを請求、製作費を上乗せ請求する場合もあり。一時金、ロイヤルティなどを要求する場合は MTA ではなく、ライセンス契約として処理。

エモリー大学； 無償が原則、運送費・製作経費を上乗せするケースあり。

（対企業はライセンス契約として処理するケースが大半）

アリゾナ大学； 対 Academia は無償が原則、対企業は製作費などの実費。

UCSF； MTA により提供されているサンプル対価については Academia, non-Academia を含め無償もしくは作製実費程度（例えば癌細胞で 200-250$/tissue 程度）、これは Research の進展を優先させるという UCSF の基本 POLICY に基づくものであり、大学によっては MTA を income の有力な手段としているところもある。

ワシントン大学； 対 Academia は無償。

対企業 OUTGOING Research tool については、Upfront と Annual Maintenance Fee を要求。

◇バイオプロダクツの分類

NIH； あらゆる種類にわたるが、糖尿病 G では実験マウスが年 30 件程度。

ヒト組織由来のサンプルの取り扱いが、現在もっとも sensitive issue。

メリーランド大学； 抗体、DNA、プラスミド、微生物、細胞、実験動物など。

UCSF； Human 由来のサンプルの MTA は個人情報の問題など多くの検討すべき点があるため、別のグループで扱う。

Human tissue のうち human embryotic cell を使った研究については連邦政府からの厳しい規制があるため、サンプルの移動などについても厳しい管理を行っている。

ワシントン大学； スクリーニング目的の実験マウスについては特別な契約形態を用意。

2. INCOMING MTA（受け入れ）について

2-1. 1 年間の INCOMING MTA の件数

メリーランド大学； 170-180 件/年（過去 3 年の平均、申し入れの内 85%が締結）

エモリー大学； 2004 年 217 件、2005 年 288 件、2006 年 240 件

アリゾナ大学； 約 95 件

UCSF; Human 由来のものを含め年間 450-500 件の MTA を締結。

ワシントン大学； 年間 300 件(2006 年)

2-2. 分類

◇Academia/非アカデミア(企業)

メリーランド大学； 大学・企業が半々。

エモリー大学； Academia 199 件、非アカデミア 42 件。

アリゾナ大学； 臨床試験サンプル(特に抗がん剤関連)を中心に企業よりが過半。

UCSF； Academia と non-Academia の比率は 50% ：50%。

ワシントン大学； Non-Profit(Academia)251 件、For-Profit(企業)49 件。

◇地域別

エモリー大学； 2006 年、北米 87%、欧州 8%、アジア 3%。

アリゾナ大学； 50%以上が北米。

UCSF； 地域的には 75%が北米。

◇対価

メリーランド大学； 無償受け入れが原則、運送費を請求されるケースがしばしばあり。

UCSF； 対価については、無償あるいは最小限の実費での提供を求めるのが UCSF の原則。

◇移転マテリアルの種類

メリーランド大学； 典型的には Bioproducts、その他化学合成品および医薬品。

UCSF； 75%が Bioproducts、25%が Chemicals。

B.マテリアルに関する取り扱い規定あるいはポリシーについて

1. 成分化したルールを有しているか

NIH； 知識の拡散を最大優先原則とする NIH ガイドラインに従う共に、NIH より資金をファンドしている各施設・大学にも、その遵守を強く求めている。

メリーランド大学； 大学としての取り扱い規則(ヒトを対象とした試験についての規定、動物保護、環境保全、安全性、知的財産規定など)、さらにメリーランド州法、連邦法・連邦ガイドラインなどによって規定。

エモリー大学； YES、Emory University's Intellectual Property Policy に準拠する。
Emory University's Outgoing MTA Template など。

UCSF； 有、UCSF OTT Sample Outgoing MTAs

スタンフォード大学； Web Site で公開(Stanford 大学、INDUSTRIAL CONTRACT OFFICE)

ワシントン大学； 有、University of Washington Administrative Statements, University of WashingtonHandbook, Washington State Public Records

2. マテリアル（OUT）の帰属について

メリーランド大学； 大学の設備を使い、大学に雇用されたものによるマテリアルであるならば施設に帰属。

エモリー大学； 大学機関。

UCSF； 大学の設備を使い、大学に雇用されたものによるマテリアルであるならば機関に帰属。

ワシントン大学； 構成員の全ての発明は大学に帰属。

3. 対価の分配

メリーランド大学； 大学は対価分配について特定の算出式に基づき、大学機構および発明者などへ分配。

エモリー大学；（ライセンス契約については Emory University's Intellectual Property Policy、Distribution of Cumulative Net Revenue で規定）

アリゾナ大学； 対価の配分については MTA の場合、研究室へ 50%またライセンス契約へ移行した場合は諸経費を除いた NET REVENUE の 15%が OTT、85%が研究者。

UCSF； MTA あるいはライセンス契約の収入配分については OTT の経費を控除した後、35%が Researcher、25%が大学財団、40%が学部に配分される。

ワシントン大学； OTT 経費 20%控除、発明者 1/3、学部 1/3、Research Fund 1/3。

MTA Fee が製作費のみの場合、20%控除後、全経費が研究室に還元。

4. 事務処理フローチャート

NIH；通常 24 時間あるいは 48 時間以内に処理。

メリーランド大学； 別表参照。

エモリー大学； 添付別図参照。IN、OUT とも大半が約 3 日間程度、一部修正を必要とする場合でも 17 日程度が平均処理期間。

UCSF；（別表参照）

ワシントン大学； OUTGOING、INCOMING 別表参照。

締結までに要する日数

OUTGOING： Non-Profit 平均 33 日、For-Profit 平均 77 日

INCOMING： Non-Profit 平均 29 日、For-Profit 平均 65 日

C.マテリアル移転契約について

1. MTA の雛型は有しているか

NIH；NIH ガイドラインに基づく SLA（Simple Letter Agreement）および UBMTA を使用。

メリーランド大学；UBMTA に準拠した大学としての雛型を用意。可能な限り outgoing、incoming とも UBMTA および Simple Letter Agreement を利用。また Incoming の場合は提供者よりの Draft があ

る場合はそれを使用。MTA については研究試料の入手を通じていかに効率良く研究を遂行するかに重点がおかれ、その観点から種々の legal 条項を組み立ている。

エモリー大学; 有、Emory University's Outgoing MTA Template

アリゾナ大学; ・Simple Letter Agreement,
・Material Transfer Agreement, University of Arizona
・Material Transfer Agreement(Non-Biological), University of Arizona
の 3 類型

UCSF; 有、UCSF OTT Sample Outgoing MTAs さらに outgoing, incoming とも UBMTA および Simple Letter Agreement を利用。

ワシントン大学; 有、Washinton 大学 template、さらに UBMTA,
Simple Letter Agreement を使用(全体の 10%)、ヒト組織、実験動物については特殊形式を使用

2. 有償・無償、有償の場合の対価決定はどのように行っているか

メリーランド大学; 製作費を請求する場合は、研究者のコスト算出を尊重。ただし客観的な根拠が必要。

UCSF; MTA により提供されているサンプル対価については Academia、non-Academia を含め無償もしくは作製実費程度(例えば癌細胞で 200-250$/tissue 程度)。これは Research の進展を優先させるという UCSF の基本 POLICY に基づくものであり、大学によっては MTA を income の有力な手段としているところもある。

3. MTA 交渉の責任者

NIH; Academia の場合は、NIH 各施設の TT office, 対企業の場合は NIH の Central OTT が責任部署。

メリーランド大学; 担当部に 2 名いる Corporate Contracts Officer。

エモリー大学; Technology Transfer Office(17 名)の MTA section(3 名)が担当。

アリゾナ大学; OTT Group。

UCSF;

OUTGOING; 雛型 MTA を用いて non-profit 施設に提供される場合は OTT を経由せず Researcher に一任。For Profit へのサンプル提供では、OTT が交渉・調整にあたる。

INCOMING; incoming MTA についてはすべて OTT が担当する。

ワシントン大学; OTT 部門 MTA チーム。

4. 契約書決裁(サイナー)は誰が行っているか

NIH; 各 Institution によってそれぞれ独自に取り決め。

メリーランド大学; OTT 部門の部長、副部長クラス。UBMTA・SLA を用いる場合は担当者(Corporate Contracts Officer)。

エモリー大学; サイナーについては、outgoing については UBMTA に完全に従う場合、学部・学科の責任者となり、それ以外特に IN については、必ず OTT の責任者。

アリゾナ大学； サイナーは OUT および IN とも OTT の責任者、Read and Understood の項に研究責任者がサイン。

UCSF； Incoming MTA についての、サイナーは OTT 責任者で Researcher も witness としてサインを行う。

スタンフォード大学； 大学あるいは企業が Research Purpose で大学の MTA がそのまま受け入れられる場合は、Researcher 自身に委ねている。

D. マテリアル移転契約交渉の論点となる交渉項目について

1. 譲渡契約（OUT MTA）交渉において最も論点となる事項

NIH； NIH ガイドラインが徹底されているため、OUT GOING については改変不可ということで論点なし。

メリーランド大学； 研究目的、研究結果の譲渡主体への報告について、研究結果の発表について

アリゾナ大学； 交渉事項については州立大学であるため、免責事項、準拠法などについての厳しい制約があるが、それ以外は経済条件をふくめ、大きな困難はない。これは企業関係者も UBMTA の存在・内容を熟知しており、かつ OUT Bound についてはリーチスルーを要求しないこと、また対価については、リサーチ目的については対企業のケースでも実費以外は要求しないことからそれほどの時間的労力は要求されない。

UCSF； OUT GOING の場合、3rd Party の権利が絡んでいる場合は利益の conflict となるケースもあることから、MTA を結ぶ前に慎重にその権利関係を調査している。このような場合、NIH による UBMTA が必ずしも有効でないためケースバイケースで対応せざるを得ない。

スタンフォード大学； MTA については incoming、outgoing とも問題は年々複雑化している。

MTA OUT going の場合、純粋な Research Purpose に限られ、何らかの商業的用途と関係する場合はライセンス契約で処理する。

ワシントン大学；

OUT GOING の場合 Material に 3rd Party の権利が含まれていないか含まれている場合は UWOTT が transfer の許可を得るべく交渉。

大学自身の創出になるもので他のライセンス案件と関係ない場合は、Standard Form で処理。

対 For-Profits（企業）については、

- ✧ サンプル要求が UW の研究者を介してのものであることが前提で、以下の項目について慎重に検討・交渉。
- ✧ マテリアルの使用目的、マテリアルの起源、Funding Source、Publication そのマテリアルが既にライセンスされていないかどうか。

2. 受け入れ契約（IN MTA）交渉において下記の項目のうち、最も論点となる事項

NIH；

- ➢ マテリアルの定義についておよび ア.カデミックフリーダム・発表権について、とくにマテリアル

の定義については、NIH ガイドラインにおいて、derivative について提供者の権利を認めていないため、企業・欧州の大学との間で大きな discussing point となる。

メリーランド大学;

- 全てであるが、大学にとって致命的に重要なのはアカデミックフリーダム・発表権の確保、さらに、マテリアルを用いた新規知的財産の取り扱いについて、マテリアルの定義（derivatives の取り扱い）などが大学の研究継続を制限無く続行するためには重要度が高い。
- その他州法遵守の観点から免責、保証条項、準拠法なども重要でこれらは海外の施設との契約の場合デッドロックになる場合がある。

エモリー大学;

- 対企業との MTA については、他大学とも共通して Incoming MTA に最も交渉の労力を割いている。
- 研究の自由確保という側面のほかにも、その Material に基づく研究成果を Emoly 大学の資産として確保するという面からも極めて重要なため。

アリゾナ大学;

- IN Bound MTA の 20%はかなり交渉が長引くケースとなる、これはベンチャー企業などからリーチスルー、免責事項について過大な要求をされることが多いため。

UCSF;

- バイドール法との関係で Material を用いた研究成果について Ownership を要求されるケースがあるが（特にバイテク会社の場合）、これは明らかに法律違反につながるため拒否。
- また、legal 条項の内 confidentiality、Rep and Warranty、免責、準拠法などについても連邦法・カルフォルニア州法による規定を絶対的に遵守する必要があるため、しばしば交渉（特に海外との企業・大学との場合）で問題となり時に、Dead Lock あるいは Deal Braker となりうる。
- また、confidentiality clause についてはカルフォルニア州法との情報公開原則との背反が問題となる。

スタンフォード大学;

- Incoming/Industry がもっとも注意を払うケースで human tissue であるのかないのか、Biosafety（embryo stem cell）、さらに funding がどうなっているのか、新しく受け入れるものについて利益競合関係がないのか、さらに購入が可能でないのかどうかなどをチェックする。
- その他の交渉事項； 新規創出の IP right、confidentiality の拒否（情報公開の原則）、Publication の確保、免責の確保など。

ワシントン大学;

- 対 non-profits については通常交渉は最小限にとどめるが、ライセンス要件・公表前の Review などについての記載が増加傾向。
- 対企業については、交渉は極めて複雑かつ困難。
- 主な論議事項

- ✧ 研究室の全体の研究成果とマテリアルを用いた今後の成果との混同
- ✧ 研究室のほかのプロジェクトをも包含する研究の幅広い定義
- ✧ 不公平なリーチスルー権の主張
- ✧ 学生・院生を含む研究室全員が契約の義務下におかれる危険
- ✧ マテリアルの定義が広範となり既にある研究室の成果も包含されうること
- ✧ 研究成果を含む秘密情報範囲の拡大
- ✧ ライセンス権の制約により Bay-Dohle 法あるいは NIH 基準への抵触
- ✧ 修飾マテリアルの移転の制限
- ✧ 義務事項の相互 conflict

➢ とくに DEAL BRAKER となる事項

- ✧ 発表および研究成果の公衆への還元への制限
- ✧ 知的成果へのリーチスルー権の主張
- ✧ マテリアルの定義の拡大
- ✧ UW データおよび研究への不適切なアクセス
- ✧ 不適切な Liability

E. ガイドラインあるいは規制の影響について

メリーランド大学; 現在の US Academia の知的財産政策については 1980 Bayh-Dole ACT の成立が決定的な結節点となっている。

UCSF: カルタヘナ議定書については、gene therapy との関連から CBD（生物多様性条約）については、天然物化学のグループを有するオークランド大学で問題となる（いずれも米国は未批准であるが）。

●その他

NIH:

- 対企業への提供、commercial use と research use をどのように定義するかは微妙な問題で、ケースバイケースで central OTT と話し合って判断、マテリアル提供にあたって明らかな commercial use は MTA ではなく、License 契約で処理する。Exclusive/non-exclusive license も同様。

メリーランド大学;

- 州立大学であるが、研究資金の 50%以上は連邦政府よりの競争的資金、メリーランド州よりの資金は 10-20%にすぎない。従って MTA を含め、種々のバイオ・医学関係の研究成果移転に関しても NIH ガイドラインの遵守が原則である。
- MTA によって大学 income を確保することは、少なくとも UMB にとっては第一義的なものではない。
- 対企業へ大学の知的財産をライセンスするにあたっては商業化するにあたっての能力をチェックするための Due Diligence を実施している。これは大学関係者が設立するベンチャーといえども例外ではない。

- リサーチツール/Platform technology ライセンスについて、原則的に exclusive は許されない。特にリサーチツールについては、研究の拡散・発展・進化を阻害しないという観点から条件を厳密に規定している。
- MTA Legal 条項について、Indemnification、準拠法、Rep and Warranty 条項については、州立大学は米国政府・州政府の方針によって規定されており修正の余地は原則ないことから、企業あるいは海外の大学との間でしばしば問題となり、これらの条項が Deal Braker となるケースあり。

エモリー大学;

- Emory 大学は、他の米国の大学と同じく、外部研究資金の大半(70%)を連邦に依存しており、MTA をはじめとする各種契約においても NIH ガイドラインに従っている。
- ただ州立大学ではないため、たとえば各種契約において州法に準拠するなく自由度は高い。"全ては negociable である"というのが Emory大学 OTT(Office of Technology Transfer)のモットー。
- Emory 大学は、今後さらに医薬品関連の Technology Transfer 活動を展開するため外部よりの人材獲得にも力を入れているが、ジョージア州という地理的条件から必ずしも十分でなく、内部人材の育成にも力を入れている。
- 臨床研究と並んで、医薬品シーズの創成にも基礎研究の 1 つとして精力を注いでおり、重点事項として POC/Proof of Principle の finding があり、大規模な医薬スクリーニングセンターを設立している。
- それらの成果として、Emory 大学よりライセンスした化合物の内、現在 PIII 段階にあるものが 1、PII 段階にあるものが 4、さらに PI 段階に 4、Pre-C が 6、リード化合物の段階のものが 6 となっている。

スタンフォード大学;

- 800million$の研究費のうち大半(95%)が連邦政府からの受け入れ資金で当然、NIH などのガイドラインを遵守しなければならない
- リーチスルー、License(exclusive-non-exclusive)などについては NIH ガイドラインに従う。

ワシントン大学;

- MTA が不適切な場合は積極的にライセンス契約・共同研究などに切り替え。
- MTA は Industry と大学の最初のドア、一定の試料提供がすめば研究契約に移行させるのが目的。

●NIH の MTA に対する基本姿勢について

NIH は、国家機関であり、NIH に投入された国家予算をいかに還元するかに最も重点が置かれている。NIH の 99 発行の MTA ガイドラインもすべてその視点から構成されている(また、このガイドラインは NIH 資金を受け入れているすべての施設のガイドラインともなっている)。

企業との個別の契約においては独占的契約なども否定されるものでもないが、社会的還元という観点を最重視して、諸条件を議論している。

NIH ガイドラインの中で、最も強く遵守を要求しているものの 1 つは、Material/Derivative の定義。すな

わち、Derivative には提供者のコントロールは及ばないとする点であり、これは研究の発展を保証する上からも、企業よりのサンプル受け入れ（特に対ベンチャー）の際に大きな論点の１つとなるが譲れない点である。

Ⅲ. 米国大学・研究所ヒアリング（個別聞き取り調査概略）

1. NIH <National Institute of Health>（Bethesda, MD）

（聴取した部門）

NIAID（National Institute of Allergy and Infectious Disease）

NIDDK（National Institute of Diabetes and Digestive and Kidney Diseases）

NIHLB（National Institute of Heart, Lung and Blood）

●NIAID/NIH の Technology Transfer 活動について

- NIH は主に疾患別に区分される NCI など 27 の施設から成り立っている。今回は内 3 施設の TTG 代表者に聴取。
- それぞれの施設に Technology Transfer Group が存在すると同時に NIH 中央にも Technology Tranfer Office（NIHOTT）が機能している。
- MTA に関しては、各施設の TTD が主として Academia 間の MTA を取り扱い、対企業との MTA の交渉は施設 TTG と連携して、NIHOTT が中心になって行う。また、特許出願・ライセンス交渉は NIHOTT の責任となる。

●Technology Transfer Group の組織について

- NIAID の TTG は 40 名程度の陣容を擁している。
- NIAID 自体は約 70 の研究室より成り、研究員数は約 1,500 名以上。

●各質問事項に対する回答

A. マテリアル出入状況について

MTA 総数

- アレルギー・感染症 G（NIAID）； 約 150 件/年（OUT が 80-90%、IN が 10-20%）
- 糖尿病 G（NIDDK）； 約 600 件/年（殆どが OUT）
- 肺疾患・高血圧 G（NIHLB）； 約 300-400 件（殆どが OUT）
- 癌 G（NCI）； 約 600 件

有償・無償

- Academia については無償。原則、対企業については研究目的などを審査して有償とするかどうかを

決定。

移転マテリアルの種類

- あらゆる種類にわたるが、糖尿病 G では実験マウスが年 30 件程度。
- ヒト組織由来のサンプルの取り扱いが,現在もっとも sensitive issue。

B. マテリアルに関する取り扱い規定あるいはポリシーについて

ルールについて

- 知識の拡散を最大優先原則とする NIH ガイドラインに従うと共に、NIH より資金をファンドしている各施設・大学にも、その遵守を強く求めている。

事務処理・フローチャートについて

- 通常 24 時間あるいは 48 時間以内に処理。

研究者の移動に伴うサンプルの所属について

- 研究者を educate し、かつ施設間での話し合いを行う。

C. マテリアル移転契約について

MTA の雛型

- NIH ガイドラインに基づく SLA（Simple Letter Agreement）および UBMTA を使用。

対価決定など交渉の責任部署

- Academia の場合は、NIH 各施設の TT office、対企業の場合は NIH の Central OTT が責任部署。

契約書決済（サイナー）は

- 各 Institution によってそれぞれ独自に取り決め。

D. マテリアル移転契約交渉の論点となる交渉項目について

- 譲渡契約（OUT MTA）交渉において最も論点となるのは NIH ガイドラインが徹底されているため、OUT GOING については改変不可ということで論点なし。
- 受け入れ契約（IN MTA）交渉において、最も論点となるのは d.マテリアルの定義についておよび h.アカデミックフリーダム・発表権について。とくに d. については、NIH ガイドラインにおいて、derivative について提供者の権利を認めていないため、企業・欧州の大学との間で大きな discussing point となる。

E. その他

- 対企業への提供、commercial use と research use をどのように定義するかは微妙な問題で、ケースバイケースで central OTT と話し合って判断、マテリアル提供にあたって明らかな commercial use は MTA ではなく、License 契約で処理する。Exclusive/non-exclusive license も同様。

●NIAID　OTG について

- NIAID OTG（Office of Technology）の関与した Tech Transfer の実数は、
  - MTA 149 件（内企業対象 17 件）
  - CDA 92 件
  - CRADA 4 件 etc.
- またパテント出願数は 212 件

- Technology Transfer 活動の内、最も重視されるのは CRADA と呼ばれる共同開発研究契約。

●NIH の MTA に対する基本姿勢について

- NIH は、国家機関であり、NIH に投入された国家予算をいかに還元するかに最も重点が置かれている。NIH の 99 発行の MTA ガイドラインもすべてその視点から構成されている（また、このガイドラインは NIH 資金を受け入れているすべての施設のガイドラインともなっている）。

- 企業との個別の契約においては独占的契約なども否定されるものでもないが、社会的還元という観点を最重視して、諸条件を議論している。

- NIH ガイドラインの中で、最も強く遵守を要求しているものの 1 つは、Material/Derivative の定義。すなわち、Derivative には提供者のコントロールは及ばないとする点であり、これは研究の発展を保証する上からも、企業よりのサンプル受け入れ（特に対ベンチャー）の際に大きな論点の 1 つとなるが譲れない点である。

2. メリーランド大学（UMB）（UNIVERSITY OF MARYLAND, Baltimore, MD）

●メリーランド大学　産学連携活動について

- メリーランド大学は、メリーランド州最初の公立医療施設として独立戦争後間もない 1807 年創立の歴史を有する州立大学。
- ボルティモアに本拠を有する医学部を中心にバイオテクノロジー関係の研究も活発で、国内外のベンチャー医薬関連企業の誘致を目指して UMB BioPark をボルティモアキャンパスに建設、日本よりも CRO 1 社が進出している。
- 州立大学であるが、研究資金の 50%以上は連邦政府よりの競争的資金、メリーランド州よりの資金は 10-20%にすぎない。従って MTA を含め、種々のバイオ・医学関係の研究成果移転に関しても NIH ガイドラインの遵守が原則である。

●各質問事項に対する回答

A. マテリアル出入状況についての一般的質問

1. OUTGOING MTA（譲渡）について

1-1. 1 年間の OUT MTA の件数

50-80 件/年（過去 3 年の平均、申し込みの内 80%が締結）

1-2. 分類

◇Academia/非アカデミア（企業）

大半が大学。企業よりの申し入れに対してはライセンス契約で処理が原則。

◇地域別（北米・欧州・日本など）

Academia について米国以外の地域からの申し込みも多い。企業では米国以外からは少ない。

◇対価

一般に運送経費のみを請求、製作費を上乗せ請求する場合もあり。一時金、ロイヤルティなどを要求する場合は MTA ではなく、ライセンス契約として処理。

◇バイオプロダクツの分類

抗体、DNA、プラスミド、微生物、細胞、実験動物など

2. INCOMING MTA（受け入れ）について

2-1. 1 年間の INCOMING　MTA の件数

170-180 件/年（過去 3 年の平均、申し入れの内 85%が締結）

2-2. 分類

◇Academia/非アカデミア（企業）

大学・企業が半々。

◇対価

無償受け入れが原則、運送費を請求されるケースがしばしばあり。

◇移転マテリアルの種類

典型的には Bioproducts、その他化学合成品および医薬品。

B. マテリアルに関する取り扱い規定あるいはポリシーについて

1. 成分化したルールを有しているか

・ 大学としての取り扱い規則(ヒトを対象とした試験についての規定、動物保護、環境保全、安全性、知的財産規定など)、さらにメリーランド州法、連邦法・連邦ガイドラインなどによって規定。

2. マテリアル(OUT)の帰属について

・ 大学の設備を使い、大学に雇用されたものによるマテリアルであるならば施設に帰属。

3. 対価の分配

・ 大学は対価分配について特定の算出式に基づき、大学機構および発明者などへ分配。

4. 事務処理フローチャート

・ 別表参照。

C. マテリアル移転契約について

1. MTA の雛型は有しているか

・ UBMTA に準拠した大学としての雛型を用意。可能な限り outgoing、incoming とも UBMTA および Simple Letter Agreement を利用。また Incoming の場合は提供者よりの Draft がある場合はそれを使用。MTA については研究試料の入手を通じていかに効率良く、研究を遂行するかに重点がおかれその観点から種々の legal 条項を組み立ている。

2. 有償・無償、有償の場合の対価決定はどのように行っているか

・ 製作費を請求する場合は研究者のコスト算出を尊重、ただし客観的な根拠が必要。

3. MTA 交渉の責任者

・ 担当部に 2 名いる Corporate Contracts Officer。

4. 契約書決裁(サイナー)は誰が行っているか

・ OTT 部門の部長、副部長クラス。UBMTA・SLA を用いる場合は担当者(Corporate Contracts Officer)。

D. マテリアル移転契約交渉の論点となる交渉項目について

1. 譲渡契約(OUT MTA)交渉において、最も論点となる事項、研究目的、研究結果の譲渡主体への報告について、研究結果の発表について

2. 受け入れ契約(IN MTA)交渉において、最も論点となる事項

・ 全てであるが、大学にとって致命的に重要なのはアカデミックフリーダム・発表権の確保、さらに、マ

テリアルを用いた新規知的財産の取り扱いについて、マテリアルの定義（derivatives の取り扱い）などが大学の研究継続を制限なく続行するためには重要度が高いその他州法遵守の観点から免責、保証条項、準拠法なども重要でこれらは海外の施設との契約の場合デッドロックになる場合がある。

E. ガイドラインあるいは規制の影響について

- 現在の US Academia の知的財産政策については 1980 Bayh-Dole ACT の成立が決定的な結節点となっている。

●その他

- MTA によって大学 income を確保することは、少なくとも UMB にとっては第一義的なものではない。
- 対企業へ大学の知的財産をライセンスするにあたっては商業化するにあたっての能力をチェックするための Due Diligence を実施している。これは大学関係者が設立するベンチャーといえども例外ではない。
- リサーチツール/Platform technology ライセンスについて、原則的に exclusive は許されない。特にリサーチツールについては、研究の拡散・発展・進化を阻害しないという観点から条件を厳密に規定している。
- MTA Legal 条項について、Indemnification、準拠法、Rep and Warranty 条項については州立大学は米国政府・州政府の方針によって規定されており修正の余地は原則ないことから企業あるいは海外の大学との間でしばしば問題となりこれらの条項が Deal Braker となるケースあり。

3. エモリー大学（Emory University, Atlanta, GA）

●エモリー大学の産学連携活動について

- Emory 大学はアトランタ市街北東に位置するプライベート大学。医学関連の学部が中心（構成人員全 22,000 名中、医学関連で 8,000 名を占める）。アトランタには Solvay US、ベンチャー企業 Athrogenics が立地する程度であるが、医薬品産業との関連は深い。
- 特に Emory 大学は、抗 HIV 薬のカクテル療法の標準薬として著名な nucleoside reverse transcriptase 阻害剤 lamivudine（GSK/Shire）及び emitricitabine（Gilead）の創薬者が在籍することで著名。
- 2005 年には両剤の一括ライセンスアレンジで、Emory 大学は、Gilead より 540 million$の一時金を獲得した。従って、医薬品関連の技術移転にも大きな人員を割いている。IP 部門とは別に Technology Transfer Office には 17 名のスタッフを有しており、内 MTA セクションには 3 名が専従している（組織図 別表参照）。
- Emory 大学は、他の米国の大学と同じく、外部研究資金の大半（70%）を連邦に依存しており、MTA をはじめとする各種契約においても NIH ガイドラインに従っている。
- ただ州立大学ではないため、たとえば各種契約において州法に準拠することなく自由度は高い。“全ては negociable である”というのが Emory大学 OTT（Office of Technology Transfer）のモットー。

●各質問事項に対する回答

A. マテリアル出入状況についての一般的質問

1. OUTGOING MTA（譲渡）について

1-1. 1 年間の OUT MTA の件数

2004 年 74 件、2005 年 134 件、2006 年 101 件。

1-2. 分類

◇Academia/非アカデミア（企業）

2006 年； 101 件中、非アカデミア 4 件。

◇地域別（北米・欧州・日本など）

2006 年； 北米 65%、欧州 27%、アジア 8%。

◇対価

無償が原則。運送費・製作経費を上乗せするケースあり。

（対企業はライセンス契約として処理するケースが大半）

2. INCOMING MTA（受け入れ）について

2-1. 1 年間の INCOMING MTA の件数

2004 年 217 件、2005 年 288 件、2006 年 240 件。

2-2. 分類

◇Academia/非アカデミア（企業）

Academia 199 件、非アカデミア 42 件。

◇地域別（北米・欧州・日本など）

2006 年； 北米 87%、欧州 8%、アジア 3%。

B.マテリアルに関する取り扱い規定あるいはポリシーについて

1. 成文化したルールを有しているか

・ YES。 Emory University's Intellectual Property Policy に準拠する Emory University's Outgoing MTA Template など。

5. マテリアル（OUT）の帰属について

・ 大学機関

6. 対価の分配

・ （ライセンス契約については Emory University's Intellectual Property Policy、Distribution of Cumulative Net Revenue で規定）

7. 事務処理フローチャート

・ 添付別図参照、IN、OUT とも大半が約 3 日間程度、一部修正を必要とする場合でも 17 日程度が平均処理期間。

C.マテリアル移転契約について

1. MTA のひな形は有しているか

有。 Emory University's Outgoing MTA Template。

3. MTA 交渉の責任者

Technology Transfer Office（17 名）の MTA section（3 名）が担当。

6. 契約書決裁（サイナー）は誰が行っているか

なお、サイナーについては、outgoing についてはUBMTA に完全に従う場合、学部・学科の責任者となり、それ以外特に IN については必ず OTT の責任者。

D. マテリアル移転契約交渉の論点となる交渉項目について

交渉において下記の項目のうち、最も論点となる事項

・ 対企業との MTA については、他大学とも共通して Incoming MTA に最も交渉の労力を割いている。研究の自由確保という側面のほかにも、その Material に基づく研究成果を Emoly 大学の資産として確保するという面からも極めて重要なため。

●その他

- Emory 大学は、今後さらに医薬品関連の Technology Transfer 活動を展開するため外部よりの人材獲得にも力を入れているが、ジョージア州という地理的条件から必ずしも十分でなく、内部人材の育成にも力を入れている。
- 臨床研究と並んで、医薬品シーズの創成にも基礎研究の 1 つとして精力を注いでおり、重点事項として POC/Proof of Principle の finding があり、大規模な医薬スクリーニングセンターを設立している。
- それらの成果として、Emory 大学よりライセンスした化合物の内、現在 PIII 段階にあるものが 1、PII 段階にあるものが 4、さらに PI 段階に 4、Pre-C が 6、リード化合物の段階のものが 6 となっている。
- 特に Emory 大学関係者が設立した Athrogenics 社へライセンスした抗動脈硬化剤 AGI1067 は、PIII 段階にあるが、2006 年 AstraZeneca にライセンスされ高額の一時金の獲得に成功した。

4．アリゾナ大学（The University of Arizona, Tucson）

●アリゾナ大学の　産学連携活動について

- Arizona 大学は、Tucson にキャンパスを持つ州立大学。アリゾナ州立としては、他に Northern Arizona 大学，Arizona state（フェニックス）があるが、Arizona 大学がもっとも歴史が古い。農業科学関係を中心に発達したが、現在医学および宇宙工学では、全米でも有数のレベルにあると自負している。
- 研究費は約 550mil$、内外部よりの受け入れ資金が約 400mil$、1/3 が NIH より、それに続くのが NASA よりの資金。
- Technology Office が設立されたのは、2001 年と比較的新しいが、大学としては本部門を重点的に整備していく方針。
- TT office は FTE 約 10 名、IN Bound 担当と OUT Bound 担当に分かれており、Dr. Jones は IN Bound 担当（添付組織図参照）。

●各質問事項に対する回答

A マテリアル出入状況についての一般的質問

1．OUTGOING MTA（譲渡）について

1-1．1 年間の OUT MTA の件数

2004 年 46 件、2005 年 43 件、2006 年 45 件（2000 年 9 件）。

1-2．分類

◇Academia/非アカデミア（企業）

アカデミア ： 非アカデミア　 50％ ：50％。

◇地域別（北米・欧州・日本など）

50％以上が北米。

◇対価

対 Academia は無償が原則、対企業は製作費などの実費。

2．INCOMING MTA（受け入れ）について

2-1．1 年間の INCOMING MTA の件数

約 95 件。

2-2．分類

◇Academia/非アカデミア（企業）

臨床試験サンプル（特に抗がん剤関連）を中心に企業よりが過半。

◇地域別（北米・欧州・日本など）

50％以上が北米。

B. マテリアルに関する取り扱い規定あるいはポリシーについて

3. 対価の分配

・ 対価の配分については MTA の場合、研究室へ 50%またライセンス契約へ移行した場合は諸経費を除いた NET REVENUE の 15%が OTT、85%が研究者。

C. マテリアル移転契約について

1. MTA の雛型は有しているか

・ Simple Letter Agreement, Material Transfer Agreement, University of Arizona Material Transfer Agreement (Non-Biological), University of Arizona の 3 類型。

3. MTA 交渉の責任者

・ OTT Group

7. 契約書決裁(サイナー)は誰が行っているか

・ サイナーは OUT および IN とも OTT の責任者、Read and Understood の項に研究責任者がサイン。

D. マテリアル移転契約交渉の論点となる交渉項目について

1. 譲渡契約(OUT MTA)交渉において最も論点となる事項

・ 交渉事項については州立大学であるため、免責事項、準拠法などについての厳しい制約があるが、それ以外は経済条件をふくめ、大きな困難はない。これは企業関係者も UBMTA の存在・内容を熟知しており、かつ OUT Bound についてはリーチスルーを要求しないこと、また対価についてはリサーチ目的については対企業のケースでも実費以外は要求しないことからそれほどの時間的労力は要求されない。

2. 受け入れ契約(IN MTA)交渉において最も論点となる事項

・ IN Bound MTA の 20%はかなり交渉が長引くケースとなる、これはベンチャー企業などからリーチスルー、免責事項について過大な要求をされることが多いため。

5. UCSF（University of California,San Francsco、CA）

●UCSF　産学連携活動について

- UCSF は、医薬関係の特許ライセスやスタートアップで世界的に有名。
- 2005 年のライセス収入は$28,543,000。そのうち B 型肝炎ワクチン（1979 に Apply）が$16,434,000。150 件の新規発明を出願。スタートアップ 3 件。
- OTT G はサンフランシスコ市内に、6 年前にオフィスを設け（それまではバークレイに集中していた）弁護士 4 人。博士 6 から 8 名を有する。
- UCSF OTT G は IN BOUND　MTA/OUT　BOUND　MTA を取り扱う G を分けており、それぞれ 2-3 名が従事。

●各質問事項に対する回答

A. マテリアル出入状況についての一般的質問

1. OUTGOING MTA（譲渡）について

1-1. 1 年間の OUT MTA の件数

契約件数は年間 total 1,000 件程度。

1-2. 分類

◇Academia/非アカデミア（企業）

20%程度が For Profit（企業）へのサンプル提供で、100-200 ケース/年。

◇対価

MTA により提供されているサンプル対価については Academia、non-Academia を含め無償もしくは作製実費程度（例えば癌細胞で 200-250$/tissue 程度）。これは Research の進展を優先させるというUCSF の基本 POLICY に基づくものであり、大学によってはMTA を income の有力な手段としているところもある。

◇バイオプロダクツの分類について

Human 由来のサンプルの MTA は個人情報の問題など多くの検討すべき点があるため、別のグループで扱う。Human tissue のうち　human embryotic cell を使った研究については連邦政府からの厳しい規制があるため、サンプルの移動などについても厳しい管理を行っている。これは Bush 政権の間は続けざるを得ない。

2. INCOMING MTA（受け入れ）について

2-1. 1 年間の INCOMING MTA の件数

Human 由来のものを含め年間 450-500 件の MTA を締結。

2-2. 分類

◇Academia/非アカデミア（企業）

Academia と non-Academia の比率は 50：50。

◇地域

地域的には 75%が北米。

◇対価

対価については、無償あるいは最小限の実費での提供を求めるのが UCSF の原則。

◇移転マテリアルの種類

75%が Bioproducts、25%が Chemicals。

B. マテリアルに関する取り扱い規定あるいはポリシーについて

1. 成化したルールを有しているか

・ 有、UCSF OTT Sample Outgoing MTAs。

2. マテリアル（OUT）の帰属について

・ 大学の設備を使い、大学に雇用されたものによるマテリアルであるならば機関に帰属。

3. 対価の分配

・ MTAあるいはライセンス契約の収入配分についてはOTTの経費を控除した後、35%がResearcher、25%が大学財団、40%が学部に配分される。

4. 事務処理フローチャート

・ 別表参照。

C. マテリアル移転契約について

1. MTA のひな形は有しているか

・ 有、UCSF OTT Sample Outgoing MTAs さらに outgoing、incoming とも UBMTA および Simple Letter Agreement を利用。

2. 有償・無償、有償の場合の対価決定はどのように行っているか

・ MTA により提供されているサンプル対価についてはAcademia、non-Academia を含め無償もしくは作製実費程度（例えば癌細胞で 200-250$/tissue 程度）。これは Research の進展を優先させるという UCSF の基本 POLICY に基づくものであり、大学によってはMTA を income の有力な手段としているところもある。

3. MTA 交渉の責任者

・ OUTGOING； 雛型MTA を用いて non-profit 施設に提供される場合はOTT を経由せずResearcher に一任、For Profit へのサンプル提供では、OTT が交渉・調整にあたる。

・ INCOMING； incoming MTA についてはすべて OTT が担当する。

4. 契約書決裁（サイナー）は誰が行っているか

・ Incoming MTA についてのサイナーは OTT 責任者で Researcher も witness としてサインを行う。

D. マテリアル移転契約交渉の論点となる交渉項目について

1. 譲渡契約（OUT MTA）交渉において最も論点となる事項

・ OUT GOING の場合、3rd Party の権利が絡んでいる場合は、利益の conflict となるケースもあることから、MTA を結ぶ前に慎重にその権利関係を調査している。このような場合、NIH による UBMTA が必ずしも有効でないためケースバイケースで対応せざるを得ない。

2. 受け入れ契約（IN MTA）交渉において最も論点となる事項

・ バイドール法との関係で Material を用いた研究成果について Ownership を要求されるケースがあるが（特にバイテク会社の場合）、これは明らかに法律違反につながるため拒否。

・ また、legal 条項の内 confidentiality、Rep and Warranty、免責、準拠法などについても連邦法・カルフォルニア州法による規定を絶対的に遵守する必要があるため、しばしば交渉（特に海外との企業・大学との場合）で問題となり時に、Dead Lock あるいは Deal Braker となりうる。

・ また confidentiality clause についてはカルフォルニア州法との情報公開原則との背反が問題となる。

E. ガイドラインあるいは規制の影響について

・ カルタヘナ議定書については、gene therapy との関連から CBD（生物多様性条約）については、天然物化学のグループを有するオークランド大学で問題となる（いずれも米国は未批准であるが）。

6. スタンフォード大学（Stanford Univ.、Palo Alto、CA）

●スタンフォード大学産学連携活動について

- サンフランシスコ南郊 Palo Alto にキャンパスを展開する私立大学。バイオ分野では Cohen 教授 G の遺伝子組み換えの基本特許を有していたことで著名。
- 技術移転 G は 1970 年代に設立され、30 年の歴史を有している、現在人員が 29 名、その半数が Industrial Contract G に所属。Research Agreement、MTA などを扱う。MTA は 4 名で処理する。
- 800million$の研究費のうち大半（95%）が連邦政府からの受け入れ資金で当然、NIH などのガイドラインを遵守しなければならない。
- 1 年間で 650 件の Research Agreement を OTL は締結。その内訳は、
  - Sponsored Research Agreement 150 件
  - Consortium Agreement 50 件
  - 0$ collaboration（相互無償の共同研究契約） 30 件

●各質問事項に対する回答

A. 1 年間の OUTGOING/INCOMING MTA の件数

MTA 450 件。

B. マテリアルに関する取り扱い規定あるいはポリシーについて及び C.マテリアル移転契約について

Research Policy/各種契約雛型について

- Web Site で公開（Stanford 大学、INDUSTRIAL CONTRACT OFFICE）

サイナー/締結権限について

- 大学あるいは企業がResearch Purposeで大学のMTAがそのまま受け入れられる場合は、Researcher自身に委ねている。

D. マテリアル移転契約交渉の論点となる交渉項目について

- MTA については incoming、outgoing とも問題は年々複雑化している。
- MTA OUT going の場合、純粋な Research Purpose に限られ、何らかの商業的用途と関係する場合はライセンス契約で処理する。
- Incoming/Industry がもっとも注意を払うケースで human tissue であるのかないのか、Biosafety（embryo stem cell）、さらに funding がどうなっているのか、新しく受け入れるものについて利益競合関係がないのか、さらに購入が可能でないのかどうかなどをチェックする。
- その他の交渉事項として、新規創出の IP right、confidentiality の拒否（情報公開の原則）、Publication の確保、免責の確保など。

●その他

・　リーチスルー、License（exclusive/non-exclusive）などについては NIH ガイドラインに従う。

7. ワシントン大学（University of Washington、Seattle、WA）

●ワシントン大学産学連携活動について

- ワシントン大学は、マイクロソフト社、ボーイング社を始めとした先進技術産業が極めて活発な活動を展開している、シアトル地域の中心をなす州立大学。バイオ産業の分野でも最近 Lilly 社による買収が決定された Icos 社など近年、多くの会社が活動を展開している。
- ワシントン大学 OTT（Office of Technology Transfer）部門は約 50 名の人員で構成。MTA については 4 名の FTE が担当。いずれも 5 年−10 年の経験を有している（組織図添付）。
- 2006 年の実績は、
  - 発明受理　310 件
  - 締結した Commercialization Agreement　153 件
  - US 特許出願　151 件
  - 締結した MTA　600 件
  - 締結した CDA　171 件
  - Start Up Companies　10 件

●各質問事項に対する回答

A. マテリアル出入状況についての一般的質問

1. OUTGOING MTA（譲渡）について

1−1. 1 年間の OUT MTA の件数

年間 298 件（2006 年）。

1−2. 分類

◇Academia/非アカデミア（企業）

Non−Profit（Academia） 282 件、For−Profit（企業）16 件。

◇対価

対 Academia は無償

対企業　OUTGOING Research tool については、Upfront と Annual Maintenance Fee を要求。

◇バイオプロダクツの分類について

スクリーニング目的の実験マウスについては特別な契約形態を用意。

◇締結までに要する日数

Non−Profit 平均 33 日、For−Profit 平均 77 日。

2. INCOMING MTA(受け入れ)について

2-1. 1 年間の INCOMING MTA の件数

年間 300 件(2006 年)。

2-2. 分類

◇Academia/非アカデミア(企業)

Non-Profit(Academia) 251 件、For-Profit(企業) 49 件。

◇締結までに要する日数

Non-Profit 平均 29 日、For-Profit 平均 65 日。

B. マテリアルに関する取り扱い規定あるいはポリシーについて

1. 成化したルールを有しているか

有。University of Washington Administrative Statements, University of Washington Handbook, Washington State Public Records

2. マテリアル(OUT)の帰属について

構成員の全ての発明は大学に帰属。

3. 対価の分配

OTT 経費 20%控除、

発明者 1/3、学部 1/3、Research Fund 1/3。

MTA Fee が製作費のみの場合、20%控除後全経費が研究室に還元。

4. 事務処理フローチャート

OUTGOING、INCOMING 別表参照。

C. マテリアル移転契約について

1. MTA の雛型は有しているか

有。Washinton 大学 template、さらに UBMTA、Simple Letter Agreement を使用(全体の 10%)。ヒト組織、実験動物については特殊形式を使用。

3. MTA 交渉の責任者

OTT 部門 MTA チーム。

D. マテリアル移転契約交渉の論点となる交渉項目について

1. 譲渡契約(OUT MTA)交渉において、最も論点となる事項

- OUT GOING の場合 Material に 3rd Party の権利が含まれていないか、含まれている場合は UW OTT が transfer の許可を得るべく交渉。
- 大学自身の創出になるもので他のライセンス案件と関係ない場合は、Standard Form で処理。
- 対 For-Profits(企業)につていは、サンプル要求が UW の研究者を介してのものであることが前提、

以下の項目について慎重に検討・交渉

- マテリアルの使用目的、マテリアルの起源、Funding Source、Publication
- そのマテリアルが既にライセンスされていないかどうか

2. 受け入れ契約（IN MTA）交渉において最も論点となる事項

- 対 non-profits については通常交渉は最小限にとどめるが、ライセンス要件・公表前の Review などについての記載が増加傾向。
- 対企業については、交渉は極めて複雑かつ困難。主な論議事項は、
  - 研究室の全体の研究成果とマテリアルを用いた今後の成果との混同
  - 研究室のほかのプロジェクトをも包含する研究の幅広い定義
  - 不公平なリーチスルー権の主張
  - 学生・院生を含む研究室全員が契約の義務下におかれる危険
  - マテリアルの定義が広範となり既にある研究室の成果も包含されうること
  - 研究成果を含む秘密情報範囲の拡大
  - ライセンス権の制約により Bay-Dohle 法あるいは NIH 基準への抵触
  - 修飾マテリアルの移転の制限
  - 義務事項の相互 conflict
- とくに DEAL BRAKER となる事項
  - 発表および研究成果の公衆への還元への制限
  - 知的成果へのリーチスルー権の主張
  - マテリアルの定義の拡大
  - UW データおよび研究への不適切なアクセス
  - 不適切な Liability

●その他

- MTA が不適切な場合は積極的にライセンス契約・共同研究などに切り替え。
- MTA は Industry と大学の最初のドア、一定の試料提供がすめば研究契約に移行させるのが目的。

Ⅳ. 参考資料

Synopsis of MTA INTERVIEW FORM

January 2007, NAIST

A. General questions on Material Transfers at your institution

1 Outgoing MTAs

i) Total number of MTAs per year
ii) Classification

- To Which; Academic / Industry
- North America/Europe/Japan/Third World
- Cost; no cost/appropriate fees (upfront/running royalty)
- Materials;Bio Product/Chemicals/Others
- Bio Product; Microorganism/Cultured Cells/Experimental Animals/Experimental Plants, Antibody/Gene

2 Incoming MTAs

i) Total number of MTAs per year
ii) Classification

- From Which; Academic / Industry
- North America/Europe/Japan/Third World
- Cost; no cost/appropriate fees(upfront/running royalty)
- Materials; Bio Product/Chemicals/Others
- Bio Product; Microorganism/Cultured Cells/Experimental Animals/Experimental Plants, Antibody/Gene

B. Questions on Rules for Handling Material Transfers

1. Do you have written rules or policies for handling Material Transfers?

2 Who owns the outgoing Materials? (e.g., Institution, Department or Laboratory, Researcher, Recipient)?

3 Income Distribution policy (University/Laboratory/Researcher)

4 Flow Chart of MTA processing

C Questions on MTA

1. Do you have model MTA documents?

2. How do you make decisions regarding fees for MTAs?

3. Who is the main person negotiating MTAs?

4. Who has signature authority for MTAs?

D Questions on MTA Negotiation

1. Which are the most serious issues for Outgoing MTAs?
   a. Handling New Intellectual Property created by using the Material
   b. Quality Control of the Material itself
   c. Royalties/Fees
   d. Definition of Research Purpose
   e. Disclosure of the Research Results to your Institution's researcher
   f. Publication of Research Results
   g. Confidentiality
   h. Modification of materials (progeny, duplicates, derivatives, etc.)
   i. Ability of your Institution to use New Intellectual Property or Modifications
   j. US Government Rights
   k. Grants of License
   l. Warranties
   m. Indemnification and other legal issues
   n. Other

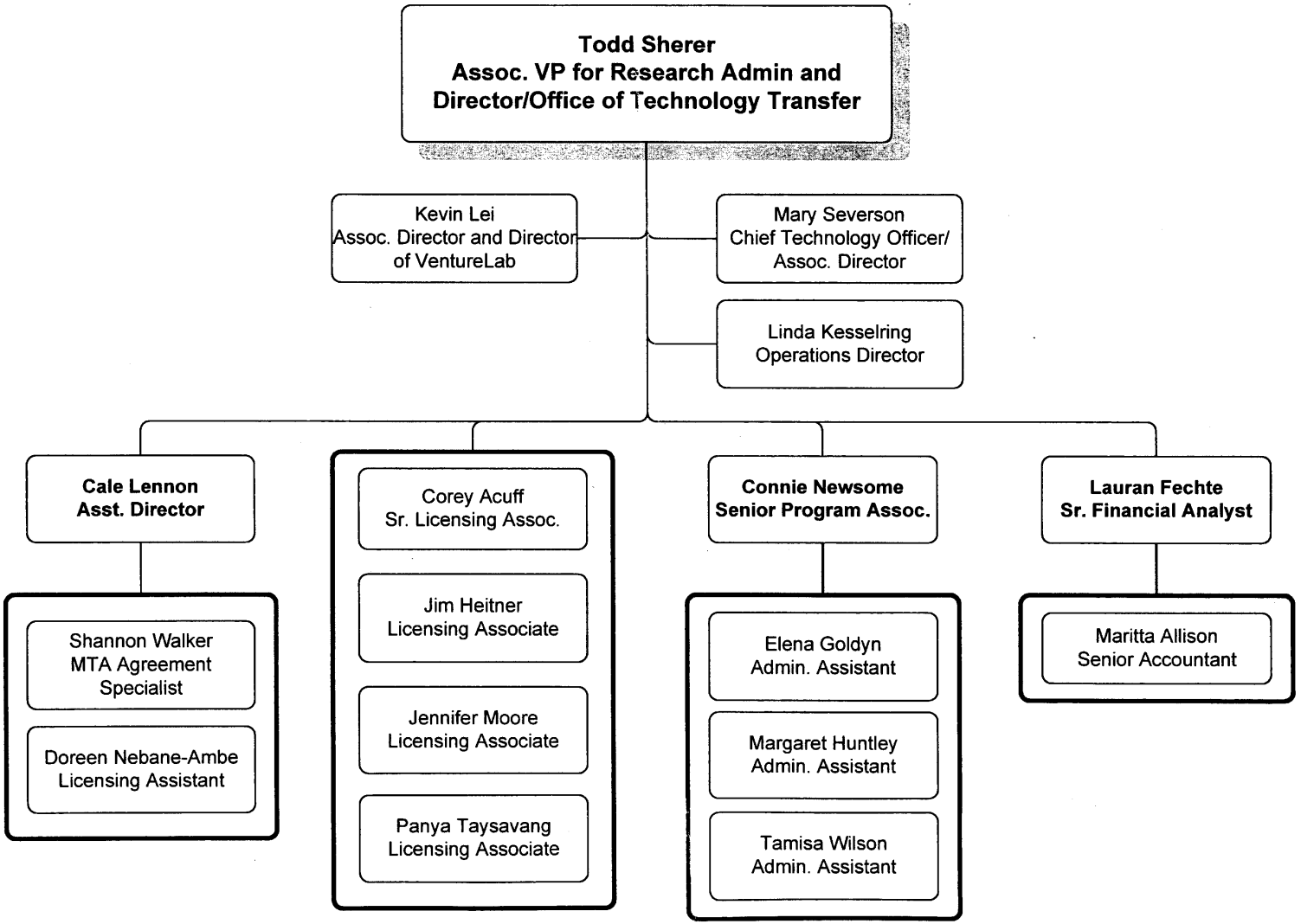
2. Which are the most serious issues for Incoming MTAs
   a. Handling New Intellectual Property created by using the Material.
   b. Royalties/Fees
   c. US Government Rights
   d. Definition of Materials
   e. Ownership
   f. Grants of License
   g. Conflicts with existing agreements
   h. Academic Freedom/Publication Rights
   i. Confidentiality
   j. Warranties
   k. Indemnification and other legal issues
   l. Other

E. Questions on the practical outcome of various Guidelines and

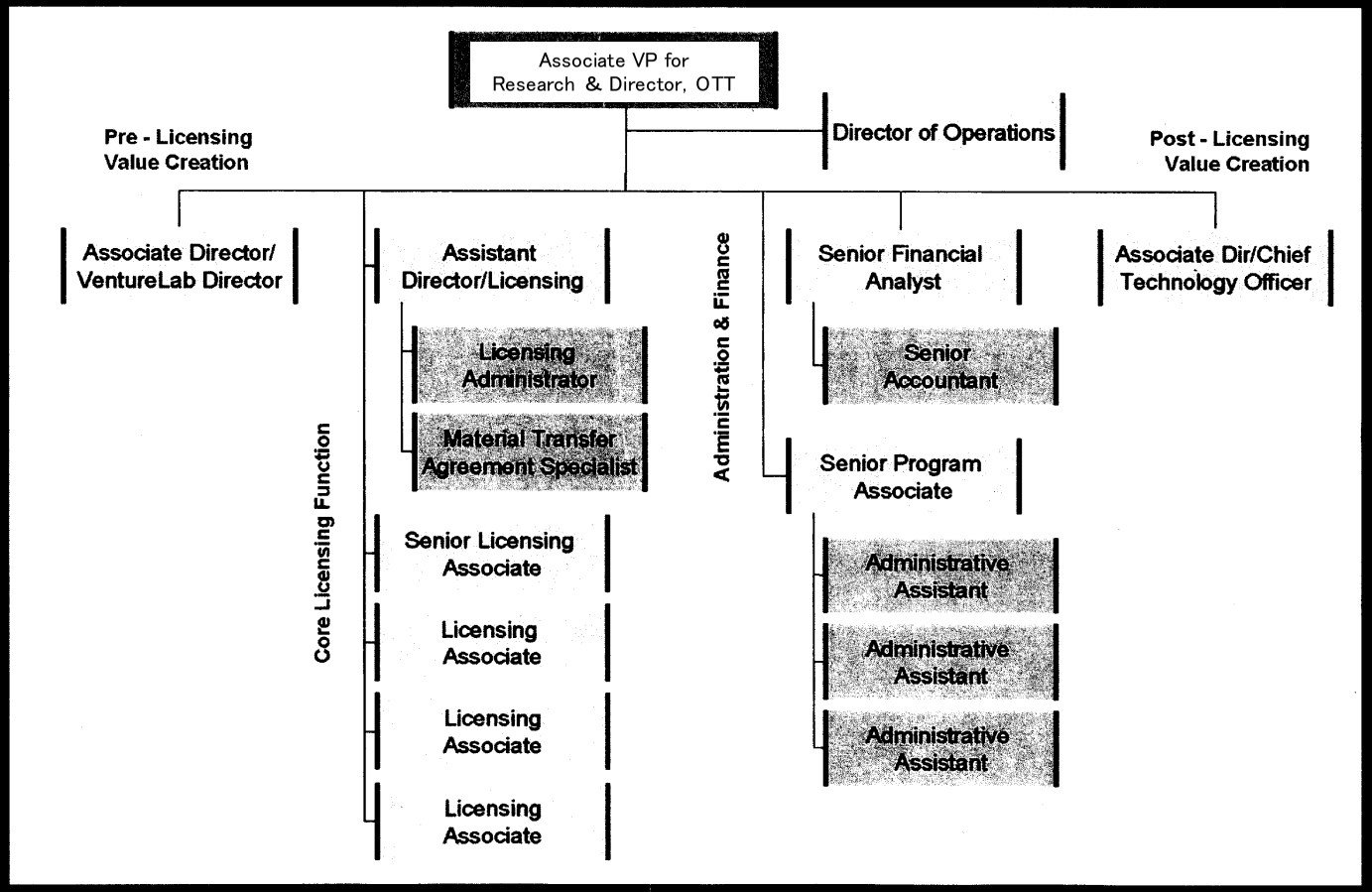
Regulations

1. Bayh-Dole ACT
2. NIH guidelines
3. Cartagena Protocol of Biosafety
4. CBD (Convention on Biological Diversity)
5. Local Regulations
6. Other

Office of Technology Transfer



Office of Technology Transfer Org Chart



MATERIAL TRANSFER AGREEMENT (MTA) QUESTIONNAIRE
REQUEST FOR OUTGOING MATERIALS
UNIVERSITY OF MARYLAND, BALTIMORE (UM)
OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
This form can be downloaded from http://www.ord.umaryland.edu

Please fully complete and sign this form and e-mail or fax to the Office of Research and Development (see details below). You MUST complete this form for us to process your MTA.

1. Your name and title **(name of faculty member and title):**
Department:
Phone:
Fax:
Email:

2. Provide the name, title, phone and fax number and address of the scientist at the institution that has requested the Material ("Requestor"). If you also have contact information for the institution administrator who deals with technology transfer, that will expedite processing.
Scientist Name and Title:
_____
_____
Phone and Fax Number:
_____
_____
Institution and Address:
_____
_____
_____
Administrator Name and Title:
_____
_____
Phone and Fax Number:
_____
_____

3. What is the type and amount of material requested from you ("Material")?
_____
_____
_____
_____

4. Describe the proposed use of the Material by the Requestor (you may attach a copy of the request).
_____
_____
_____
_____
_____
_____

4a. Does the Requestor intend to use the material outside his/her institution?
_____ Yes _____ No

4b. Will the Requestor be combining the materials with other materials?
_____ Yes _____ No

4c. What is the funding source for the Requestor's project?

__Federal __Other non-profit __Corporate

5. Is the Material **related** to an invention that has been or will be disclosed to ORD?
_____ Yes _____ No

6. Is the Material available commercially or through any other source such as a research reagent bank or depository (such as the ATCC, Hybridoma Bank, etc.)?
_____ Yes _____ No

7. Have you already provided the Material to the Requestor?
_____ Yes _____ No

8. Do you have a consulting relationship with the Requestor?
_____ Yes _____ No

9. Do you have any role in the Requestor's research?
_____ Yes _____ No

10. Has the material been the subject of publication?
_____ Yes _____ No
If so, please describe:
_____
_____

11. Was the Material:
a. Obtained under a Material Transfer Agreement or any other form of agreement?
_____ Yes _____ No

b. Created using other biological material obtained under a Material Transfer Agreement or any other form of agreement (such as the DuPont cre-lox transgenic mouse technology)? If so, please attach a copy of the Agreement.
_____ Yes _____ No

c. Created in conjunction with non-UMB personnel?
_____ Yes _____ No

d. Created as part of a research project for which you received External Support?
_____ Yes _____ No

If yes to any of the above, attach Agreement, identify non-UMB personnel, and/or External Support:
_____
_____
_____

12. Is the material a unique animal model?
_____ Yes _____ No
If so, please describe:
_____
_____

13. Is the material a novel, unique method, material, process, idea, technology, compound, research tool, screening device, therapy or diagnostic?
_____ Yes _____ No
If so, please describe:
_____
_____

14. Would you like the Requestor to reimburse the costs of providing the Material?
_____ Yes _____ No

I certify that all information provided is accurate.

_____ _____
Signature Date

Please fax the completed, signed form and attachments to ORD at 706-6630 or E-mail to Nancy Cowger, Ph.D. (Corporate Contracts Officer) at ncowg001@umaryland.edu or Carol Foreman (Contract & Grant Associate) at cfore002@umaryland.edu

MATERIAL TRANSFER AGREEMENT (MTA) QUESTIONNAIRE
REQUEST FOR INCOMING MATERIALS
UNIVERSITY OF MARYLAND, BALTIMORE (UM)
OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
This form can be downloaded from http://www.ord.umaryland.edu

Please fully complete and sign this form after thoroughly reading your MTA and e-mail or fax to the Office of Research and Development (see details below). You MUST complete this form for us to process your MTA.

1. **Principal Investigator** requesting Materials:
Name:
Title:
Department:
Phone: Fax:
Email:

2. **Provider of Material**
a. Describe Provider Organization:
_____Non-profit/University
_____Commercial Entity

b. Name and Address of Provider Organization:
_____
_____
_____

c. Contact person & phone# or e-mail address:
_____
_____

3. **Type of Material** (please define if necessary)
_____
_____

4. **Proposed Use of Material.**
a. Explain how you will use the Material (you may attach a scope of work). Identify if used for pre-clinical data or research tool and highlight the part relating to the use of the Material:
_____
_____
_____
_____

b. Does the use of the Material involve _____animals/_____human subjects? Please attach IRB or IACUC approval document(s).

b. Is a unique animal model involved?
_____ Yes _____ No

If so, please describe, including who developed the unique model (UM or other):
_____
_____

d. Does the scope of work involve other UM employees or Graduate Students? If yes, please identify:
_____ Yes _____ No
_____

e. Will the Material be used by collaborators outside of UM? If yes, please identify:
_____ Yes _____ No
_____

f. Does the research involve hazardous substances? If yes, please identify:
_____ Yes _____ No
_____

5. Is the material encumbered by patent(s) or license(s) of which you are aware? Please explain:
_____ Yes _____ No
_____

6. Is the Material available commercially or through any other source such as a Research Reagent Bank or Depository (such as the ATCC, Hybridoma Bank, etc.)
_____ Yes _____ No

7. Do you have the material in your possession?
_____ Yes _____ No

8. Do you have a consulting relationship with the provider of the material?
_____ Yes _____No

9. **Corporate/Industrial Support**
a. Do you receive industrial support for any portion of your salary or the salary of

individuals working under your supervision on the project in which the Materials will be used?
_____ Yes _____ No

b. Do you receive industrial support for the research project in which materials will be used?
_____ Yes _____ No

c. Do you receive industrial support for purchase of supplies, reagents, animals, tissues or cells which will be used in the research project for which materials are being requested?
_____ Yes _____ No

If "yes" to any of the above, please explain briefly:
_____
_____

If "yes" to any of the above, has the project been routed?_____

10. Will the provider participate in the research?
_____ Yes _____ No

11. **Funding for the project in which the Materials will be used:**
a. Please list the sponsor(s) (for-profit, Foundations, Federal etc.), title of research project(s) and, if appropriate grant number(s) of the on-going sponsored research project(s) in which material will be used.
_____
_____

b. Are you using material to generate preliminary data for support of a grant application? If so, identify the granting agency and the deadline.
_____ Yes _____ No
_____

12. Will the material be used in conjunction with any other material(s) or used in experiments involving other materials obtained from a third party under another agreement (e.g., license, Sponsored Research, MTA)?
_____ Yes _____ No

a. If yes, please identify the other material(s) and where it/they come from:
_____

b. If yes, were there any Agreement, Statement of Investigator Form, letter of intent or correspondence of any kind between you and the provider of the Other Material(s)?
_____ Yes _____ No
If yes, and you have not already provided a copy to ORD, kindly do so now.

13a. Will the Material be used in conjunction with any other materials developed at UM?
_____Yes _____ No

13b. Is the UM material subject of a disclosure to Tech Com., license, patent application, or discussion with Tech Com? If so, please provide further information and identify UM employee(s) who created the material.
_____ Yes _____ No
_____
_____

14. Does the research involve any material or method of value or potential value that you have developed? If yes, please describe and list relevant patents or invention disclosures.
_____ Yes _____ No
_____
_____

15. Do you anticipate that novel, unique methods, materials, processes, ideas, technologies compounds, research tools, screening devices, therapies or diagnostics will be developed from the use of the Material? If so, please describe:
_____ Yes _____No
_____
_____

Please be aware that there may be terms and conditions in the Material Transfer Agreement which may (i) preclude your use of the Materials in research sponsored by third parties, or (ii) prevent you from obtaining Materials in the future from third parties whose policies do not allow distribution of biological materials to investigators whose rights to commercialized technology may be limited by pre-existing obligations. DO NOT RELEASE MATERIAL TO A THIRD PARTY (INLCUDING UM PERSONNEL) WITHOUT THE WRITTEN PERMISSION OF THE PROVIDER.

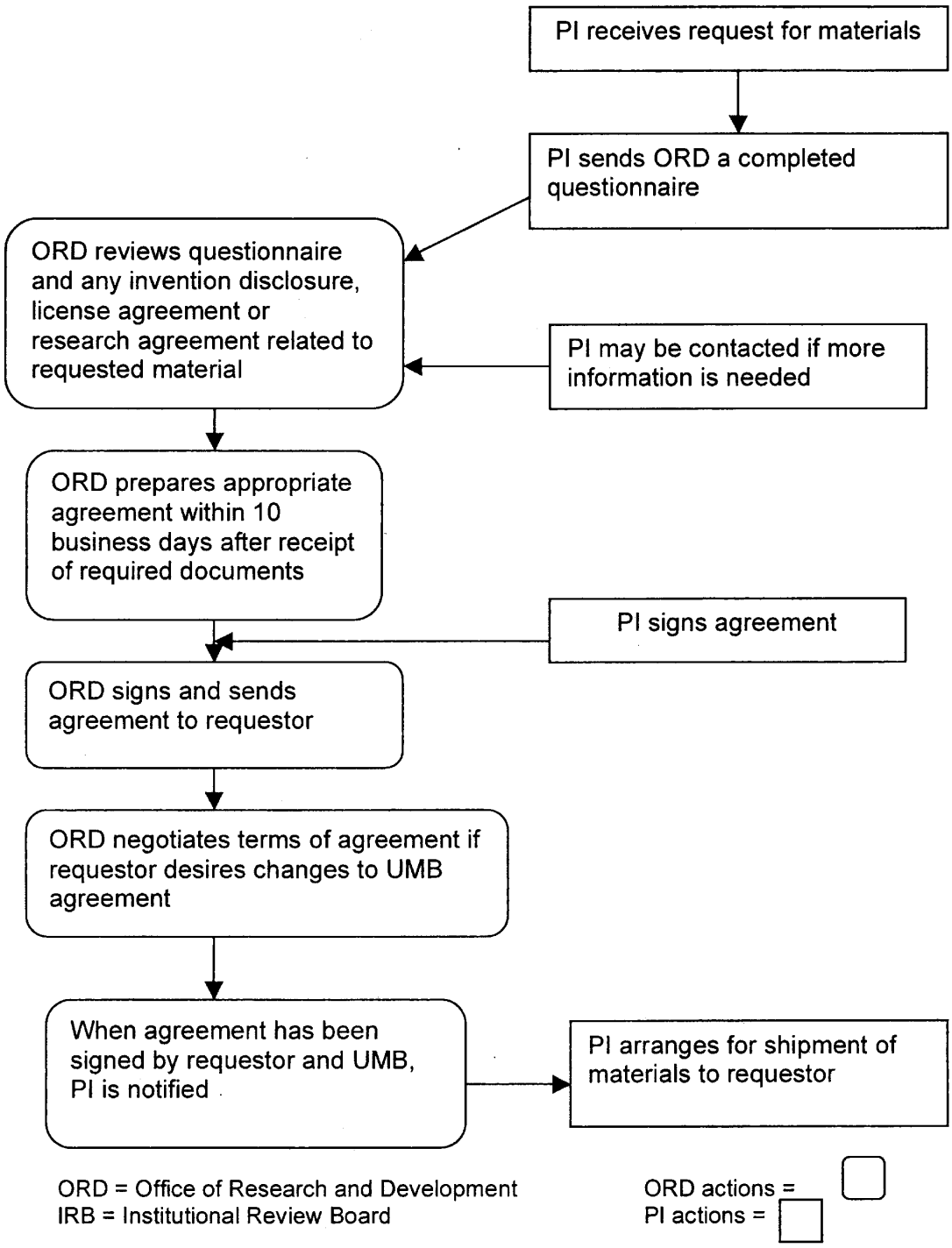
I certify that all information provided is accurate

_____ _____

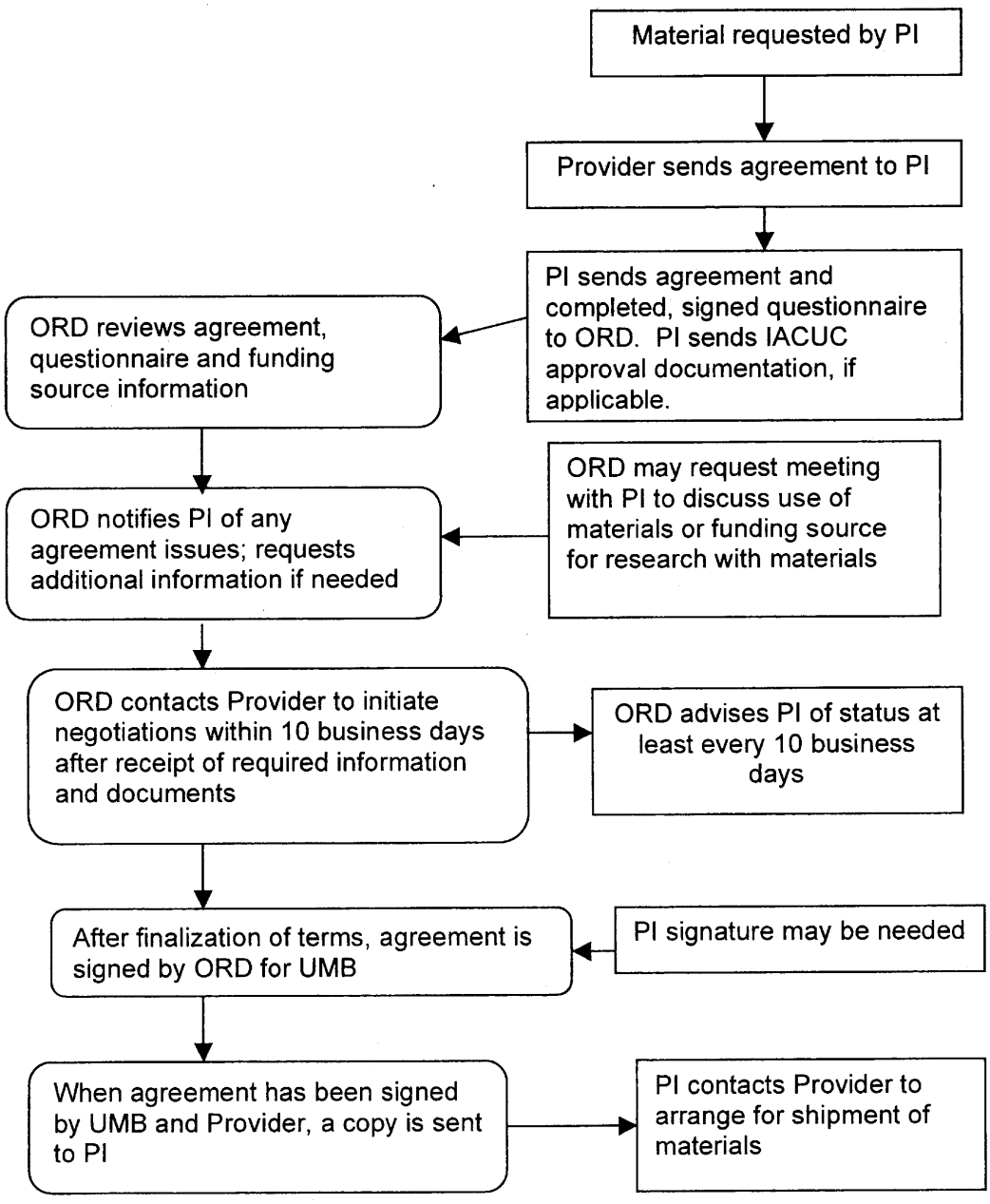
Signature Date

Please fax the completed, signed form and attachments to ORD at 706-6630 or E-mail to Nancy Cowger, Ph.D. (Corporate Contracts Officer) at ncowg001@umaryland.edu or Carol Foreman (Contract & Grant Associate) at cfore002@umaryland.edu

MATERIAL TRANSFER AGREEMENTS – OUTGOING MATERIALS



MATERIAL TRANSFER AGREEMENTS – INCOMING MATERIALS

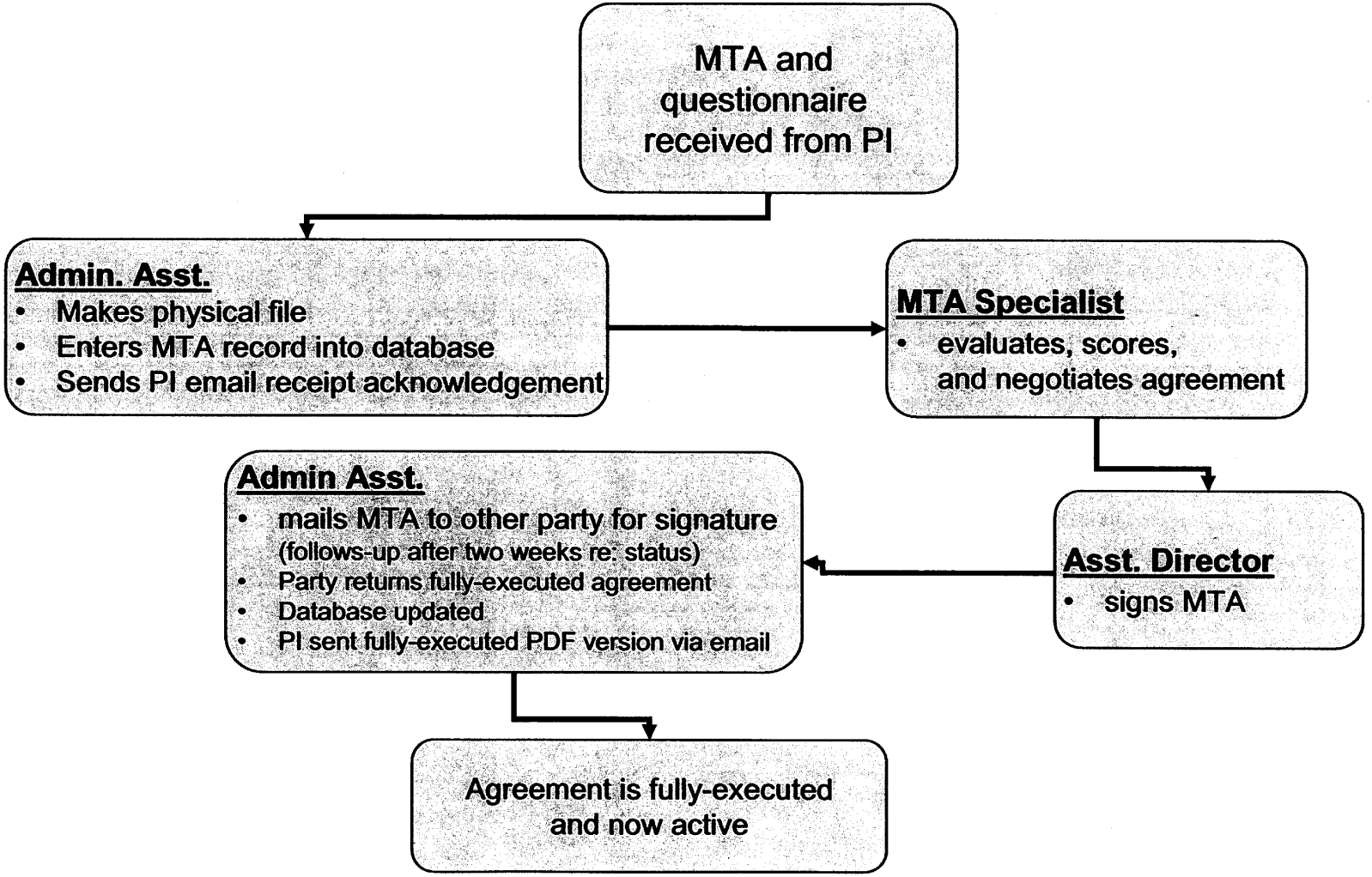


ORD = Office of Research and Development

ORD actions = ☐
PI actions = ☐

Office of Research and Development
www.ord.umaryland.edu

Material Transfer Agreement Process



SEND COMPLETED FORM TO: INDUSTRIAL CONTRACTS OFFICE: Phone: 3-0651; Fax: 5-7295
1705 El Camino Real, Palo Alto CA 94306--1106, m/s 1850

MATERIAL TRANSFER AGREEMENT (MTA) ROUTING FORM

Admin. Dept.:	PI: _____ Co – PI: _____ Admin: _____	Phone: _____ Phone: _____ Phone: _____	Email: _____ Email: _____ Email: _____

Provider Name & Address:	Project Title: Name/Description of the Material:

Provider Contact (Name, Phone, Fax, Email)

Remarks/Special Instructions

Conditions Requiring Special Consideration

Note: Protocols and special approvals should be prepared/requested AS EARLY AS POSSIBLE

YES	NO	
		Is the Material to be used in living persons? If YES, research is not permitted under MTAs.
		Is the Material obtained from a living person? If YES, please (1) attach a copy of your IRB approval letter and (2) provide a copy of the Provider's IRB approval letter to Stanford's IRB Office.
		Is the Material a live vertebrate animal?** If YES, please provide A-PLAC protocol # _____ ***You must submit a completed SU-45 to the Research Animal Facility administrative office.*
		Is the Material to be used in a live vertebrate animal? If YES, please provide A-PLAC protocol # _____
		Is the Material a radiological hazard? If YES, please provide CRA#/SMN# _____
		Is the Material rDNA?
		Is the Material infectious or biohazardous?
		If the answer to either of the previous two questions is YES, do you need approval from the Biosafety Panel (APB)? If YES, please provide your APB project # _____
		Does the research involve human embryonic or fetal stem cells and/or embryo research? (If yes, complete and attach Stem Cell Tracking Form.)
		Have all participating researchers who are currently identified, including postdocs, students and visiting scholars, signed Stanford's Patent and Copyright Agreement form (SU-18 or SU-18A)?
		Do any of the involved Stanford researchers have a financial relationship with the Provider such as consulting, serving on an Advisory Board or Board of Directors, or ownership of stock or stock options? If yes, describe the relationship on a separate sheet.
		Do any of the involved researchers receive gift funds from Provider?
		Will you be modifying the Material? If so, how?
		Specify the funding source(s) for the research project (check all that apply): ❑ Industry sponsor name(s): ❑ Federal contract(s) or grant(s): sponsor name(s) ❑ Nonprofit grant: grantor name(s): ❑ Gift funds giver name(s): ❑ Other Please provide the sponsored project number(s):
		Will the Material be used in conjunction with other Materials from commercial parties? If so, what are these other Materials and who provided them? Were Material Transfer Agreements signed for these other Materials?
		Is the Material commercially available for purchase?

PI Certification

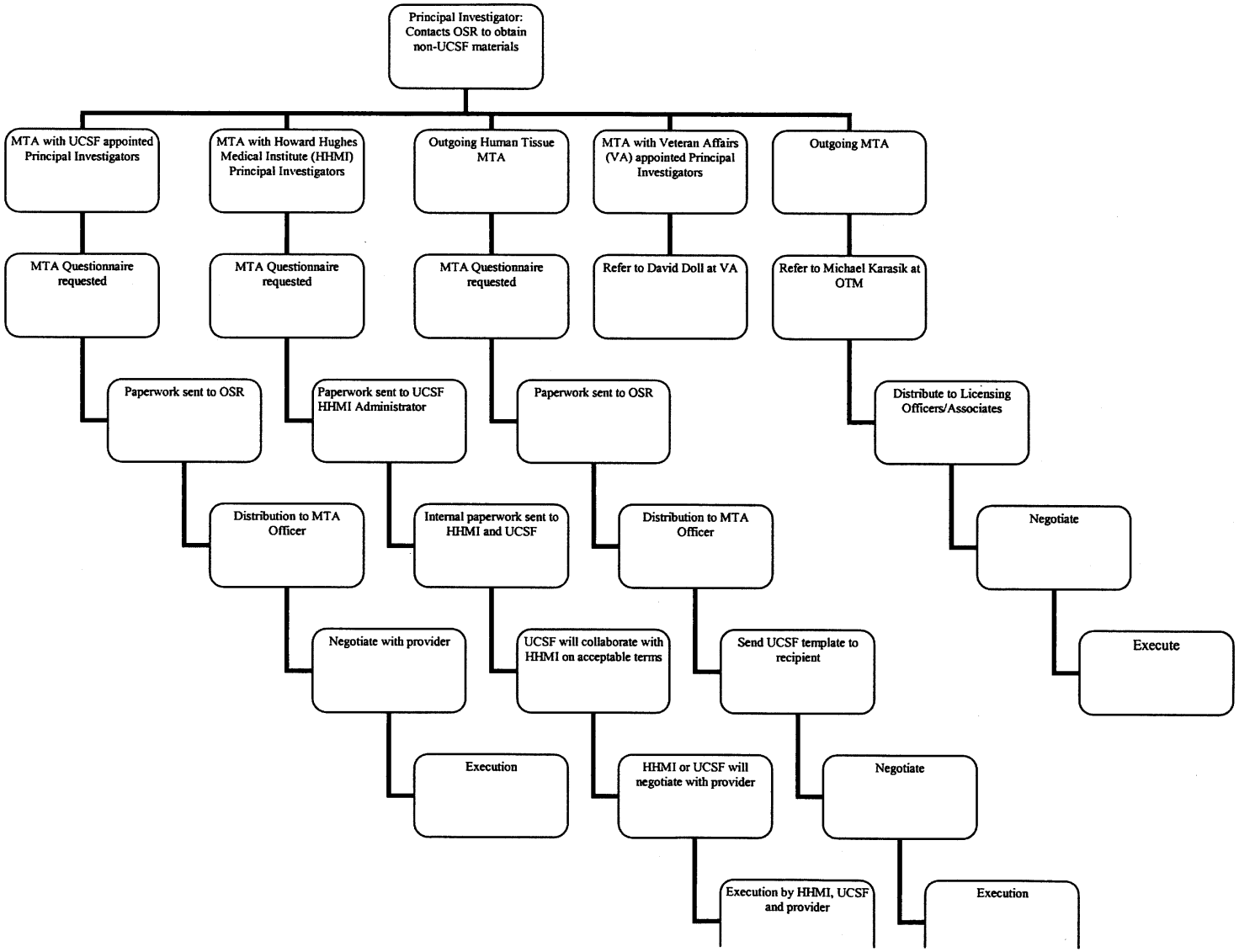
I certify that the information I have provided about this project is accurate. Furthermore, I certify that I will direct this project in compliance with Stanford University policies, with the terms and conditions of Stanford's agreement with the provider and with all applicable laws and regulations and will uphold the responsibilities of PIship.

Signature: **Date:**

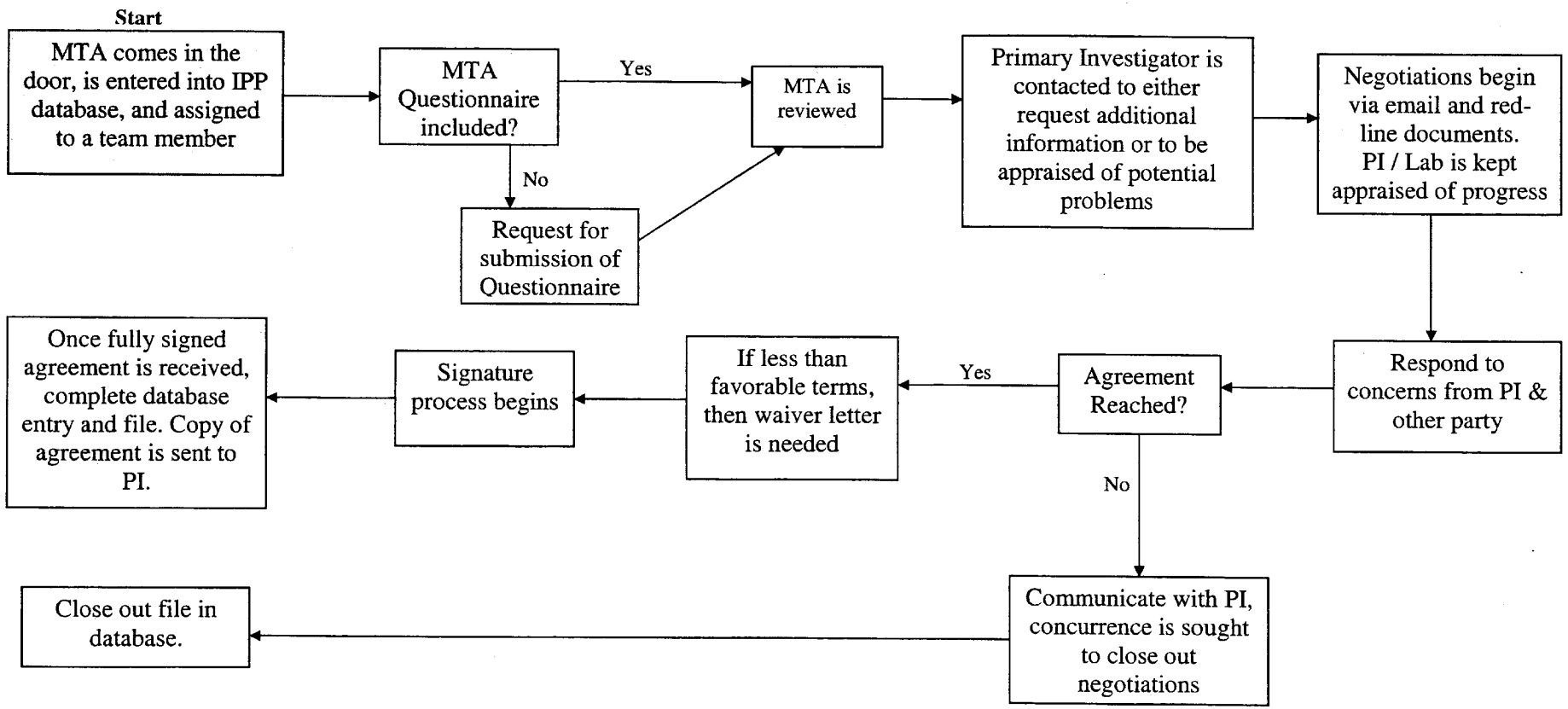
As required, ICO will cc: **Lance Phillips** -- EH&S (Radiation Safety), **Ellyn Segal** -- EH&S (Biosafety), **Alice Haskett** -- Research Compliance (Human Subjects/Medical), **Valerie Fratus** -- Research Compliance (Animal Subjects)

ICO 4/10/06

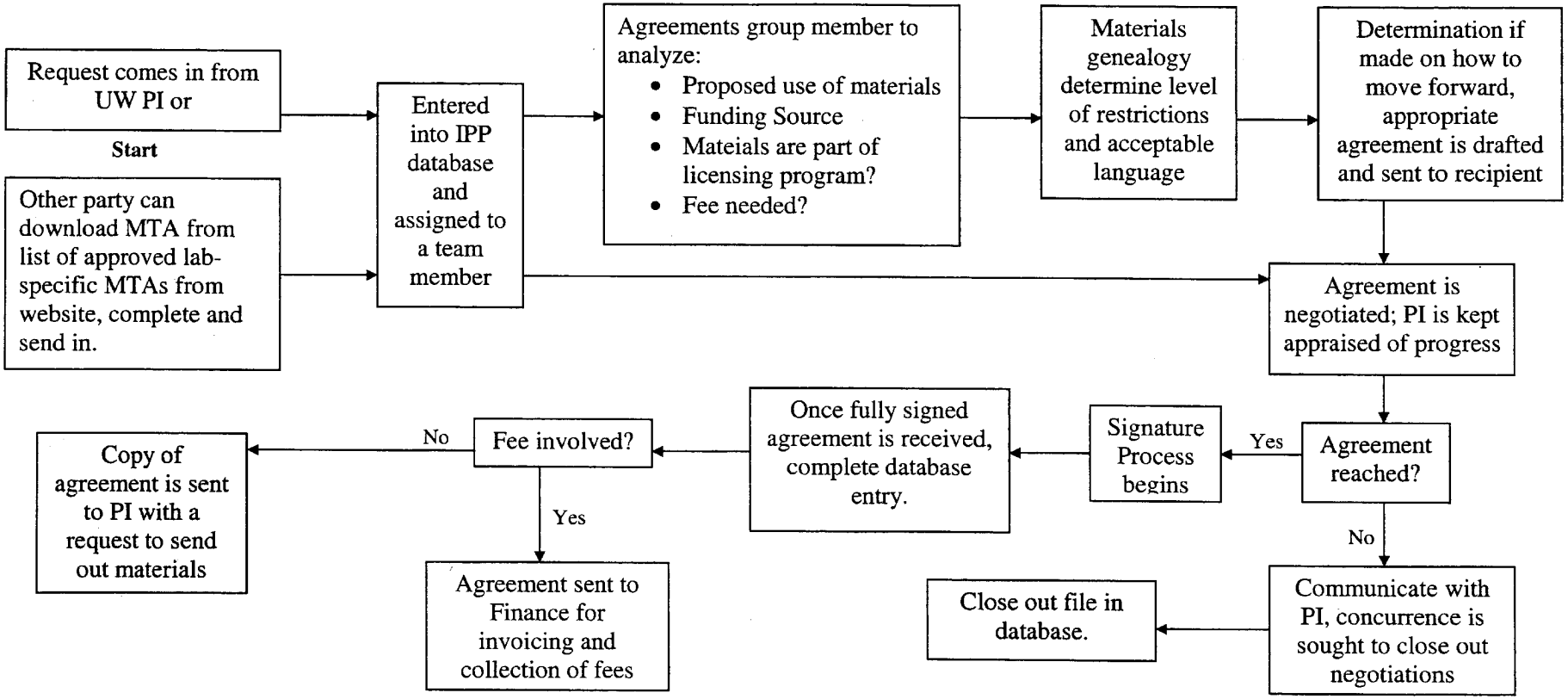
UCSF Office of Research, Office of Industry Partnership MTA Flow Chart 2007



Incoming MTA Flowchart



Outgoing MTA Flowchart



第四章　米国アカデミアにおける MTA の現況と問題点について

（The Present Situation and the Issues of MTA in US Academia）

第四章　米国アカデミアにおける MTA の現況と問題点について

（The　Present　Situation and the Issues　of MTA in US Academia）

本第四章は、学外協力を委託した元オレゴン健康科学大 Dr. S. Shotwell（Alta Biomedical Group 事務所を主宰）を中心とするスタッフにより米国アカデミアにおけるバイオマテリアル・トランスファーの現状と問題点について、契約（MTA; Material Transfer Agreement, BML; Biomaterial Licences）という側面に焦点をあて、数多くの実例をもとに、その分析を行ったものである。

本章は本文、脚注、さらに本文で引用されている各種契約例等を集積した資料より構成されており、原文（英文）のまま記載したが、読解の便のため本文の章立ておよび簡単な要約を以下に記載する。

著者：　Ms. Karen Deyerle, Ph. D.
Ms. Sandra Shotwell, Ph. D.

本文要旨；

Ⅰ．背景；バイドール法および MTA の増加
（BACKGROUND: BAYH-DOLE AND THE RISE OF MTAs）

◇バイドール法以前（Before Bayh-Dole）
- バイドール法成立以前の米国における政府資金を原資とした発明の移転の状況を概説。

◇バイドール法（The Bayh-Dole Act）
- 1980 年成立したバイドール法の意義について詳述。

◇バイドール法および MTA の増加（Bayh-Dole and the Rise of MTAs）
- バイドール法の成立により発明およびマテリアルが大学の所有とされたことから、その移転を統括する MTA の締結およびその交渉の必要が飛躍的に増大。

Ⅱ．MTA およびバイオマテリアルライセンスとは
（INTRODUCTION TO MTAs AND BIOMATERIAL LICENSES）

◇MTA とは何か（What is an MTA ?）
- MTA の典型的な構成について解説。

◇なぜ MTA を用いるのか（Why Use an MTA）
- サンプル移転時に MTA を用いる意義について。

◇バイオマテリアルライセンス（BML）とは何か（What is a Biomaterial License?）

・ 大学より企業へのマテリアル移転の場合、多くバイオマテリアルライセンス契約（BML）を用いる、その典型的な構成について解説。

◇どのような場合に BML を用いるのか（When to Use a BML）

・ 大学が BML を用いるべきケースについて。

Ⅲ．MTA およびバイオマテリアルライセンスその基本原則と手段（MTA/BIOMATERIAL LICENSE POLICY & PROCEDURE）

◇リサーチツールを入手可能とすること;歴史とその展開（Making Research Tools Available: History & Developments）

・ バイドール法の予想外の影響として研究試料が自由に流通されるケースが大幅に減少し MTA が研究開発の発展を阻害するに至ったこと、それを回避するために UBMTA を始めとする MTA の書式が整備されるに至ったこと、NIH がそのような情況を憂慮し、98 年にはリサーチツールの非排他的な拡散をうながすガイドラインを公表するに至った経緯、さらにその議論が現在も続いていること、また OECD においても同様の展開・状況にあることなどが解説。

◇大学における MTA の基本方針（University MTA Policies）

・ 大学 MTA の現状および対処方針についていくつかの大学の MTA 書式およびそれに関連する規則を引用して解説。

◇大学における BML の基本方針（University BML Policies）

・ BML についての大学の方針について触れている。

◇MTA 契約書の雛型（Model MTA Agreements）

- 譲渡時の MTA（Outgoing MTA）
- 受け入れ時の MTA（Incoming MTA）

・ NIH 主導による UBMTA を始めとするいくつかの MTA 書式を解説。

◇バイオマテリアルライセンス（BML）の雛型（Model Biological Material License Agreements）

・ NIH の用意する BML 書式について解説。

◇MTA 締結のプロセス（The MTA Process）

- 譲渡時 MTA の場合（Outgoing MTA）

- 受け入れ時 MTA の場合（Incoming MTA）

・ サンプル譲渡あるいは受け入れ要求の受理より MTA 契約締結に至るまでのフローについて解説。

◇BML 締結のプロセス（The BML Process）

・ BML 締結のプロセスについても同様に解説。

◇契約署名の権限（Signature Authority）

・ 各大学における契約サイナーの現状について解説。

◇収入の配分（Distribution of Income）

・ MTA および BML、特に BML より得られる収入の配分について各大学のケースを解説。

Ⅳ. MTA と BML の各条項について（MTA AND BML CLUSES）

PART（1） 標準条項（STANDARD CLAUSES）

・ MTA、BML における大きくは論議とならない標準的条項について項目ごとにとりあげ解説。

◇立場・見方の相違（Different Perspectives）

・ 大学・アカデミアは基本的に公共の福祉のために存在しており知識の追求とそれの公表が必須の存在であるのに対し、企業はステークスホルダーに利益を還元するために存在している。

・ この基本的な立場の相違が MTA、BML の各種条項に時に鋭い対立を引き起こすことが述べられ特に各条項においては以下、大学−企業との交渉を中心に分析されている。

◇マテリアルの用途（Use of the Material）

・ MTA、BML におけるマテリアルの使用の契約文言上の表現について。

◇支払い（Payment）

・ 支払い規定の叙述。

◇保証（Warranties）

・ 大学・アカデミアにとって企業の要求するような保証条項は受け入れられないこと、さらに対立した場合の解決語句などが解説。

◇その他（Miscellaneous）

PART(2) 論点となる条項(CONTENTIOUS CLAUSES)

・ 企業-アカデミアの MTA、BML において時に DEAL BRAKER となりうるような条項について詳述。

◇マテリアルの定義および所有権(Definition of the “Material” and Ownership)

・ 特に大学が企業よりマテリアルを受け入れるケースにおいてはマテリアルの定義をできる限り狭くすること、その理由などを解説。

◇研究成果および新規発明の所有権について; 妥協点(Ownership of Results & Inventions; Compromises)

・ 大学における研究成果について企業はしばしばその所有権を主張する、対処法および妥協点について解説、特に NERF(Non Exclusive Royalty Free)ライセンスを採用すべきケースについて。

◇秘密保持(Confidentiality)

・ 企業がしばしば要求する秘密保持についてその問題点、さらに妥協方法などを叙述。

◇公表(Publication)

・ 大学の基幹とするデータ公表について企業としばしば鋭く対立するが、その妥協点について分析。

◇研究成果および生成物の所有権について; バイオマテリアルライセンス(Ownership of Results/ Product: Biomaterials license)

・ 大学が企業にバイオマテリアルをライセンスする BML において研究成果に関わる規定について叙述、さらに特異なケースとして Dupont よりアカデミアにライセンスされた Cre-Lox 技術およびそれへの NIH の介入について解説。

◇報告(Reporting)

・ 企業からサンプルを受け入れた場合の試験結果報告義務について。

◇既存契約との相反(Conflict with Existing Agreements)

・ 企業より要求される場合の妥協点について叙述。

◇係争の解決法(Dispute Resolution)

・ 大学にとって本条項は “Silent”であることが望ましいことが解説。

◇準拠法(Governing Law)

・ 大学、特に州立大学にとって準拠法を州法とすることが必須となっているが、その背景。

・　特に経済的背景などについて分析。

◇免責条項（Indemnification）

・　免責とすべき種々のケースにおいて分析・解説。

◇輸出規制（Export Control）

・　US 政府の行う輸出規制とくにバイオマテリアルについてはバイオテロリズムに関連した規制に留意することが必要。

Ⅴ．結論（CONCLUSION）

・　マテリアルの移転は研究およびライセンスの領域において依然、重要な事項の 1 つである。

・　研究の自由と、ビジネスゴールそして社会の必要の間のバランスをとることは困難な作業であるが最大限の柔軟性を持って対応しなければならない。相手の立場、さらにこれまでの例、法律および基本原則を駆使することによってそれらのバランスをとった契約を締結することが可能となろう。

I. BACKGROUND: BAYH-DOLE AND THE RISE OF MTAs

Before Bayh-Dole. After World War II, the United States federal government significantly increased support for research and development ("R&D") in the areas of the military and in human and health services; both governmental agencies and non-governmental contractors (including universities) received R&D funding to support various projects.[1] Today the U.S. spends more on non-military R&D ($23.3 billion in fiscal year 2002) than any other country in the world.[2] In the mid-1900s, however, the U.S. government did not have a unified policy on how to handle the inventions that arose from the R&D work that it funded. Instead, each of twenty-six government agencies had its own individual patent and licensing policy. If a company wanted to develop a government-funded invention it first had to determine which of the twenty-six policies covered that invention. This bureaucratic hurdle discouraged companies from using government-funded inventions.

In the 1960s the U.S. Congress, aware of the problem and wanting U.S. industry to successfully compete with foreign companies, began to work toward making it easier for companies to license government-funded inventions. Policies were developed that allowed each government agency that funded R&D to own any inventions resulting from that R&D, and to make those inventions available for commercialization through non-exclusive licenses; the research group (funded by the agency) that actually made the invention retained a non-exclusive royalty-free ("NERF") license to use the invention. Pressured by universities to do more, Health and Human Services and the National Science Foundation eventually entered into the Institutional Patent Agreements, which allowed universities that had approved patent policies to own inventions arising from government-sponsored research. Even with that improvement, before passage of the Bayh-Dole Act only about five percent of some thirty thousand government patents were licensed to for-profit entities.

The Bayh-Dole Act. In 1980 Congress passed Public Law No. 96-517, (35 U.S.C. §§ 200-212, 37 CFR 401.1-.14) more commonly known as the "Bayh-Dole Act" or just "Bayh-Dole" (after the two sponsors of the law, Senators Birch Bayh and Robert Dole).[3] The law was an effort by Congress to reverse the low rate at which federally-funded inventions were then being commercialized, and to promote interaction and cooperation between universities and commercial entities for the development of those inventions into products. It provides the framework for "technology transfer", that is, the transfer (usually through licensing or some other form of distribution) of technology (inventions and discoveries arising from government-funded research) from universities to for-profit companies, with the companies then developing the inventions into commercial products. Simply put, Bayh-Dole was envisioned as the mechanism by which government-sponsored research, paid for by taxes, would result in products that would benefit the taxpayers.

The most important aspect of the law is that it allows universities to own the government-funded inventions and discoveries made by their researchers. The rationale is that if grantees *own* the inventions, they are more likely to patent and commercialize those inventions or otherwise make them available for the public good. *Ownership* engenders some measure of self-interest that, in part, motivates grantees to transfer their technology to the public and to companies; in return, the grantees gain recognition of their R&D accomplishments, and also share in the monetary profits from the sale of products by the companies to whom they license their inventions.

In return for the right to own inventions made through government-sponsored R&D, Bayh-Dole requires that universities take on certain responsibilities. Amongst these responsibilities, if a university makes the decision to own any given federally-funded invention, then it must:

- seek patent protection for that invention and actively seek to commercialize the invention
- report on its efforts to commercialize the invention to the federal agency that funded the research that gave rise to the invention
- with few exceptions, not assign rights to that invention to another entity
- give first priority to U.S. companies, preferably small U.S. companies, when licensing rights to the invention
- in any license, reserve certain worldwide non-exclusive rights for the federal government
- share a portion of the licensing royalties with the inventor(s), and the remaining portion for research and education

While Bayh-Dole states the law in broad terms, it does not give all necessary or specific information on how the law should be interpreted, implemented or enforced. Detailed information on how the law is actually carried out is laid out within the Code of Federal Regulations (see https://s-edison.info.nih.gov/iEdison/37CFR401.jsp).

Bayh-Dole and the Rise of MTAs. The Bayh-Dole Act defines "invention" as "any invention or discovery which is or may be patentable or otherwise protectable under this (law), or any novel variety of plant which is or may be protectable … and that is (first thought of) or first (made)" during the course of federally funded research (see 35 U.S.C. §201d,e). Through this definition, universities may own the tangible materials arising from federally-funded research, as well as the patented property. If it owns the material, the university has many reasons for being interested in what happens to that material. For example, it might want to exploit the commercial value of the material, or protect itself from a lawsuit in the case the material harms someone In order to protect these interests, the university needs to control the use and distribution of the material; it does this through a contract known as a Material Transfer Agreement ("MTA").

As the field of technology transfer has grown and matured, and as universities increasingly view technology transfer as a means to generate income, more and more emphasis is being placed on protecting the potential value of the tangible materials generated by research. This in turn has given rise to a huge increase in the number of MTAs implemented each year[4], and to a corresponding increase in the negotiations necessary to complete many MTAs. To better understand these negotiations, it is necessary to understand what the MTA is, its purpose, and some of the more important – and more contentious – issues addressed by the MTA.

II. INTRODUCTION TO MTAs AND BIOMATERIALS LICENSES[5]

What is an MTA? The sharing of research materials, particularly in the biological sciences, is one of the major forces that drive the development of discoveries and advancement of knowledge. Historically, companies have almost always placed restrictions on the outside use of materials made by their scientists, but, until recently, easy accessibility to materials developed by academic researchers was the rule rather than the exception within the research community. Since the passage of Bayh-Dole and the resulting rise of university ownership interest in research materials, however, the free exchange of research materials has been greatly diminished.[6] Today it is becoming increasingly rare for research materials to be transferred outside of the university where they were created without an accompanying MTA, even if that transfer is merely from one university to another.

The MTA is a legally binding, enforceable contract governing the transfer of tangible research material from one entity to another. It specifies conditions and uses of a specific material sent by one organization to another organization. Materials commonly transferred include animal models (e.g., transgenic or knockout mice), cell lines, bacteria, plasmids, phage, nucleotides, proteins, pharmaceuticals, chemicals and other useful research reagents. The materials may be patented or unpatented; if unpatented, the material might be included in a pending patent application, or it may be completely free of any patenting activity.

The exact terms of each MTA are negotiated between the provider of the materials and the recipient. Although efforts have been made to develop a "model" MTA (see Chapter III, "MTA/Biomaterial License Policy and Procedure"), there is no universally-used standard MTA. Despite that, it is not uncommon for a given pair of institutions to negotiate a "model" agreement that will be used for most transfers between those institutions. Unfortunately, the terms of even these limited-use model MTAs often undergo significant changes within just a year or two of their first being negotiated. As a result, most MTAs are negotiated on a case-by-case basis.

Although there is no universally-used MTA, most MTAs do address similar issues and concerns, including the following:

1. Definition of the material to be transferred;
2. Rights and interests each party may have in the material being transferred;
3. Planned use of the material;
4. Restrictions on use of the material (use of a material received under an MTA is almost always restricted to non-commercial internal research purposes only, and almost always excludes use in humans);
5. Confidentiality;
6. Publication rights;
7. Rights and interests each party may have in the results, new materials, and inventions created through the use of the transferred materials;
8. Payment from the recipient to the provider for costs associated with the transfer (for example, the recipient may reimbursement the provider for the provider's cost of producing or shipping the material);
9. Compliance with local, state, and federal regulations;
10. Warranty disclaimer and indemnification, including the scope of the provider's liability arising from the recipient's use, storage, and disposal of the material;
11. Governing law; and,
12. Disposal of unused material.

Why Use an MTA? MTAs benefit the provider by giving it control over where, when and how its material may be used. They may reduce the provider's legal liability for the recipient's handling and use of the material. In addition, the provider can often use an MTA to gain access, limited or otherwise, to the recipient's research results and reagents and the ability to use those results and materials for its own purposes, which may include commercial uses.

One of the primary benefits an MTA offers a university recipient is that it almost always protects the recipient's ability to publish his research using the material. Often an MTA also will protect the recipient's right to own the research results.

What is a Biomaterials License? MTAs and Biomaterial Licenses ("BMLs") have some key differences, but retain many similarities. Each is a negotiated contract governing the transfer of tangible material from one entity to another. Each typically addresses material definition, ownership and use of the material; ownership of reagents created through the use of the material; payments; responsibilities of each party relating to compliance with local, state, and federal regulations; warranties and indemnification; and governing law.

One significant difference between an MTA and a BML is how the materials can be used. An MTA generally limits the recipient to using the material in non-commercial research. A BML often grants the additional right to use the material more broadly for commercial purposes. Specifically, the licensee may be granted "the right to make, use, sell, have made, have sell, or import" the biomaterials and/or materials made through use of the biomaterials. The BML grant also may convey the right to use certain of the licensor's patent rights.

Because the BML generally confers the right to use the biomaterial for commercial purposes, it usually requires the licensee to pay the licensor a significant amount of money (or some other form of value). This payment can take as many forms as a licensor-licensee may negotiate, but there are two general types:

- a fully paid-up license (the licensee pays the licensor an agreed upon amount of money shortly after the license is fully signed, and then has no further obligation to pay the licensor anything for the term of the license);
- a license with upfront fee and running royalties (the licensee pays the licensor a sum of money shortly after the license is signed, then also pays the licensor a portion of its profits on the sale of the material and/or products it makes using the material; in this case the signing fee typically is less than in a fully paid up license).

The BML will specify how and when money is to be transferred, and what currency is to be used. If the licensee will be using the material to make a product that it intends to sell to third parties, the BML likely will contain clauses dealing with insurance that must be carried by the licensee. It also will contain clauses about the term and termination of the contract, and how to resolve disputes that may arise.

When to Use a BML? Generally speaking, a university almost always will use an MTA when transferring a material to another university. When transferring material to a company, a university may choose to use either an MTA or a BML, depending on the nature of the material and how the company intends to use it. A company will almost always use an MTA when transferring material to a university, because a university is by definition a non-profit organization and so should not be using the material for commercial purposes.

In some cases a researcher may be *willing* to provide his research reagent to the scientific community, but if demand for the reagent is high he may be unable to accommodate the large number of requests. In these cases the researcher's university

might contract with a central non-profit repository[8] or a for-profit entity (through a BML) to generate and distribute the reagent. The material will then be made available according to the terms of the contract, perhaps through an MTA between the repository and the recipient, or by the BML licensee selling the material and making some form of payment to the university (upfront and/or royalty).

III. MTA/BIOMATERIAL LICENSE POLICY & PROCEDURE

Making Research Tools Available: History & Developments. An unforeseen consequence of Bayh-Dole was a marked decrease in the free and easy exchange of research reagents developed in the course of federally funded research. Barriers arose, largely MTAs, which not only greatly increased the length of time between requesting and receiving a material, but sometimes made the material largely unavailable. In an effort to remove some of the barriers the NIH developed the Uniform Biological Materials Transfer Agreement (UBMTA; see Appendices 1 and 2, "UBMTA 3.8.95" and "UBMTA letter"), which it hoped would become a standard, widely-used MTA and so streamline transfers. Although over three hundred institutions have agreed to use the UBMTA (see http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm, "Signatories to the March 8, 1995, Master UBMTA Agreement"), very few actually used the document without changing at least some of its language, thus defeating its purpose. Concern about the materials exchange problem rose to such a level that the Director of the NIH convened a group of prominent researchers and professionals knowledgeable in the matters of technology transfer to explore the issues and make recommendations on how to improve the situation.[9]

In June of 1998 the group issued its report.[10] One of its recommendations was that the NIH should develop and publicize guidelines describing reasonable MTA and license terms to be used whenever possible in transfers of federally-funded research tools between organizations. In response, in May of 1999 the NIH proposed draft *Research Tool Guidelines*, which stated the NIH's expectations of organizations that received NIH funding. The *Guidelines* were finalized on December 23, 1999.[11,12, 13] The *Guidelines* set forth four principles:

(1) Scientists should be free to collaborate with colleagues and publish their research results on a timely basis;
(2) Restrictive licensing and indiscriminate patenting of research tools should be avoided;
(3) Paperwork and delay involved in transferring research tools should be minimized; and,
(4) Unique research resources arising from NIH-funded research should be made available to the scientific research community.[14]

Issuance of the *Guidelines* did not stop dissatisfaction with how reagents were – or were not – being transferred, and there was much discussion about whether the *Guidelines* were helpful or practical.[15,16,17,18] In October of 2001 the National Academies of Science, with the support of the National Cancer Institute, National Human Genome Research Institute, National Science Foundation, and the Sloan Foundation, created the Committee on Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Biological Sciences. The committee's task was "to conduct a study to evaluate the responsibilities of authors of scientific papers in the life sciences to share data and materials referenced in their publication.s"[19] In its report the committee elaborated on the cardinal principle that it set forth, "the uniform principle for sharing integral data and materials expeditiously (UPSIDE): Community standards for sharing publication-related data and materials should flow from the general principle that the publication of scientific information is intended to move science forward."

The problem of sharing materials was not confined to the U.S. In January 2002 the Organisation for Economic Co-Operation and Development(OECD), a forum of thirty democratic countries, held a workshop to evaluate whether the worldwide web of intellectual property systems was helping to advance science or impede it by denying access to research reagents.[20] It concluded that, in general, intellectual property systems did work to encourage innovation and publication of scientific work, but that there were some problems. The OECD

subsequently set forth its own guidelines on principles and best practices of licensing genetic inventions.[21]

Despite the many sets of guidelines available and ongoing efforts by the NIH to make federally funded research tools readily available[22], the problem of delayed or denied access to those tools not only remains but may still be growing. There are continued calls and efforts towards developing a "standard" MTA.[23]

University MTA Policies. The NIH has worked diligently to develop what it considers reasonable principles and practices for material transfers. Although universities each have their unique ways of handling MTAs, and the UBMTA is not used consistently, overall there are more similarities than differences amongst university MTA policies. Most universities have policies that share the spirit, if not the actual language, of the NIH principles. Because of this, most universities do not have any significant difficulty dealing with transfers to and from other non-profit organizations. However, the transfer of material developed at a for-profit entity (which generally is not bound by NIH guidelines) to a university often is plagued with difficulty.

At the heart of university MTA policy is protection of academic freedom, in particular protection of the ability to publish research results in a timely manner. In the past, many universities simply would not agree to MTAs containing many restrictions on publication. Today, however, with almost frenzied competition in some fields of biological research, and companies determined to protect their materials to the fullest degree possible, even the inability to adequately publish research results is not always an absolute "deal breaker". If the provider refuses to modify what the university considers onerous publication terms, and the researcher desiring the material is aware of the problematic publication language but continues to seek the material, some universities will reluctantly agree with the provider's terms.

While academic freedom is still central, over the past twenty years university MTA policies have matured and grown to reflect the current difficulties in the sharing of research reagents. Quite a few universities append "primers" to their policies, explaining what an MTA is and what it does (see Appendices 3 and 4, "U of GA MTA description" and "UCLA MTA info"). Many universities have policies that not only state their positions on certain issues, but also go on to explain (for the benefit of their researchers) the rationale for those positions, and why difficulties often arise when a researcher wishes to obtain a material from a for-profit organization.[24,25] In addition, universities often attach "checklists" to their policies that researchers wishing to receive materials must complete, to give the university information it deems necessary to review and carefully consider the proposed MTA terms (see Appendices 5, 6 and 7, "Cornell MTA request Checklist", "MIT MTA Questionnaire" and "MTA checklist"). The University of California-Berkeley has a combination of policy and information that defines an MTA, discusses university-university and university-company exchanges, potential problem areas, and compliance issues, in a short, easily readable but thorough format that also includes a link to that university's (incoming) MTA review form (see Appendices 8 and 9, "A Quick Guide to Material Transfer Agreements at UC Berkeley" and "Berkeley MTA review form").

University BML Policies. BMLs, being of a more commercial nature than MTAs, generally are governed by a university's licensing policy and procedures rather than its MTA policy and procedures.[26] Nonetheless, because they lack the complexity of many other types of licenses, they are comparatively easier to negotiate and complete. Issues associated with BMLs are discussed in detail in Chapter IV, Clauses.

Model MTA Agreements. A great deal of effort has gone into development of standardized MTA language, as exemplified by the UBMTA. It is clear that while hundreds of universities agree with the UBMTA in principle, many prefer to use their internally-developed model agreements that contain much of the UBMTA language but with some changes. Similarly, model BMLs developed by universities have many common concepts, but they are expressed in different words, with different emphases, and some differences in issues addressed. Model BMLs also may differ depending on the planned use of the material, its potential for negative consequences, and the value the university ascribes to the material.

Outgoing MTAs.[27] The NIH has at least three model MTAs, one a very simple letter for uncomplicated transfers (Appendix 10), one for somewhat more complex needs (Appendix 11) and one tailored for use with transfer of animals (Appendix 12). In an example of a university taking the NIH's lead, Harvard University's simple letter MTA is almost identical to that of the NIH. [28] In contrast, a comparison of the NIH's longer model MTA (Appendix 11) with Iowa State University's model MTA shows that the latter is written in very formal, legal language and goes into considerably more depth in areas such as defining the material, commercial purposes and how the recipient may handle the material (see Appendix 13, "IA MTA template"). The Iowa State model also addresses concerns that the NIH model does not, for example, how long the MTA will be in effect, what law will govern the MTA, and payment provisions. The University of Washington takes a flexible approach, in some circumstances being willing to use the UBMTA with a choice of two different cover letters (see Appendices 14 and 15), in others using a more complex MTA (see Appendix 16). The latter is more similar in complexity to the Iowa State MTA (Appendix 13) than it is to the NIH MTA (Appendix 11). Generally speaking, when universities send materials to for-profit entities under an MTA they use language similar to the models they use when sending materials to non-profit organizations.

Incoming MTAs.[29] Other than exchanges governed by the UBMTA, there is no "model" agreement for MTAs coming in to a university, because each provider uses its own particular set of model agreements. Yet exchanges between non-profit entities tend to move fairly readily, because most non-profits use model MTAs that, while they may differ in form, are very similar in substance. Many for-profit entities also use similar MTA terms when sending their proprietary materials to universities, but these MTAs more often than not contain terms that are problematic for the university. As a result, negotiations on incoming MTAs from companies can take weeks, or even months.

In an effort to speed up transactions, some universities negotiate model agreements specific for a company (see Appendices 17 and 18, "Texas.Biogen MTA rev 1994" and "Texas.Wyeth MTA outdated"). As a rule these model agreements have significant differences from the model agreements discussed in the previous section (Outgoing MTAs). These differences may include the provider having rights to review the research results prior to the researcher publishing them; a NERF license to improvements or to new uses of the material; and an option to negotiate an exclusive license to those improvements or new uses.

Model Biological Material License Agreements. BML agreements can range from very simple, almost "MTA-like" agreements, to fairly complex patent-based licenses. For the purposes of this report, most BMLs are for materials owned by universities and licensed to for-profit organizations; universities generally do not receive biomaterials governed by licenses. For examples of BMLs, in order of increasingly complexity, see Appendices 19 (Simple BML), 20 (NIH Biological Materials - Internal Use), 21 (NIH Biological Materials License Agreement), 22 (NIH Non-Exclusive Patent License Agreement - Internal Commercial Only) and 23 (NIH Non-Exclusive Patent License Agreement).

The MTA Process.

Outgoing MTAs. Outgoing MTAs can be initiated in two ways: (1) the entity desiring the material (the potential recipient) contacts the potential provider's technology transfer office ("TTO"); or (2) the outside entity directly contacts someone (usually the head of the laboratory, often called the principle investigator or "PI") in the laboratory where the material was developed. In the first case, the next step would be for the TTO professional who handles MTA requests to contact the PI and discuss the potential transfer with him; in many cases a university will have one, and possibly two, professionals dedicated to processing outgoing and incoming MTAs. If the PI is agreeable to the transfer, then the professional will draft an MTA for the transaction and send it to the appropriate office of the potential recipient. If the recipient is a university, the MTA will likely be sent to a TTO; if a company, the MTA will likely be sent to either the company's licensing group or its legal department. There the draft MTA language will be reviewed, and that entity will either agree to the draft terms or will suggest modifications. The MTA is completed when it has been signed by an authorized person at each of the recipient and provider organizations.

If a potential recipient contacts the PI whose laboratory developed the desired material directly, it is hoped that the PI will direct the recipient to the appropriate in the PI's university TTO. In that case the MTA will be negotiated and signed as described above. Sometimes the PI mistakenly believes that he can negotiate and sign the MTA himself, in which case an MTA is completed but the TTO is not informed of the transaction. This results in an MTA that may be invalid because it was not signed by a university representative who had legal authority to bind the university. In other cases, the PI sends out the material along with a letter (not an MTA) in which the PI spells out conditions for the use of the material, but such a letter again may not be legally binding. Finally, sometimes the PI simply sends the material without any accompanying documentation.

Outgoing MTAs are complicated by confusion over who actually owns the material to be transferred. Ownership of the material is generally determined by the source of the funding that supported the development of the material. Typically, the university owns materials developed in its laboratories. In some cases the organization that funded the research co-owns the material, and the university and that organization will work together to craft an appropriate MTA. It is not unusual for PIs to take the position that *they* own the material developed in their laboratories, and even though they may not be legally correct, it can be an issue that must be handled with a certain degree of sensitivity on the part of the TTO.

Incoming MTAs. When the university is the potential recipient of a material, the draft MTA is generally sent to the university's TTO by either the PI who wants the material or by the organization that owns the material. In either case, the TTO professional will review the terms of the draft agreement. If those terms are acceptable, the MTA will be signed by the appropriate university representative. If not, the TTO professional will request changes of the potential provider; if the latter is a for-profit entity, the negotiations over the MTA terms can be protracted. Sometimes the two parties are not able to come to an agreement, and the PI does not get the material. In other situations, the university weighs the risks of accepting the material on undesirable terms against the potential benefits of the planned research, consults with the PI, and makes an informed decision. The enthusiasm of the PI for getting the material, combined with the PI's level of power and prestige within the university, can be factors in these decisions.

The BML Process. BMLs are almost always for materials that are being transferred out of the university to a company, and the process is very similar to that for outgoing MTAs.

Often, however, the BML may be handled by a TTO professional at a higher level than the professional who handles MTAs, because of the greater complexity of the BML terms.

Signature Authority. In every university, as with most organizations, there is a hierarchy of who is authorized to sign agreements that place obligations on the university. The more important the agreement, the "bigger the boss" needed to sign it. Since MTAs are simple agreements, they often can be signed by a professional in the TTO; sometimes the professional who negotiates the MTA can also sign it on behalf of the university, or a non-negotiator at the same job level might have authority to sign the agreement. (The latter avoids the conflict of the negotiator signing the contract which he negotiated, and has the advantage of two people reviewing the agreement). However, because even the simplest MTA is a legally binding, enforceable contract, some universities require that a higher level professional or even a university attorney sign the MTA.

Universities may require that BMLs be signed by a university representative with greater authority than the representative who can sign MTAs. In some universities the official needed to sign the BML depends on the size of the licensing fee; the larger the fee, the more authority the signing representative must have.

Ultimately, each university has its own system of who is allowed to sign various kinds of documents and contracts, and there is no simple rule to follow *except* that a PI typically does not have the authority to sign a legally binding MTA or a BML. The best solution is to contact the provider university's TTO and ask for the appropriate person to negotiate an MTA or a BML. The university negotiator will certainly know whose signature(s) is required.

Distribution of Income. MTAs, unlike BMLs, do not usually require the recipient to pay the provider for the privilege of receiving and using the material. The provider may, however, ask the recipient to pay the cost of making and sending the material; these costs can be significant when the material is, for example, a cell line or mice. When the recipient makes a payment to cover the costs of providing the material, that payment is not usually considered "income" or "licensing income". The payment is not usually shared between various university departments and the inventors of the material as licensing income would be. Instead, it often goes into an account for the laboratory that made and shipped the materials, so that the laboratory is reimbursed for its costs.

Some BMLs make provisions for reimbursing the laboratory of the provider its expenses for the initial supply of material sent to the licensee/recipient, as described above, and that payment would be handled as would a payment for an MTA. Some BMLs also require the licensee to make more such "reimbursement payments" if the provider has to send more material beyond the initial shipment, as would happen if the licensee irreparably damaged the material in some way.

Beyond these "reimbursement costs," the rest of the income from BMLs is usally treated as licensing income. Most universities have well defined rules that govern how licensing income is to be distributed; usually the income is shared between the TTO, the inventors, the department or school of the inventors, and perhaps one or more universities offices of various functions, in a fixed formula that assigns each recipient a certain percentage of the income. If the materials were developed in the course of federally funded research, then the Bayh-Dole Act requires that the income be shared with the inventors and also used for education or research purposes. Under some circumstances – for example, when there are no easily identified "inventors" - the income is directed back into the laboratory to support more research and education.

IV. MTA AND BML CLAUSES

PART (1). STANDARD CLAUSES

Most MTAs and BMLs address similar issues. The more standard clauses that typically do not cause problems during negotiation are addressed in this Chapter IV, Part I. More contentious issues are addressed in Part II below.

Different Perspectives. When negotiating MTAs and BLMs, non-profit and for-profit entities often have trouble agreeing on certain terms (e.g., definition of the materials being transferred, ownership of the results of the research performed with the material, freedom to publish the research results, indemnification, and governing law.) This difficulty stems from the very different missions and cultures of non-profit and for-profit entities.

Non-profit organizations, particularly universities, view themselves as institutions of education, research, and public service. They seek a balance between social and commercial benefits, with the pursuit of knowledge and academic freedom as paramount. The negotiation approach of TTO professionals is guided by the preservation of their academic mission; commercialization is viewed as a method to bring academic results forward for public benefit. The Mission Statement of Harvard University provides a typical example of this balanced mission:

"To bring University-generated intellectual property into public use as rapidly as possible while protecting academic freedoms and generating a financial return to the University, inventors and their departments."[30]

For-profit entities, in contrast, strive for a competitive edge. Their R&D is geared not towards the pursuit of knowledge for knowledge's sake, but toward product development and profit. In pursuit of those goals, companies routinely deal in confidentiality and trade secrets, and view blocking and defensive patenting as good business practices rather than barriers to research. While their mission statements may discuss the public good, companies have a primary responsibility to their shareholders to generate profit.

The discussions in this chapter will consider the situation that poses the greatest challenges, and therefore is the most instructive – negotiation between a for-profit provider and non-profit recipient. Disagreement over similar clauses may arise in a non-profit/non-profit interaction, or in a non-profit provider/for-profit recipient interaction, but it is less common. When it does happen, it is most often driven by the presence of a for-profit partner.

Use of the Material. When requesting a material under an MTA, the potential recipient usually submits to the provider a description of the planned use of the material. The recipient and provider work together to carefully define how the recipient may use the material, and often they also define how the material may *not* be used. Generally speaking, it is the potential provider who sets these terms, because it is only through the provider's agreement that the material will be made available. The provider, then, has the last word on what the recipient may and may not do with the material.

In the case of a BML, the description of the how the recipient may use the material generally takes the form of a *grant*, and uses more formal, legalistic language. This is because the BML is usually an agreement governing a *commercial* use of the material, rather than just academic research. The grant will generally consist of three or four paragraphs setting forth how the licensee/recipient may use the material ("field of use"); where the licensee may use or sell the material or products made using the material ("territory"); whether the licensee may share its rights with another organization (sublicensing); and, what

rights, if any, are kept by the licensor or federal government ("reserved rights"). If the licensee is obtaining the right to evaluate the material, rather than licensing it outright, the grant will reflect this. (For samples of grant language see Appendix 24)

Payment. The section of an MTA or BML dealing with payment is generally straight forward. Any disagreements are usually settled quickly. This section includes requirementf for when and how the payment will be made (see Appendix 25 for sample payment language).

Warranties. As a rule, non-profit organization providers (in the case of MTAs) and Licensors (in the case of BMLs) not only will *not* agree to warrants about the material, they will add specific *disclaimers*, such as not guaranteeing the material to be useful for a particular purpose or that use of it will not infringe on a third party's patents. This "No Warranties" language is fairly standard from agreement to agreement; while the wording may be changed slightly, in substance it is identical and almost always non-negotiable (see Appendix 26, "Sample Language, Warranties). The "No Warranties" language will often be entirely in capital letters to make it easily visible; some state laws require capitalization to make the disclaimers valid.

Non-profit organizations will not guarantee the material because usually they have not tested it for the particular purpose in which the recipient is interested, or they have not tested it thoroughly enough. More importantly, non-profits often do not have the kind of insurance required to back such guarantees, nor do they have the financial resources to defend themselves from lawsuits should the materials not perform in the manner desired by the recipient. Similarly, non-profit organizations will not usually guarantee lack of infringement of third party patents; thorough patent searches are expensive to conduct, and non-profits generally do not have the financial or personnel resources to do such patent searches; also, they do not have sufficient insurance resources to make promises of non-infringement. Some non-profits – particularly large university systems – will not even guarantee non-infringement of their *own* patents, either because they hold a large number of patents, or because they have branch campuses that are quasi-independent entities. Compromise language might be, "To the best of University's knowledge" the intended use of the material will not infringe. Some universities, skittish about use of the word "best", will only agree to language such as, "University has no knowledge" of infringement, or, to make it more narrow yet, "the TTO has no knowledge" of infringement. To try to cover all aspects, a university might want to include language containing the points that "No one at the University, including the TTO, has any knowledge or reason to believe" that use of the material will infringe, adding "University, including the TTO, has not done patent searching of any kind".

It should be pointed out that although non-profits will not warrant usefulness and non-infringement of their materials, this is generally reflected in licensing fees that are much lower than those of organizations that will provide such guarantees.

Miscellaneous. MTA or BML clauses discussing compliance with laws[31], insurance[32], and disposal of unused material[33] are fairly standard from agreement to agreement.

PART (2). CONTENTIOUS CLAUSES

Definition of the "Material" and Ownership. In any negotiation for an exchange of material, ownership of the original material should not be a question; the provider owns the material that it is providing or licensing. The provider may be asked to "warrant and represent" that it owns the material and has the right to provide it to the recipient or licensee.

This "warrant and representation" is a definitive legal statement of ownership, and providers usually agree to this. If the provider does not agree, it may mean that the provider is not certain that it owns the material, or that there are complicating factors; the potential recipient should proceed with caution and explore what those factors may be before deciding whether to get the material from this source. However, once the provider agrees to warrant and represent that it owns the material and has the right to license it or provide it to the researcher, the question arises – what *exactly* is the material that the provider is providing? (See Appendix 27 for clauses useful in defining materials.)

Ownership of materials and improvements is linked to specific definitions. Therefore, when working on an incoming MTA where the material is coming from a for-profit entity, the recipient university wants to make the definition of the material as narrow as possible, confining it to a precise description of the exact materials being received by the university. Philosophically, from the university's perspective, any modifications, derivatives, improvements or other materials arising from the research reflect the expertise of and "value added" by the recipient university's researcher, and so should belong to the recipient university; to do otherwise would be a loss of academic freedom and control over its own research. On the other hand, it often is acceptable to a recipient university to include "progeny and unmodified derivatives" in the definition of "the materials" that are owned by the provider, as merely propagating the original materials does add value.

It is the practicalities of the research funding, however, that often prevent the recipient university from agreeing to a broad definition of "the material". The source of financial support for the research with "the material" will have a large impact on the ownership of any reagents developed during the research, and the university will argue that because the provider is not funding the research it should not have any rights to the research results. If a collaboration between the provider and the recipient is under consideration, then the agreement negotiated should be a research funding contract, not simply an MTA Unlike an MTA, a research funding contract is a more extensive document in which research results and intellectual property are routinely addressed. If the company provider also financially sponsors the research, then the recipient university will be more likely to allow the company to view and comment upon the research results prior to publication. The university would still prefer that it own all discoveries arising from the research; it might, however, be open to sharing ownership in proportion to the relative contributions of company personnel and university personnel to any given discovery arising from the research collaboration.

If the proposed research will be federally funded, then NIH policies and certain Bayh-Dole requirements press heavily upon the university recipient to retain ownership of any discoveries arising from the research done with the material. (See, for example, § 202 "Disposition of rights" of the Bayh-Dole Act, "In the case of a nonprofit organization … a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency…"). If the proposed research will be funded by a non-federal agency, or by another for-profit organization, the TTO professional will need to check the terms of those other agreements to make sure that there will not be any conflicts between the contractual obligations of those funding contracts and the MTA under consideration. Serious legal entanglements can result when a material, received under an MTA that promises certain rights to the results to the provider, is used in research financially supported by a sponsor that has been also been promised certain rights to the results.

Non-profit organizations must also take certain tax laws into consideration when negotiating a definition of "the materials". Their non-profit status gives them certain tax privileges which can be jeopardized if they engage in too much commercial activity, and sometimes agreeing that the provider has certain ownership rights in research results might result in unfavorable tax issues. These same tax issues strongly discourage setting financial

licensing terms in advance of the reagents actually being developed, because the true value and use of a reagent cannot, of course, be adequately determined before its development. This area of U.S. tax law – called "Unrelated Business Income Tax", or "UBIT" – is extremely complex and is often not well understood except by tax experts specializing in the particular details of UBIT. Nonetheless, non-profits are loathe to venture into any area that may have serious negative federal tax implications for them, and so for this reason as well will decline to grant the provider ownership of anything more than the original, unmodified materials.

The providing company, on the hand, is likely to start from the position that theye own the material, and so should own any modifications, derivatives or other materials made from or using the material, because those things could not have been made without the proprietary material. Following this logic, a company may argue for a definition of "the material" that includes "all derivatives, modifications, improvements, or other materials that could not have been made without the provided material" or, more simply, "all inventions arising from use of the Materials". Companies often insist on having these "reach through" rights (that is, "reaching through" from the materials originally provided into the research to claim ownership of or rights to anything that may be developed from that material), and may refuse to provide the material unless guaranteed these rights to some extent.

Ownership of Results & Inventions: Compromises. Negotiations over how to define "the materials" being provided are really arguments over who is going to own or control the inventions, tangible and intellectual property, arising from the research done with that provided material. Although the recipient university will argue for a narrow definition, and the for-profit provider for a broad definition, there can be room for compromise. (See Appendix 28, "Useful Language in Negotiating MTA License Issues" for examples of language that may be used in these situations.)

Inventorship is often used to determine ownership in these situations; if only a recipient researcher(s) is an inventor then the recipient would own the invention; if only a provider researcher(s) was an inventor then the provider would own the invention; if the inventors included both recipient and provider inventors, then the invention would be co-owned between the two organizations. If this method is acceptable to both parties, then the MTA would have language to the effect that ownership of inventions will be determined in accordance with applicable patent laws and the relative contributions of each party to the invention.

If the above method of determining ownership is not acceptable to the company provider, then the university might negotiate for the university to own all the research results, while granting the company a NERF license for *internal research purposes only*, sometimes also including the right to use the research results in regulatory filings and patent applications. The university might argue for a NERF license for "*non-commercial* research purposes only", but that may be unacceptable to the for-profit provider since, to some degree, *all* of its research is for a commercial purpose.

A company may refuse to accept the restriction "internal research purposes only" and demand, at a minimum, an unrestricted NERF license, giving the company the right to do whatever it wishes with the tangible research results, including commercializing or sublicensing them. Since the company likely has dominating patents/applications covering the material, and would enjoy other competitive advantages relating to its material, granting it an unrestricted NERF license is problematic for the university because, in some ways, it is (almost) the same as granting the company an exclusive license; it does not, however, attach the balance of rights and responsibilities to the parties typically found in an exclusive license. An unrestricted NERF embedded in an MTA is also disadvantageous to the university

because the MTA is unlikely to address issues such as indemnification and product liability that may arise through the company's use of the research results. A university may (reluctantly) agree to an unrestricted NERF if: (1) the potential researcher recipient understands the terms and still has a strong desire to receive the material (some universities may require the researcher to sign a statement acknowledging that he understands the restrictions and agrees to them); and, (2) university officials agree that the potential benefits of receiving the material are greater than the potential problems or losses. This decision is always made on a case-by-case, university-by-university basis.

In addition to an unrestricted NERF license, the company might also demand an option to negotiate for an exclusive license. While this is not desirable from the university perspective, the university may agree on a case-by-case university-by-university basis, weighing potential gains against potential problems. If the university can not avoid granting an option to negotiate for an exclusive license, it may try to: (1) restrict the length of time in which the company must use the option[34]; (2) avoid setting financial terms upfront (before any inventions are actually made)[35]; (3) make the option subject to the university's obligations to third parties[36]; and, (4) reserve a non-exclusive right for the university to use any inventions and new reagents made using the material and to share that right with other non-profit organizations. The company may insist that the university's non-exclusive right be restricted to "non-commercial research purposes only", which should be acceptable to the university; even with this restriction, academic freedom is somewhat preserved if the inventions and new reagents would still be available to the research community. With regard to the university's obligations to third parties, the company may ask the university to represent or warrant that no conflicting rights in any inventions that may result from the research have been granted to any other for-profit entity; in this case, the university must carefully evaluate the risk of using the material in research funding or with other materials carrying third party obligations[39]. Before agreeing to any of the above terms, the university will likely want to have a written and signed statement from the researcher, saying that he understands and accepts the terms under which the material will be received.

Finally, even if it is willing to settle for a NERF for research purposes only, a company may demand that the university agree to a "penalty clause". Penalty clauses generally award the company/provider ownership of any research reagents and results developed using the material to the extent that those results and reagents were developed doing work *not included* in the research plan described in the MTA. This reduces some of the risk a company takes on when it provides proprietary materials. Although giving the company ownership of these kinds of research results and reagents carries with it the same problems as giving the company ownership of inventions made *in* the described research plan, it is difficult for the university not to agree to this request. After all, its researchers should not be doing any work with the material other than under the research plan included in the MTA. As an alternative to ownership, the university may be willing to grant the providing company a non-exclusive, royalty-free, irrevocable license to use such inventions for any purpose.

Confidentiality. Many MTAs for materials provided by a commercial entity contain confidentiality clauses, even though the company is not providing any information but just the material itself. Confidentiality clauses can be problematic for universities if they are so onerous that they will impede publication of research results, or, in the case of a graduate student using the material, if they impede the ability of that student to defend her thesis and submit her dissertation to the university library. Also, the federal government has a Freedom of Information ("FOIA") law[37], and many states have public disclosure/open record laws[38], and organizations subject to these laws cannot always guarantee absolute confidentiality.

If a company provider insists that the MTA contain confidentiality language, the university often requires that all the confidential information provided by the company be marked "CONFIDENTIAL", so that the recipient researchers will know what is confidential and what isn't. Any confidentiality clauses should exclude certain standard types of information from confidentiality (see Appendix 29, "Confidentiality Clauses").

When considering confidentiality language in an MTA (or any other contract, for that matter) the university evaluates the potential impact on publication. If, for example, the material to be transferred is a chemical compound, the company demands that the chemical structure be kept confidential, and knowledge of the structure would be essential to publication, then confidentiality would impede publication. The university likely either would not agree to the demand of confidentiality for the chemical structure, or would not accept the material. A similar situation would arise if the company's confidential information is reasonably needed to interpret the research results.

The requirement to keep information confidential should be limited to a certain span of time, generally three years after receiving the information, but certainly no longer than five years.

Publication. From a university perspective, the right to freely share scientific information is a cornerstone of academic freedom. Few universities will accept MTA terms that restrict publication, presentations, or other forms of publicly disclosing research results. In contrast, a for-profit organization can gain a competitive advantage by keeping information secret, at least until it has had a chance to seek patent or some other form of legal protection for the information. Despite these different perspectives, compromises often can be reached in which the non-profit recipient's right to make its research results public is protected, but also delayed long enough for the company to review the proposed disclosure and take protective measures that it considers necessary.

While few universities will allow any MTA provider the right to *approve* a planned public disclosure, it is fairly standard to allow the provider the right to *review* the proposed disclosure.[40] A typical arrangement will give the provider notice of a proposed disclosure before it is to be made, for example, thirty days before a manuscript is submitted to a journal, or an abstract is to be submitted to a conference. This allows the provider to look for and remove any of its confidential information that may have been included in the planned disclosure, and to review the disclosure for potentially patentable inventions that may be described. A for-profit provider may prefer at least 60 to 90 days in which to review the planned disclosure, but somewhere between thirty and ninety days is common.

A provision is usually made that, if the company does identify a potentially patentable invention in the planned disclosure, then the public disclosure may be delayed for another thirty to ninety days. During this delay a patent application could be written and submitted to the desired patent office. Again, universities generally prefer the delay to be as short as possible, whereas companies are usually more comfortable with longer periods of time, but thirty to sixty days is a common period of delay for the purpose of patenting. Typically, universities prefer that the total delay – review plus patenting period – be no longer than ninety days. Their researchers often are eager to make their research discoveries public as soon as possible.

In negotiating MTA terms, both the recipient and provider need to be mindful that publication in a scholarly journal sometimes carries with it an obligation on the part of the recipient/authors to make reagents described in the publication available to the scientific community. Some journals have an explicit expectation that their authors will share reagents, in line with a 2003 National Academies of Science report that concluded, "An author's obligation is not only to release data and materials to enable others to verify or replicate

published findings (as journals already implicitly or explicitly require) but also to provide them in a form on which other scientists can build with further research."[41] When publishing, it is customary for the recipient to acknowledge the contribution of the material by the provider; some MTAs might address this specifically.

Ownership of Results/Product: Biomaterials license. The most common direction of a BML is for a non-profit to license a reagent to a for-profit entity, either for internal use or for commercial production. It is unusual for a for-profit entity to insist on a biomaterials license being in place before sending a reagent to a non-profit, but there have been several high profile cases of this; one such case will be reviewed below. Non-profit organizations rarely license biomaterials to other non-profit organizations, and so that case will not be considered.

When transferring a biomaterial to a company, a university may choose a BML over an MTA for several reasons, amongst them the purposes for which the material will be used and perhaps the commercial value of or demand for the material. In the simplest case, the material may be non-exclusively transferred to the company for that company's internal research only (or internal "commercial" research), with all other uses specifically excluded. In this case the university may grant the company "a worldwide non-exclusive license to make, have made, use and have used, but not to sell, offer for sale, or have sold, the Material and processes using the Material." In addition to any licensing fee, the BML will usually address whether the university is to receive benefit, in the way of royalties or other payments, of any commercially useful reagents or products the company discovers using the material. The university will likely insist that the company indemnify the university for the company's use of the material, and for any reagents or products the company makes as a result of its using the material. It is important to note that this indemnification often continues even after the license ends. The university also may wish to clarity that it is free to non-exclusively license the biomaterial to other for-profit, or non-profit, entities. (See Appendix 30, "Useful Language for Simple BML".)

When a company licenses a biomaterial specifically for the purpose of producing and selling it commercially, along or in combination with other materials, the BML will likely contain indemnification language similar to that in Appendix 30, but other language will be different (See Appendix 31, "Useful BML Language"). The license will likely define a "Licensed Product" (what the company actually plans to sell), the "Field" (uses for which the biomaterial may be sold) and a geographical area ("Territory") in which the company may use and sell the biomaterial. The grant clauses will recognize that the company plans to sell the biomaterial and make if clear whether the BML is exclusive of non-exclusive. Other issues, such as the right to sublicense, may be addressed. If the company is required to pay the university royalties on the sale of products, then it is useful if the BML contains information on how much the royalty will be, and when and how it will be paid, along with any accounting information that the university may want the company to provide. The financial terms may also anticipate that the biomaterial might be incorporated into a product containing other materials, and in that case the license will address how a royalty is to be calculated on these "combination products". The BML will state how long the license will be valid (the "Term"), that is, how long the licensee is allowed to use and sell the biomaterial, and how the license is to be terminated if for some reason either party wishes to terminate it sooner than the term of the license ("Termination", often combined in "Term and Termination") The termination language will often address what, if any, responsibilities the parties will have to each other after the license ends.

Although uncommon, there have been cases in which a for-profit provider insisted that a potential non-profit recipient license a material rather than receive it under an MTA. An

example of this was Dupont Pharmaceutical's Cre-lox technology, a powerful and popular research tool that was freely used in the research community up until the mid-1990s. Starting about 1996, however, Dupont made a business decision to require all organizations – including non-profits - that used the Cre-lox technology to take a non-exclusive license from Dupont. Initially Dupont required that a license fee be paid, required that all proposed publications of research using the Cre-lox technology be sent to Dupont for review prior to publication, and restricted the sharing of reagents incorporating Cre-lox between scientists. Dupont later amended the licensing terms, removing the upfront fee and adding "reach through" rights requiring that universities pay Dupont a share of revenues from any university invention which used the Cre-lox technology in its development and which the university subsequently commercialized. The outcry from the academic community was so great that the NIH eventually stepped in and negotiated an umbrella agreement with Dupont that would cover all NIH grantees, and which relaxed or removed the requirements that universities found most objectionable[42].

Reporting. Companies have a legitimate interest in the results of research involving their proprietary materials, and when they send materials to a university the governing MTA may require the university recipient to report research progress to the company provider. The university will evaluate whether the reporting requirements would place an undue burden on the researcher, for example, by interfering with his other university responsibilities or requiring him to prematurely share results with the company. To ease demands on a researcher's time, or help prevent release of premature or raw data to the company, the TTO may suggest reporting language that requires only a summary report being sent to the company. If a company insists that a researcher recipient report more than just a final summary, the TTO may require the company to keep any earlier reports confidential until the researcher has had a chance to publicly disclosure results directly.

Conflict with Existing Agreements. In a BML, as with any license, the licensee may wish to protect itself from liability stemming from other obligations on the part of the licensor by asking the licensor to "warrant and represent" that it does not have any obligations that will conflict with the obligations it will assume under the contemplated agreement. Although this is a reasonable request, if the licensor is a university – particularly a large university, with multiple campuses – the university may be reluctant to absolutely assert that it does not have any conflicting obligations, perhaps because its TTO operations do not have a strong central organization or authority. In this case, the university might offer as a compromise language such as "to the best of the Licensor's knowledge, and after reasonably inquiry, Licensor asserts that it has not entered into any conflicting agreements".

Dispute Resolution. Universities may prefer that MTAs and BMLs not specify any particular method of dispute resolution, for the simple reason that remaining silent on the issue preserves all options of dispute resolution. Should a disagreement arise, the university can evaluate how it thinks the disagreement can best be resolved and pursue that method, and the entire range of options –from informal discussions between appropriate officials of each party to bringing legal action – will be open to it.

If a potential recipient or licensee is unwilling to remain silent on dispute resolution, some universities have a hierarchy of preferred options. In general, the preferred options will permit some flexibility combined with lower financial burdens, while the least preferred or unacceptable options impose some rigidity coupled with a probability of large expense. If silence on the subject is not acceptable, a university might offer language such as:

> "In case of any dispute regarding this Agreement, the parties agree to attempt resolution of such dispute through good faith negotiation between the parties. In the event the parties cannot resolve such dispute, the parties are then free to pursue other legal remedies as deemed necessary."

Companies, however, may not be comforted by such language because it offers little in the way of enforcement. In that case, the following language provides a more clearly defined pathway to dispute resolution, and so might be acceptable:

> The parties must attempt to resolve through good faith discussions any dispute which arises under this Agreement. Any dispute may, at the election of either party, be referred to the chief executive officers of each party. If they are unable to resolve the dispute, except one having to do with the scope, enforceability, infringement or validity of a patent or trade secret, within thirty (30) days after delivery of written notice of the dispute from one party to the other, either party may seek to resolve it by initiating … (here insert either mediation, or non-binding arbitration, or binding arbitration; the parties might wish to name a mediator, or suggest that the American Arbitration Association be used).

Although universities may be reluctant to accept it, some licensees may insist on alternative dispute resolution or binding arbitration as a means of dispute resolution. Sometimes the specifics of the how the dispute will be resolved are clearly set forth, for example, the "Alternative Dispute Resolution" language of Appendix 32.

Governing Law. As a rule, state universities - which are agencies of their home states in one form or another - will always prefer that the MTA or BML be governed by the law of their own state. One reason is practicalities: attorneys for the state institution are likely most familiar with the laws of their own state; travel and lodging expenses for the state university attorneys are much less than if they have to travel to a different state or country; and, they will not have to hire additional local counsel, as they might if the governing law where that of another state or country. Universities generally do not have large legal budgets with which to pursue lawsuits, as either a plaintiff or defendant, so minimizing legal costs is an important factor for them. Another consideration is that its own state law might give the university certain benefits, such as limiting its legal liability. For example, the California Tort Claims Act shields state entities, such as the University of California, from punitive damages, and Oregon has a law limiting the liability of its state agencies (including its universities) to US $200,000. Similar to state institutions, private universities prefer that the law of their home state govern agreements, because their attorneys are most familiar with their own state law, and expenses will be less if a matter is litigated close to home rather than in another state or country.

If the other party to the agreement is unwilling to accept the preferred state law, then the university, public or private, may prefer that the agreement be silent on the matter of governing law. The advantage of silence to the university is that if a mishap occurs, and the other party brings a lawsuit in a court outside the state, the university is free to ask that the lawsuit be moved to its home state. In cases where the university has received a material from a provider; there has been a mishap with the material; the provider brings a lawsuit (in a court outside the state); the MTA is silent on governing law; and, the state requests that the suit be moved to a court in its home state, there is a reasonable probability that the state's request will approved because the physical location of the mishap was the university. In contrast, if the MTA (or other contract) stipulates that a foreign law ("foreign" meaning outside of the state or outside of the country) will govern, then the lawsuit will be heard in that venue and the university has no hope of having the lawsuit moved to an in-state court.

Some examples of language that can be useful when negotiating a compromise in a governing law clause are:

> "Each party agrees that all claims, charges, or lawsuits brought by it against the other party will be brought and adjudicated in the courts of the location of the party being sued."[43]

and

> "This agreement shall be interpreted and construed in accordance with the laws of the country of the defending party, namely laws of the state of X in the United States, in cases where Recipient is the defending party, or the laws of Y, where Provider is the defending party."[44]

Some universities are very aggressive in refusing any governing law other than that of their home state.

Indemnification. When a material is transferred from one party to another it is common for the provider to require that the recipient indemnify, defend and hold it harmless against costs, claims, and other liabilities arising from the recipient's use, handling, storage, or disposition of the materials. When considering whether to indemnify the provider, the recipient may ask that the provider give the recipient explicit notice and warning of any known hazards or dangers relating to the materials. Before a recipient agrees to indemnify a provider it will often insist that any indemnification exclude negligence, omission or misconduct on the part of the provider. In response, the provider may ask that only "gross" negligence or omissions and "willful" (intentional) misconduct be excluded from the indemnification; this qualified language limits the extent of the exclusion, because the egregious behavior has to reach a certain minimal threshold before it is excluded. Finally, if an agreement requires the recipient to share research results with the provider, the recipient might ask the provider to indemnify it against the provider's use of that information.

In the case of a for-profit organization transferring a material to a university, the for-profit will reasonably expect the university to indemnify and hold it harmless. Many universities will fairly readily agree to hold the provider harmless, although a small number of states prohibit their state universities from indemnifying, defending *and* holding a provider harmless. Offering a provider indemnification, however, can be problematic for a university recipient for several reasons. Some state universities can not indemnify third parties because their state constitutions or laws expressly prohibit them from doing so; sometimes this is because indemnification is viewed as using or loaning taxpayer money without the permission of the state legislature. For example, Article 3, Sections 50-52, of the state of Texas Constitution prohibits the state (and, by extension, the University of Texas) from giving, lending or pledging "the credit of the State to any person, association or corporation, or make any grant of public monies to any person, association or corporation without express authority". [45] If the University of Texas were to indemnify a third party, it would be considered a misuse of the taxpayer's money.[46] In contrast, Article VIII, Section 5 ("Credit not to be Loaned") of the constitution of the state of Washington provides that, "The credit of the state shall not, in any manner, be given or loaned to, or in aid of, any individual, association, company or corporation." Although this language sounds similar to the language from the Texas Constitution, unlike for Texas, the Washington clause is *not* interpreted as a prohibition of against indemnifying third parties.

Not all state universities are limited by state law in their ability to offer indemnification; for them and for private universities, limits can be placed on the university by standing orders or policies issuing from their regents or other governing authority. For example, neither the California constitution nor state law prohibits the University of

California from indemnifying third parties. In this case standing orders of the Regents of the University of California limit the extent to which the University can offer indemnification; it can be offered only in cases for which the Regents have specifically given their approval. [47] Finally, even when they are able to offer full indemnification to providers, some universities are reluctant to do so, citing the lack of financial resources to obligate themselves to such a burden.

Even in the cases where universities are prohibited from offering broad indemnification, many can and will indemnify third parties to the extent that negligence, misconduct, or omissions on the part of the university, its employees and students caused the alleged damage at issue, although some have a strong preference for *gross* negligence, *willful* misconduct or omissions. In contrast, some universities are able to indemnify against negligence, misconduct, and omission, but not against *willful* (that is, *intentional*) misconduct or omission. For example, Washington state law does authorize the University Regents to indemnify its personnel and students against liability arising out of their university performance, duties or employment;[48] the Regents provide this indemnification, but *only* if the indemnified personnel perform their duties in a *good faith* manner. [49] If the employees deliberately misbehaved, then those employees would not be indemnified by the University. (The University could still be held legally accountable for the mishap, but it would be through another device of law other than indemnification.)

The following four paragraphs provide useful options when compromise is needed to find mutually acceptable terms between a provider and a recipient:

> "The University will defend, indemnify, and hold harmless the Provider, its officers, employees and agents against any and all liability due to and in proportion to the acts or omissions of the University resulting from the University's use of the Materials."

> "The parties agree to defend, indemnify, and hold each other harmless from and against any loss, claim, or damage arising from the negligent acts or omissions of their respective officers, employees, students, or agents in the performance of their duties under this agreement. This indemnification clause will survive the termination of this Agreement."

> "The University will defend, indemnify, and hold harmless the Provider, its officers, employees and agents against any and all liability arising from the negligent acts or omissions of University officers, employees, students, or agents to the extent permitted by (cite relevant statute)."

> "The University will defend, indemnify, and hold harmless the Provider, its officers, employees and agents against any and all liability only if the University is solely, grossly negligent in the conduct of the research with the Material."

Sometimes indemnification will be provided if certain conditions are met, such as one party notifying the other as soon as it becomes aware of a claim against it. Other conditions might include the parties cooperating with in its defense of the claim, or the not settling a claim without first obtaining the permission of the other party.

In cases where the university is the provider (of the material) and a company is the recipient, some universities may agree to reciprocal indemnification language as in the second example above ("The parties agree to defend, indemnify, and hold each other harmless…").

However, many universities will press strongly for full indemnification by the company recipient, reasoning that: they cannot control what a company might do with the university material once they have it; the company might, if it incorporates the material into a product or uses the material to develop a product, increase the university's liability; and, because of their financial structure and insurance policies, companies can often take on the burden of broad indemnification. An example from an ATCC template MTA (last updated September 8, 2003) follows:

> "Purchaser hereby agrees to indemnify, defend and hold harmless ATCC and its contributors against all third party claims, losses, expenses and damages (including reasonable attorneys' fees) arising out of or relating to the use, receipt, handling, storage, transfer, disposal and other activities relating to the Material, Replicates or Derivatives. All non-monetary settlements will be subject to ATCC's consent."[50]

Finally, in non-profit to non-profit transfers, indemnification clauses are generally agreed upon with minimal challenges. Non-profits are usually more understanding of the limitations of other non-profits in the area of indemnification, and in the spirit of collegiality sometimes accept less than what they might prefer.

Export Control. Although it does not usually come up in the context of biomaterials MTAs and BMLs, it is useful to keep in mind that the U.S. imposes restrictions on the export of certain technology and information, particularly since laboratory personnel often include non-U.S. citizens. While export controls have historically been concerned with areas such as high tech electronics and military defense technology, the threat of bioterrorism has caused increasing scrutiny of the transfer of biomaterials such as bacterial and virus samples.

Useful export control clauses as they might be used in an MTA or BML context include:

> "Provider agrees to identify in writing any technical data subject to U.S. export laws and regulations that it provides to Recipient under this agreement. Recipient agrees that such technical data will not be provided to foreign nationals or be shipped or transmitted outside the United States without appropriate U.S. Government authorization."[51]

or

> "Recipient hereby agrees that, to the best of its ability, it will comply with all U.S. export control laws and regulations with respect to the release or distribution of any information or materials provided by Provider to Recipient."[52]

V. CONCLUSION

Sharing of materials continues to be an active issue in the research and licensing field. Finding balance between research freedom, business goals, and society's needs is an imperfect art that requires negotiators and institutions to exhibit strength, grace and flexibility. By seeking to understand the needs and concerns of the other party, and taking into account common practices as well as laws and policies that apply, two parties usually can come to an arrangement that enables materials to be shared, profits to be made, and society to be advanced.

ABBREVIATIONS

ATCC - American Type Culture Collection

BML – Biomaterials License

COGR - Council on Government Relations

FOIA – Freedom of Information Act

MRA – material transfer agreement

NERF – non-exclusive royalty-free

NIH – National Institutes of Health

OEDC - Organisation for Economic Co-Operation and Development

PI - principle investigator

R&D – research and development

TTO - technology transfer office

UBIT – Unrelated Business Income Tax

UBMTA - Uniform Biological Materials Transfer Agreement

FOOTNOTES

[1] As used in the context of this report, a "grantee" is an institution that receives a grant of research funding from the federal government. Government research grants are made to non-profit research groups and small businesses, and the law gives these two groups of grantees the same rights and responsibilities as universities.

[2] Ferguson, Steven M. "Products, Partners, and Public Health: Transfer of Biomedical Technologies from the U.S. Government". *The Journal of Biolaw and Business*, Vol. 5(2), pp 35-39. 2002. For a comparison of U.S. versus Japan support for R&D, Ferguson recommends Kneller, Robert. "Intellectual Property Rights and University-Industry Technology Transfer in Japan". Science and Public Policy, Vol. 26(2), pp 113-124. 1999.

[3] The Bayh-Dole act may be referred to as PL No. 96-517 or 35 U.S.C. §§ 200-212, with or without mention of 37 CFR 401.1-.14.

Explanation of PL No. 96-517. "PL" stands for Public Law; a Public Law is an act of Congress. The "96" refers to the 96th Congress, which passed the Bayh-Dole legislation, and "517" means that Bayh-Dole was the 517th act of the 96th Congress. Public laws are organized chronologically.

Explanation of 35 U.S.C. §§ 200-212. "U.S.C." stands for United States Code; the United States Code is a collection of laws organized by subject. In the U.S.C., the Bayh-Dole law is found in Title 35, Sections 200-212.

Explanation of 37 CFR 401.1-.14. "CFR" stands for Code of Federal Regulations, the organized collection of rules and regulations (sometimes called "administrative law") published in the Federal Register by the executive departments and agencies of the U.S. federal government. The Federal Register is a federal government publication that contains most routine publications and public notices of government agencies. While the P.L. and U.C.C. collections state the law, the CFR explains how the law will be put into practice.

The text of Public Law No. 96-517, the Bayh-Dole Act, can be found at http://uscode.house.gov/search/criteria.shtml (Office of the Law Revision Counsel, U.S. House of Representatives, Title 35 (Patents), Part II (Patentability of Inventions and Grants of Patents), Chapter 18 (Patent Rights in Inventions Made with Federal Assistance.

For an excellent overview of technology transfer in general, see the Council on Government Relations ("COGR") 1995 publication "*A Review of University Industry Research Relationships*" (http://www.cogr.edu/).

[4] The University of California-Los Angeles's Office of Intellectual Property reports a four-fold increase in the number of MTAs it handles yearly over the past ten years, from 161 (1996) to 663 (2006). See http://www.research.ucla.edu/mta/

[5] For a good general overview of MTAs, see COGR's "Materials Transfer in Academia 2002" http://www.cogr.edu/docs/MTA_Final.pdf;also http://www.cogr.edu/

[6] For an interesting research report on the sharing of research materials amongst geneticists and other scientists, see Campbell, et al., "Data Withholding in Academic Genetics". *Journal of the American Medical Association*, Vol. 287(4), pp473-480. 2002.

[8] Such repositories include the non-profits American Type Culture Collection (for, among other things, cell lines and bacterial samples) and Jackson Laboratories (for genetically engineered mice).

[9] See Campbell, Paullete Walker. "Pacts Between Universities and Companies Worry Federal Officials: Research agencies fear that the restrictions in some agreements may impede scientific progress" *The Chronicle of Higher Education*, May 15, 1998.

[10] See Report of the National Institutes of Health (NIH) Working Group on Research Tools, Presented to the Advisory Committee to the Director, June 4, 1998 http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm

[11] See http://ott.od.nih.gov/policy/rt_guide_final.html, "PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES: FINAL NOTICE"

[12] See http://ott.od.nih.gov/pdfs/64FR28205.pdf, Federal Register / Vol. 64, No. 100 / Tuesday, May 25, 1999 / Notices 28205

[13]See http://ott.od.nih.gov/policy/rt_guide_final.html#use, "Simple Letter Agreement"

[14] See http://www.cogr.edu/docs/ResearchTools.htm, "Guidance to Campuses on NIH "PRINCIPLES AND GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES:"

[15] See Russo, Eugene. "Regulating Researchers' 'Picks and Shovels': Scientists continue to review NIH research tool guidelines" *The Scientist* 14(9) p. 8. 2000.

[16] See Dove, Alan. "When Science Rides the MTA." *The Journal of Clinical Investigation*, Vol. 110(4), pp 425-427.

[17] Ferguson, S.M. and Kim, J.P. "Distribution and Licensing of Drug Discovery Tools – NIH Perspectives." www.drugdiscoverytoday.com Vol.7(21) pp 1102-1106, 2002.

[18] Streitz, W.D. and Bennett, A.B. "Material Transfer Agreements: A University Perspective". *Plant Physiology*, Vol. 133, pp. 10–13, 2003.

[19] Excerpt from http://books.nap.edu/execsumm_pdf/10613.pdf, Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences. National Academy of Sciences

[20] See http://www.oecd.org/dataoecd/7/42/1949083.pdf, Short Summary Report of the Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices.

[21]See http://www.oecd.org/dataoecd/42/21/2491084.pdf, "Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies - (English) "

[22] For example, as of October 1, 2004, the NIH requires submission of a plan for sharing model organisms developed with federal funding as part of certain grant applications. The

NIH Statement on Sharing and Distributing Mouse Resources can be found at http://www.nih.gov/science/models/mouse/sharing/, and a sample plan at http://www.nih.gov/science/models/mouse/sharing/3.html

[23] See http://sciencecommons.org/;
http://sciencecommons.org/projects/licensing/background.html;
http://sciencecommons.org/projects/licensing/index.html

[24] See Harvard Office of Technology Development: http://www.techtransfer.harvard.edu/
Material Transfer Information: http://www.techtransfer.harvard.edu/MaterialXfer.html

[25] See Massachusetts Institute of Technology MATERIAL TRANSFER POLICY
http://web.mit.edu/ipcounsel/mta.html

[26] See http://www.techtransfer.harvard.edu/InfoForIndustry.html#TechnologyLicensing

[27] The term "outgoing MTA" means an MTA governing a material is being sent out of the organization to another, unrelated organization.

[28] See http://www.techtransfer.harvard.edu/MTA-SimpleLtr.html

[29] The term "incoming MTA" means an MTA governing a material that is being received by the organization from another, unrelated organization.

[30] See http://www.techtransfer.harvard.edu/MissionStatement.html)

[31] An example of compliance with laws language: "Licensee agrees in its use of the Material to comply with all applicable statutes, regulations and guidelines, including those of the Public Health Service and the University regulations and guidelines."

[32] Insurance clauses usually have two parts. The first part describes what kind of insurance the licensee must have, for example: "Insurance. Licensee must maintain general liability insurance including product liability and contractual liability coverage of at least one million dollars ($1,000,000) that must be in effect no later than the date of the first human clinical testing of Licensed Subject Matter. Licensee's general liability insurance must name (name of the licensor) as an additional insured. Licensee must declare whether the insurance is provided on a "claims-made" form and must notify (name of the licensor) if coverage is canceled. The second part describes how the licensee must prove that it actually has the insurance required in the first part, for example: "Proof of Coverage. Licensee must provide to (name of the licensor) within thirty (30) days prior to the initiation of human clinical trials with respect to Licensed Subject Matter certificates evidencing the existence of the insurance required under this section. Licensee must issue irrevocable instructions to its insurance agent and to the issuing company to notify (name of the licensor) of any discontinuance or lapse of such insurance not less than thirty (30) days prior to the time that any such discontinuance or lapse is due to become effective. Licensee must provide (name of the licensor) a copy of such instructions upon their transmittal to the insurance agent and issuing company. Licensee must further provide (name of the licensor), at least semi-annually, proof of continued coverage.

[33] Examples of disposal of material language include:

In the case of a BML. "By executing this Letter of Termination, (Licensee's name) terminates the Non-Exclusive Biomaterial License between (Licensee's name) and the Licensor, effective (effective date of the license or evaluation license). In executing this Letter of Termination, (Licensee's name) warrants that all Material provided under the aforementioned Non-Exclusive Biomaterial License have been destroyed in accordance with local, state and federal law."

In the case of a Biomaterials Evaluation Agreement. "By executing this Letter of Termination, (Licensee's name) terminates the Non-Exclusive Biomaterial Evaluation Agreement between (Licensee's name) and the Licensor, effective (effective date of the license or evaluation license). In executing this Letter of Termination, (Licensee's name) indicates that it does not wish to seek a commercialization license from the Licensor for the Material (as defined below) and warrants that all Material provided under the aforementioned Non-Exclusive Biomaterial Agreement have been destroyed in accordance with local, state and federal law.

[34] To exercise the option, the usual time limit is 90 days from the day the recipient gives the provider written notice that an invention has been mad. To negotiate the exclusive license, a the usual time period is 3 to 6 months after the option is exercised; during this time both parties must make good faith efforts to negotiate a license. If the parties cannot conclude the license by six months, the recipient should be free to offer the invention to others for license.

[35]Again, setting financial terms before the invention has actually been made may cause the non-profit recipient to run afoul of the Unrelated Business Income Tax laws.

[36] This is to protect the recipient institution in case the recipient researcher uses the provider's material in research where certain rights have already been promised to a third party. This can happen if the researcher uses the material in research being funded by another for-profit organization, or if the researcher uses two or more materials provided under MTAs from two or more for-profit entities.

[37] See http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm, "Availability of Information" and "The Freedom of Information Act"; additional information is available at Additional information is available on the NIH website at http://grants.nih.gov/grants/policy/data_sharing/index.htm. (Also see "Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.")

[38]For example, the state of Washington; see Chapter 42.56 RCW, "Public Records".
See also http://apps.leg.wa.gov/RCW/default.aspx?cite=42.56, "Requests for Public Records":

> Washington law (Chapter 42.56 RCW) requires that, upon request, identifiable public records be made immediately available for public inspection and copying. In addition, records that are exempt by law may be withheld from public disclosure. Exemptions are generally intended to prevent acts of privacy invasion and for personal or commercial gain. Exemptions include, but are not limited to:
>
> - Information regarding agency personnel, such as social security numbers, home phone numbers, home addresses, resumes and employment applications.
> - Investigative records relating to current enforcement.
> - Examination test scores.

- Data, if disclosed could result in private gain and/or public loss.
- Correspondence between agency staff and the Attorney General's Office.
- Information whose release would constitute an invasion of privacy as defined in (RCW 42.17.2551[2]).

[39]In making this evaluation the university may take into consideration how many research funding contracts the researcher recipient has for his laboratory, and whether those funding sources are the federal government, non-profit organizations, or for-profit entities. The university also may review what other materials are in the laboratory that have come into the university under restrictive MTAs. The university may consider its perception of how responsibly the recipient researcher has used materials or funding received from outside sources in the past.

[40] If pressed, a university might agree to a company having the right to approve publication with the qualifier "such approval not to be unreasonably withheld."

[41] For more information, see Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences" at http://www.nap.edu/catalog/10613.html

[42] For more information on the Cre-lox case see Russo, E. "Technology Transfer Pact Could Be A Model for Future Agreements" *The Scientist*, Vol. 12(18), pg 1, 1998 at http://www.the-scientist.com/article/display/18192/

[43] from Heidi Henning, "Negotiating the Material Transfer Agreement". National Association of College and University Attorneys, November 2004

[44] from Heidi Henning, "Negotiating the Material Transfer Agreement". National Association of College and University Attorneys, November 2004

[45] The Texas Tort Claims Act (Chapter 101, Texas Civil Practice and Remedies Code) provides a waiver of the State of Texas' sovereign immunity with respect to liability and suits against governmental units like The University of Texas System and its component institutions for property damage and personal injury (including death) proximately caused by the wrongful act or omission or the negligence of an employee acting within the scope of his or her employment. But, the property damage, injury, or death must have arisen out of the operation or use of a motor vehicle or motor-driven equipment or the condition or use of other personal or real property. Section 101.021. See
http://tlo2.tlc.state.tx.us/txconst/articles/cn000300.html and
http://www.utsystem.edu/ogc/intellectualproperty/indins.htm.

[46] The University of Texas's website contains links to useful language and discussions of indemnification from the University's perspective; start at
http://www.utsystem.edu/ogc/intellectualproperty/INDCKLST.HTM

[47] See http://www.universityofcalifornia.edu/regents/bylaws/so1004.html, Standing Order 100.4(dd)(9) "Except as otherwise specifically provided in the Bylaws and Standing Orders, the President is authorized to execute on behalf of the Corporation all contracts and other

documents necessary in the exercise of the President's duties, including documents to solicit and accept pledges, gifts, and grants, except that specific authorization by resolution of the Board shall be required for documents which involve or which are: (9) Agreements by which the University assumes liability for conduct of persons other than University officers, agents, employees, students, invitees, and guests. In circumstances where it is deemed necessary by the President, in consultation with the General Counsel, to indemnify non-University persons who have agreed at the University's request to serve as advisors on operational matters for conduct within the scope of their role as advisors, the President is authorized to provide for defense and indemnification. This restriction does not apply to agreements under which the University assumes responsibility for the condition of property in its custody."

[48] RCW 28B.20.250, "Liability Coverage of University Personnel and Students", states: "The board of regents of the University of Washington, subject to such conditions and limitations and to the extent it may prescribe, is authorized to provide by purchase of insurance, by self-insurance, or by any combination of arrangements, indemnification of regents, officers, employees, agents, and students from liability on any action, claim, or proceeding instituted against them arising out of the performance or failure of performance, of duties for or employment with the university, or of responsibilities imposed by approved programs of the university, and to hold such persons harmless from any expenses connected with the defense, settlement, or payment of monetary judgments from such action, claim, or proceeding."

[49] See standing orders of the Regents of the University of Washington, Volume1, Chapter 1, http://www.washington.edu/faculty/facsenate/handbook/Volume1.html

[50] See http://www.atcc.org/common/documents/mta/mta.cfm, "Material Transfer Agreement" Last Updated September 8, 2003"

[51] Heidi Henning, "Negotiating the Material Transfer Agreement". National Association of College and University Attorneys, November 2004

[52] Heidi Henning, "Negotiating the Material Transfer Agreement". National Association of College and University Attorneys, November 2004

The following people have provided helpful resources or discussion during the writing of this report:

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Assistant Attorney General
Attorney General's Office
University of Washington

MASTER AGREEMENT REGARDING USE OF THE
UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT
dated March 8, 1995

Upon execution of an Implementing Letter in the form attached, which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement ("UBMTA") published in the Federal Register on March 8, 1995.

Attachments: **UBMTA**
Implementing Letter

Organization: _____

Address: _____

_____

_____

Authorized Official: _____

Title: _____

Signature: _____ **Date:** _____

Please return an executed copy of this Master Agreement to:
The UBMTA Project
Association of University Technology Managers (AUTM)
60 Revere Drive, Suite 500
Northbrook, IL 60062

AUTM will be maintaining signed originals and the official list of signatory organizations.

THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT

(dated March 8, 1995)

I. Definitions:

1. **PROVIDER:** Organization providing the **ORIGINAL MATERIAL.** The name and address of this party will be specified in an implementing letter.

2. **PROVIDER SCIENTIST:** The name and address of this party will be specified in an implementing letter.

3. **RECIPIENT:** Organization receiving the **ORIGINAL MATERIAL**. The name and address of this party will be specified in an implementing letter.

4. **RECIPIENT SCIENTIST:** The name and address of this party will be specified in an implementing letter.

5. **ORIGINAL MATERIAL:** The description of the material being transferred will be specified in an implementing letter.

6. **MATERIAL: ORIGINAL MATERIAL, PROGENY,** and **UNMODIFIED DERIVATIVES**. The **MATERIAL** shall not include: (a) **MODIFICATIONS**, or (b) other substances created by the **RECIPIENT** through the use of the **MATERIAL** which are not **MODIFICATIONS**, **PROGENY**, or **UNMODIFIED DERIVATIVES**.

7. **PROGENY:** Unmodified descendant from the **MATERIAL**, such as virus from virus, cell from cell, or organism from organism.

8. **UNMODIFIED DERIVATIVES:** Substances created by the **RECIPIENT** which constitute an unmodified functional subunit or product expressed by the **ORIGINAL MATERIAL**. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the **ORIGINAL MATERIAL**, proteins expressed by **DNA/RNA** supplied by the **PROVIDER**, or monoclonal antibodies secreted by a hybridoma cell line.

9. **MODIFICATIONS:** Substances created by the **RECIPIENT** which contain/incorporate the **MATERIAL**.

10. **COMMERCIAL PURPOSES:** The sale, lease, license, or other transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **MATERIAL** or **MODIFICATIONS** by any organization, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

11. **NONPROFIT ORGANIZATION(S):** A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

II. **Terms and Conditions of this Agreement**:

1. The **PROVIDER** retains ownership of the **MATERIAL**, including any **MATERIAL** contained or incorporated in **MODIFICATIONS**.

2. The **RECIPIENT** retains ownership of: **(a) MODIFICATIONS** (except that, the **PROVIDER** retains ownership rights to the **MATERIAL** included therein), and (b) those substances created through the use of the **MATERIAL** or **MODIFICATIONS**, but which are not **PROGENY**, **UNMODIFIED DERIVATIVES** or **MODIFICATIONS** (i.e., do not contain the **ORIGINAL MATERIAL**, **PROGENY**, **UNMODIFIED DERIVATIVES**). If either 2(a) or 2(b) results from the collaborative efforts of the **PROVIDER** and the **RECIPIENT**, joint ownership may be negotiated.

3. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree that the **MATERIAL:**

   (a) is to be used solely for teaching and academic research purposes;

   (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the **PROVIDER**;

   (c) is to be used only at the **RECIPIENT** organization and only in the **RECIPIENT SCIENTIST's** laboratory under the direction of the **RECIPIENT SCIENTIST** or others working under his/her direct supervision; and

   (d) will not be transferred to anyone else within the **RECIPIENT** organization without the prior written consent of the **PROVIDER**.

4. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree to refer to the **PROVIDER** any request for the **MATERIAL** from anyone other than those persons working under the **RECIPIENT SCIENTIST's** direct supervision. To the extent supplies are available, the **PROVIDER** or the **PROVIDER SCIENTIST** agrees to make the **MATERIAL** available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at **NONPROFIT ORGANIZATION(S)** who wish to replicate the **RECIPIENT SCIENTIST's** research; provided that such other scientists reimburse the **PROVIDER** for any costs relating to the preparation and distribution of the **MATERIAL.**

5. (a) The **RECIPIENT** and/or the **RECIPIENT SCIENTIST** shall have the right, without restriction, to distribute substances created by the **RECIPIENT** through the use of the **ORIGINAL MATERIAL** only

if those substances are not **PROGENY, UNMODIFIED DERIVATIVES,** or **MODIFICATIONS.**

(b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the **PROVIDER's** rights), the **RECIPIENT** may distribute **MODIFICATIONS** to **NONPROFIT ORGANIZATION(S)** for research and teaching purposes only.

(c) Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may **NOT** provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**. It is recognized by the **RECIPIENT** that such **COMMERCIAL PURPOSES** may require a commercial license from the **PROVIDER** and the **PROVIDER** has no obligation to grant a commercial license to its ownership interest in the **MATERIAL** incorporated in the **MODIFICATIONS**. Nothing in this paragraph, however, shall prevent the **RECIPIENT** from granting commercial licenses under the **RECIPIENT's** intellectual property rights claiming such **MODIFICATIONS**, or methods of their manufacture or their use.

6. The **RECIPIENT** acknowledges that the **MATERIAL** is or may be the subject of a patent application. Except as provided in this agreement, no express or implied licenses or other rights are provided to the **RECIPIENT** under any patents, patent applications, trade secrets or other proprietary rights of the **PROVIDER**, including any altered forms of the **MATERIAL** made by the **PROVIDER**. In particular, no express or implied licenses or other rights are provided to use the **MATERIAL, MODIFICATIONS,** or any related patents of the **PROVIDER** for **COMMERCIAL PURPOSES.**

7. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license. It is understood by the **RECIPIENT** that the **PROVIDER** shall have no obligation to grant such a license to the **RECIPIENT**, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the **MATERIAL** to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

8. The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL** but agrees to notify the **PROVIDER** upon filing a patent application claiming **MODIFICATIONS** or method(s) of manufacture or use(s) of the **MATERIAL.**

9. Any **MATERIAL** delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The **PROVIDER** MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE **MATERIAL** WILL NOR INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages which may arise from its use, storage or disposal of the **MATERIAL**. The **PROVIDER** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the **MATERIAL** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **PROVIDER**.

11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **MATERIAL** or the **MODIFICATIONS**. The **RECIPIENT SCIENTIST** agrees to provide appropriate acknowledgement of the source of the **MATERIAL** in all publications.

12. The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

13. This Agreement will terminate on the earliest of the following dates: (a) when the **MATERIAL** becomes generally available from third parties, for example, through reagent catalogs or public depositories, or (b) on completion of the **RECIPIENT's** current research with the **MATERIAL**, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

    (i) if termination should occur under 13(a), the **RECIPIENT** shall be bound to the **PROVIDER** by the least restrictive terms applicable to the **MATERIAL** obtained from the then-available sources; and

    (ii) if termination should occur under 13(b) or (d) above, the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**; and

    (iii) in the event the **PROVIDER** terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the **PROVIDER** will defer the effective date of termination for a period of up to one year, upon request from the **RECIPIENT**, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS.**

14. Paragraphs 6, 9, and 10 shall survive termination.

15. The **MATERIAL** is provided at no cost, or with an optional transmittal fee solely to reimburse the **PROVIDER** for its preparation and distribution costs. If a fee is requested by the **PROVIDER**, the amount will be indicated in an implementing letter.

UBMTA IMPLEMENTING LETTER

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") published in the *Federal Register* on March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization. This Implementing Letter is effective when signed by all parties. The parties executing this implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by the terms, for the transfer specified above. Please fill in all of the blank lines below:

1. ORIGINAL MATERIAL (Enter description)

2. Optional Termination Date: _____

3. Optional Transmittal Fee (to reimburse the PROVIDER for preparation and distribution costs)
Amount: $ _____

4. PROVIDER (Organization providing the ORIGINAL MATERIAL)

a. Name of Organization: _____

b. Street Address: _____

c. City/State/Zip+4: _____

5. PROVIDER SCIENTIST

a. Name and Title: _____

b. Street Address: _____

c. City/State/Zip+4: _____

d. Signature _____ Date: _____

6. RECIPIENT SCIENTIST

a. Name and Title: _____

b. Street Address: _____

c. City/State/Zip+4: _____

d. Signature _____ Date: _____

7. RECIPIENT ORGANIZATION CERTIFICATION (Organization receiving the ORIGINAL MATERIAL)

I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (may be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization).

a. Name and Title: _____

b. Street Address: _____

c. City/State/Zip+4: _____

d. Signature _____ Date: _____

e. Name and Title: _____

UBMTA IMPLEMENTING LETTER

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization. This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above. Please fill in all of the blank lines below:

1. ORIGINAL MATERIAL (Enter Description)

_____

_____

_____

2. Optional Termination Date:

_____

3. Optional Transmittal Fee (to reimberuse the PROVIDER for perparation and distribution costs):

Amount: $ _____

4. PROVIDER (Organization providing the ORIGINAL MATERIAL)

Name of Organization: _____

Street Address: _____

City/State/Zip Code: _____

5. PROVIDER SCIENTIST

Name and Title: _____

Street Address: _____

City/State/Zip Code: _____

Signature: _____ Date: _____

6. RECIPIENT SCIENTIST

Name and Title: _____

Street Address: _____

City/State/Zip Code: _____

Signature: _____ Date: _____

7. RECIPIENT ORGANIZATION CERTIFICATION (Organization receiving the ORIGINAL MATERIAL)

I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (may be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization)

Name of Organization: _____

Street Address: _____

City/State/Zip Code: _____

Name and Title: _____

Signature: _____ Date: _____

University of Georgia

Background

A Material Transfer Agreement (known as MTA) is a contract governing the transfer of a tangible material from a provider to a recipient. Examples of tangible materials are plant or microbial cultures, plasmids, nucleotides, proteins and chemicals. In the case of the University of Georgia and the University of Georgia Research Foundation, Inc. (UGARF) an MTA would be with another university, a non-profit organization or a company.

It is essential that an MTA be put in place before materials are sent to a recipient or accepted from a provider. The purpose of an MTA is to avoid misunderstanding between the parties and to protect the interests of both parties.

An MTA should address the following topics:

- Description of the material. Provide a description that can be well understood and interpreted at a later date should questions arise about the identification of the materials.
- Definition of progeny, modifications and derivatives of the material. Because many of the materials being transferred are biological in origin, the MTA should clarify not only what the material is but also how progeny, modifications and derivatives are governed under the MTA.
- Agreement by the recipient to not transfer the material to any third party. This is fundamental to the reason for having an MTA and would be expected by any providing party.
- Description defining and limiting the recipient's use of the material for a specified purpose. Usually, the materials are being provided for research use only and for a specified field of research. (The University of Georgia Research Foundation, Inc. uses MTAs to provide proprietary materials to a company in order for the company to determine if it is interested in obtaining a license from UGARF for commercial use.)
- Ownership of data and freedom to publish. Some MTAs from companies will include language granting ownership of the data to the company. Some of these MTAs also limit the researchers right to publish his/her research results. These terms should not be accepted and can usually be modified by negotiation.
- Ownership of intellectual property arising from use of the materials. Some MTAs will define the provider as the owner of any intellectual property developed by use of the materials. Except in unusual circumstances, this is not acceptable and rights to intellectual property should be determined by inventorship. It is sometime reasonable for a company providing a material to be granted an option to obtain a license to inventions developed at UGA by use of the company's material. This option would be granted with restrictions which protect the interest of the university and comply with appropriate regulations.
- Reports of the results of the use of the material. It is reasonable for the provider to require a report from the recipient on the results of their use of the materials.
- Agreement to the legal jurisdiction that governs the agreement. UGARF and UGA cannot agree to any jurisdiction other than the State of Georgia. We often receive MTAs that require the jurisdiction of the providing party's state. This can usually be addressed by negotiation.
- Indemnification and liability of the parties. UGARF and UGA cannot agree to indemnify or hold harmless the providing or recipient institution. This sometimes presents difficulties with companies but we are generally successful in removing that requirement.
- Termination of the agreement and whether the materials should be returned or destroyed by the recipient upon termination. It is desirable to be explicit about the date of termination and the required disposition of the materials upon termination.
- An MTA may also contain a definition of "confidential information" and include terms that require both parties to protect the confidential information of the other party. When only information and no material are being transferred it is more appropriate to use a Confidentiality Agreement.

Excerpted from http://www.research.ucla.edu/mta/

Material Transfer Agreements (MTA's)

Material transfer agreements can be misunderstood or considered an annoyance, say officials... **Buffalo Case Highlights MTAs [read more]** *The Scientist*

DEFINITION

A Material Transfer Agreement (MTA) is a written agreement entered into by a *provider* and a *recipient* of research material. The purpose of the MTA is to protect the intellectual and other property rights of the provider while permitting research with the material to proceed. There are three forms of material transfer that commonly arise at academic institutions, each calling for different terms and conditions.

1) Material Transfer Between Academic Institutions
(When academic researchers receive requests from colleagues for samples of research materials.) Agency sponsors (primarily NIH) often require that research materials generated from funded research are made available to other researchers. To comply with federal sponsors' desire for easy access to research materials, the Uniform Biological Material Transfer Agreement (UBMTA) was developed. The UBMTA provides a record of the material transfer, and prohibits the recipient from transferring the material to others without the written consent of the material provider.

If the academic institution receiving UCLA materials is on the list of signatories to the UBMTA located at http://www.autm.net/aboutTT/aboutTT_umbtaSigs.cfm, please use this UBMTA form to transfer UCLA research material to another academic institution. No signature from a UC official is necessary in this case. PLEASE FORWARD A COPY OF YOUR UBMTA WHEN FULLY-EXECUTED TO UCLA'S OFFICE OF INTELLECTUAL PROPERTY ADMINISTRATION -- ATT: MTA TEAM (fax 310-794-1497). If the academic institution is not on the list of signatories to the UBMTA, please contact one of the MTA team members who will assist in preparing an MTA for the transfer of your materials to another academic institution.

2) Material Transfer from Industry to UCLA
(When a researcher at UCLA requires materials from a company.) Academic researchers may seek industrial materials for their research, which will always be accompanied by an MTA. Because industry frequently has substantial investments and revenues at stake, an industrial MTA is usually more restrictive than a UBMTA.

MTA's from industry often contain restrictive language in the areas of publication, patent rights, and licensing. Often, companies want the right to block or edit our right to publish, which contradicts the concept of academic freedom.

In the area of patents, the company often wishes to own all rights - title and interest - to inventions arising from the use of the material; a position not acceptable to the University.

In the area of licensing, companies may ask for a royalty-free, exclusive or non-exclusive, license to our future patent rights giving us no incentive to file any patents on the work done with their material.

In short, many of these agreements contain language that must be negotiated!

Please see, Approved University of California MTA Language, for an idea of what is

considered approvable for an MTA.

3) Material Transfer from UCLA to Industry
(When companies request a research material from UCLA.) Companies often request samples of research material. These requests are handled in a few different ways:

i. If the material is not patentable, i.e., the composition is publicly known, a UBMTA designed for transferring materials from Academia to Industry should be used. For this type of material transfer, USE THIS AGREEMENT.

ii. If the material is currently patented by UCLA and not yet licensed to industry, a company may obtain a sample of the material under the following agreement, which must be signed by an authorized official within the Office of Research Administration. For this type of material transfer, USE THIS AGREEMENT. This agreement also allows a company to evaluate their interest in licensing the technology related to the material.

iii. If the material is not yet patented (or, publicly disclosed) **and of possible commercial value,** a material transfer agreement with secrecy provisions may be required. In these instances, the researcher may need to fill out an invention disclosure form on the subject material. *These types of material transfers will be handled on a case-by-case basis.*

MTA REQUEST FORMS

Each Material Transfer Agreement (MTA) submitted to the UCLA Office of Intellectual Property requires an MTA Request Form. The information provided in the Request Form helps expedite the negotiation and completion of your MTA. Please add your responses directly into the form, or print out and complete a hard copy version. Once completed, please submit the form to the MTA Team by fax (310-794-1497) or email (mschultz-akerson@resadmin.ucla.edu).

Incoming Materials - MS Word
Incoming Materials - PDF

Outgoing Materials - MS Word
Outgoing Materials - PDF

- **Who is Authorized to Sign an MTA?**

Frequently, investigators are required to co-sign the MTA as evidence that they have read it and will comply with its terms. However, since the MTA is a contract, the official signature can only come from those at UCLA who are charged with the task of reviewing them, and who have been delegated authority to bind the Regents of the University of California contractually.

This authority resides in the Office of Research Administration (ORA) at UCLA, which is also the office of record [original documents are on record at ORA].
no further obligation to Company/Institution with respect to such Subject Invention."

CORNELL UNIVERSITY – OFFICE OF SPONSORED PROGRAMS
MATERIAL TRANSFER AGREEMENT STATEMENT

INVESTIGATOR requesting material: _____
Academic Title: _____
Administering Unit: _____
Location of where the Material will be used: _____
Telephone Number: _____ Email address: _____

PROVIDER supplying Material: _____
Street Address: _____
City: _____ State: _____ Zip code: _____
Telephone Number: _____ Email address: _____

AUTHORIZED REPRESENTATIVE of the Provider:
Name: _____
Street Address: _____
City: _____ State: _____ Zip code: _____
Telephone Number: _____ Email address: _____

Is this Provider a sole source provider for the material? ☐ Yes ☐ No

Identify the Material(s) being transferred and provide a brief lay description of the proposed use:
_____
_____
_____

Material(s) will be utilized during the period _____

What source(s) of funding will be used to support the research?
Sponsor: _____
Project title: _____
Grant Number: _____
OSP Number (if known): _____

What is the intended use or purpose for the materials? Please check all that apply:

☐ The material(s) will be provided for the purpose of product testing and evaluation (i.e., testing an expression system) for the providing organization.

☐ The material(s) will be the actual subject of the research.

☐ The material(s) are a tool, kit, or instrument that will be used in the conduct of research.

☐ Progeny, unmodified derivatives, or descendant copies will be made from the materials.

☐ The material(s) will be modified or will be used to produce modified derivatives.

☐ There is a possibility that the work involving this Material will be included in a graduate student's thesis or dissertation.

☐ The material(s) will be used in conjunction with other materials received from a third party. If checked, identify other materials and provider(s):

OSP #	PROVIDER	MATERIAL

Are there shipping / transportation costs? ☐ Yes ☐ No
If yes, are you, the Investigator, prepared to pay for these costs? ☐ Yes ☐ No
How is the Material(s) being shipped to the campus? _____

Are there any permits required to transport this Material? ☐ Yes ☐ No
If yes, name of agency requiring the permit: _____

Does the material involve any of the following:
Human Subjects ☐ Yes ☐ No If yes, approval date of UCHS: _____
Animal Use – Live vertebrate animals ☐ Yes ☐ No
If yes, IACUC approval date: _____ protocol number: _____
rDNA ☐ Yes ☐ No If yes, MUA # and approval: _____
GMO ☐ Yes ☐ No If yes, explain the nature: _____

Biohazard Level:
☐ L-1 ☐L-2 ☐ L-3 Name of agent(s) _____
Please attach Manufacturers Safety Data Sheet if available.

Is the Material(s) hazardous? ☐ Yes ☐ No If yes, what is the nature of the hazard?
☐air sensitive ☐antidote necessary ☐flammable liquid ☐toxic gas
☐corrosive ☐(NFPA) 4 rating ☐controlled substance(s)

Will Environmental Health and Safety need to assist you in disposing of the Material(s)? ☐ Yes ☐ No
Is there a disposal cost? ☐ Yes ☐ No
If yes, are you, the investigator, paying the disposal costs? ☐ Yes ☐ No

Will personal protective equipment need to be used when handling Material(s)? ☐ Yes ☐ No
If yes, do you, the Investigator, have the appropriate equipment on hand? ☐ Yes ☐ No

By signing this statement, I hereby am responsible for the use and appropriate storage and disposal of the Material(s) and will assure that all other users will abide by the terms and conditions of the agreement. **I understand that any violation of the terms applicable to this transfer could cause a potential liability for the University.**

_____ _____
Principal Investigator Date

_____ _____
Department Chair Date

_____ _____
College Dean / Center Director Date

Revised 10/20/03

Reset

Print

Massachusetts Institute of Technology

Richard F. Cahaly, Jr.
M.I.T. Office of Intellectual Property Counsel
Room NE25-230
rcahaly@mit.edu

Five Cambridge Center
Cambridge, MA 02142
Tel: 617-253-6009
Fax: 617-253-1850

MATERIAL TRANSFER AGREEMENT QUESTIONNAIRE

Principal Investigator:
Investigator:
Provider:
Material:

In order to evaluate the acceptability of the proposed Material Transfer Agreement from *[PROVIDER]* with applicable M.I.T. policies, please provide answers to the following questions:

1. What is the intended use of the material? Will all of the work with this material be done at M.I.T.? If not, where else will it be done?

2. Will federal government research funds be used to support the research utilizing the material? (NOTE: Please include fellowships or other funding sources for those students and/or post docs who will be working on this research.) If so, please provide the government department(s) or agency(s) and both the applicable OSP Account Number, and Grant Number.

3. Will industrial or foundation research funds be used to support the research utilizing the material? If so, please provide the sponsor(s) name(s) and both the applicable OSP Account Number, and Grant Number.

4. Will the materials be used with other materials provided by a third party? If so, what are these other materials and who provided them?**
**** (To help you answer this question regarding materials received at M.I.T. under an MTA, a list of third party materials received under an MTA naming the above-specified Principal Investigator, if any exist, is included.)**

5. Will you be modifying the material? If so, how?

6. Will any progeny be produced (i.e. - unmodified descendants from the material, such as virus from virus, cell from cell, etc.)? If so, do you insist on owning it?

7. Do you intend to publish your findings?

8. Will students be using the material? If so, will this work be part of a thesis?

9. Is the material known to be toxic?

10. Is the material sold commercially? If so, approximately what would the amount of material you are requesting cost? Is the material available from another source? If so, who?

11. The USA Patriot Act became law in October 2001. It expanded the investigative powers of U.S. law enforcement agencies to deter and punish terrorist acts, and it applies to a growing list of chemical and biological agents. Please indicate if you believe there are any potentially harmful chemical or biological properties of the material to be transferred. Ensure that this completed questionnaire contains the exact reference for the material so that our office can check against the chemical and biological agents that the U.S. government lists.

Feel free to add any additional information that you believe to be pertinent. Once you have completed the questionnaire, please return it and any attachments to my attention. Depending on the terms and conditions of the proposed Material Transfer Agreement and your responses, the Agreement may require revisions in order to protect your and M.I.T.'s intellectual property interests, and outstanding obligations.

Your patience and cooperation are appreciated.

Excerpted from http://www.uclbiomedica.com/downloads/MTA_Disclaimer.pdf

PLEASE PROVIDE THE FOLLOWING INFORMATION IF IT DOES NOT APPEAR ON THE MTA

Name of Provider organisation, address, tel, fax and e-mail), together with your initial contact at the Provider and their title/ capacity

Summary of the research for which the material will be used

Who will use the material?

Are all under your direct supervision?

How is the work in which the material will be used funded?

Will the material be used in any collaborative work?

YES (please provide details – attach further pages if necessary)

NO

Are you aware of any other existing agreements relating to your research that could potentially conflict with the terms of this MTA (e.g. research contracts, collaboration agreements, consultancies, other MTAs)?

YES (please provide details – attach further pages if necessary)

NO

Can the material be obtained elsewhere (circle)? YES /NO/Don't Know

Are you content with any clauses in the agreement that:

- impose delays/restrictions on publications? YES/NO
- claim rights to arising Intellectual Property? YES/NO
- require you to submit reports on the results of work using the materials? YES/NO

Do you wish us to contact you to discuss any such clauses? YES/NO

Please add any further specific comments or concerns you have about the MTA on a separate page.

http://www.spo.berkeley.edu/guide/mtaquick.html

A Quick Guide to Material Transfer Agreements at UC Berkeley

Material Transfer Agreements at UC Berkeley

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives. Biological materials, such as reagents, cell lines, plasmids, and vectors, are the most frequently transferred materials, but MTAs may also be used for other types of materials, such as chemical compounds and even some types of software.

Three types of MTAs are most common at academic institutions: transfer between academic or research institutions, transfer from academia to industry, and transfer from industry to academia. Each call for different terms and conditions.

At Berkeley, the Industry Alliances Office (IAO) reviews and approves incoming MTAs. To expedite the process of negotiation, Berkeley investigators are asked to complete and sign an MTA Review Form and submit it with the MTA. All MTAs from Berkeley to other organizations are issued by the Office of Technology Licensing.

Material transfer between Berkeley and another academic institution

Exchange of materials between academic (or not-for-profit) institutions is relatively straightforward. To encourage the process of sharing research tools between scientists, the National Institutes of Health and the Association of University Technology Managers developed standard language to simplify material transfers, issued as the Uniform Biological Material Transfer Agreement (UBMTA). The UBMTA is used for many transfers between academic institutions. The UBMTA includes two sample letters: the Implementing Letter Agreement and the Simple Letter Agreement. The first is used for transfer of materials that are the subject of a patent or patent application or that have been or are likely to be commercially licensed. The Simple Letter Agreement is used for all other transfers.

Material transfer from industry to Berkeley

Researchers often use materials provided by industry. For transfer of materials from industry, the campus is usually required to use the agreement written by the company providing the materials. An industrial MTA usually carries more restrictions than the UBMTA.

Industrial MTAs often contain language that conflicts with basic academic rights or that places unnecessary restrictions on investigators. Companies may ask to own all rights to inventions arising from use of the material or ask for exclusive rights to future inventions.

For these reasons, the IAO reviews, negotiates, and approves all MTAs from industry. Each industrial MTA is different and must be negotiated separately on a case-by-case basis, depending on the terms used in the agreement, the investigator's obligations to the sponsor(s) of the research, and the use the investigator plans for the material.

Potential Issues in MTAs

Confidentiality: When confidential information is exchanged along with the material, the company may request that such information not be further disclosed. If the information is necessary for interpretation of the research results obtained using the material, that same information may also be required for publication of those results. Having agreed to hold the information confidential could prohibit an investigator from ever publishing the results of work using the company's material.

Delay in publication: In order to protect potentially patentable inventions, companies often demand a review period for the investigator's manuscripts, abstracts or hard-copies of presentation materials. This demand may jeopardize the timeliness of publication.

Use of materials in sponsored research projects: Many industry MTAs contain language that prohibits the use of the material in research that is subject to licensing or consulting obligations to any third party, including the sponsor of the research project.

Definition of material: The industry provider may propose a definition of material that includes not only the original material, but also modifications or derivatives made from the material that incorporate the investigator's original ideas or concepts. If the provider also claimed ownership of the modified material, the provider could own the results of the investigator's research. The investigator could be prevented from using research results in further research, transferring them to other organizations, meeting obligations to research sponsors, or ensuring that the results are made public.

Loss of control of intellectual property: If MTAs preempt ownership rights, investigators may be restricted in their ability to interact with a future sponsor or may have conflicts with obligations to current sponsors. Intellectual property restrictions may prevent the institution from obtaining or conveying rights to future licensees.

Conflicts with existing agreements: Industrial MTAs may contain obligations that conflict with obligations in a preexisting agreement. Also, the material may be used in conjunction with a separate material received under another MTA. These situations could result in granting two or more parties conflicting rights to the same invention.

When MTAs are used in conjunction with federally funded research, the federal government has certain rights to resulting inventions (Bayh-Dole Act).

Compliance issues

MTAs for live animals or custom antibodies must have protocol(s) reviewed and approved by the Animal Care and Use Committee.

MTAs for human tissue must have protocol(s) reviewed by the Committee for the Protection of Human Subjects.

MTAs for hazardous materials and/or select agents must follow EH&S compliance procedures.

MTAs where the decision to undertake the research is based on receiving access to the materia(s) from a nongovernmental provider must follow Conflict of Interest Committee requirements for financial disclosure.

Material transfer from Berkeley to industry

The Office of Technology Licensing handles MTAs to transfer research materials from Berkeley to outside institutions. OTL ensures that the agreements conform with institutional research policies. OTL uses several formats for material transfer, depending on the intended use of the materials.

Resources

MTAs Governing Incoming Materials

Industry Alliances Office

2150 Shattuck Avenue, Suite 950, #1610

642-5758, mta@berkeley.edu

Material Transfer Agreement Review (Incoming) Form

MTAs Governing Outgoing Materials

Office of Technology Licensing

2150 Shattuck Avenue, Suite 510, #1620, 643-7201

Links

Council on Government Relations:

"Materials Transfer in Academia"

http://www.cogr.edu/docs/MTA_Final.pdf

UC Office of Technology Transfer:

Biological Materials Transfers links

http://www.ucop.edu/ott/genresources/genguidance.html#C

UC Office of the President:

"Principles Regarding Rights to Future Research Results in University Agreements with External Parties"

http://www.ucop.edu/ott/principls.html

Association of University Technology Managers: UBMTA

http://www.autm.net/aboutTT/aboutTT_umbta.cfm

National Institutes of Health:

"Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources"

http://ott.od.nih.gov/RTguide_final.html

Bayh-Dole Act:

"Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements—Patents, Trademarks, and Copyrights" - 37 CFR Part 401

http://www.access.gpo.gov/nara/cfr/waisidx_99/37cfr401_99.html

MATERIAL TRANSFER AGREEMENT REVIEW FORM

PRINCIPAL INVESTIGATOR INFORMATION:

Name: _____ Telephone: _____ E-mail: _____

Administering Unit: _____

Alternate Contact: _____ Telephone: _____ E-mail: _____

PROVIDER INFORMATION:

Provider Organization: _____ Address: _____

Contact name: _____ Telephone: _____ E-mail: _____

MATERIAL and PROJECT INFORMATION:

What is the material?: _____

Provide a description of how the materials will be used. Attach another page, if necessary.

_____

_____

What source(s) of funding, including award number(s), will be used to support the research?:

_____

How long will you use the materials (e.g., 2 years)?: _____

☐ Yes ☐ No Will the materials be used in conjunction with any other materials received from a third party? If yes, identify other materials and provider(s): _____

_____

☐ Yes ☐ No Are the materials relevant to any previous or pending disclosures of intellectual property to the Office of Technology Licensing or the Office of Technology Transfer? If yes, list all that apply:

_____

_____

☐ Yes ☐ No Has any confidentiality or nondisclosure agreement from the provider been signed in connection with the materials?

Check all that apply:

☐ The materials will be provided for the purpose of product testing and evaluation (i.e., testing an expression system) for the providing organization.

☐ The materials are a tool, kit, or instrument that will be used in the conduct of research.

☐ The materials are a reagent.

☐ Progeny, unmodified derivatives, or descendant copies will be made from the materials.

☐ The materials will be modified or will be used to produce modified derivatives.

☐ Other. Please explain: _____

COMPLIANCE INFORMATION: Please check off all categories that apply. Include existing protocol information if applicable.

☐ Human subjects: Protocol submitted: ☐ yes ☐ no Protocol #/Date: _____ / _____

☐ Vertebrate animals or custom antibodies: Protocol submitted: ☐ yes ☐ no Protocol #/Date: _____ / _____

☐ Environment, health, and safety issues: Contact EH&S for procedures.

☐ Select agents: Contact EH&S for procedures.

Financial Conflict of Interest for Non-Federal Provider Organizations:

☐ Yes ☐ No Was the decision to undertake this research based on receiving access to the material by the Provider Organization? If yes, answer the following question:

☐ Yes ☐ No Does a financial relationship exist between the Principal Investigator and the Provider Organization? If yes, a State of California Statement of Economic Interests (Form 700-U) must be filed with this MTA review form.

PRINCIPAL INVESTIGATOR SIGNATURE: *By signing this form, I certify that the foregoing is true and correct to the best of my knowledge, and I agree to comply with current university policies and federal regulations.*

Name _____ Date _____

Submit this form with the MTA to the Industry Alliances Office, 2150 Shattuck Ave., Suite 950, #1610 revised 8/05 - SPO Form

Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL _____
the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. **THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.**
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.
7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist:_____
Provider Organization: _____
Address:_____
Name of Authorized Official: _____
Title of Authorized Official:_____

Certification of Authorized Official: This Simple Letter Agreement has ☜ / has not ☜ [check one] been modified. If modified, the modifications are attached.

_____ _____
Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____
Recipient Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized: _____
Official:_____
Signature of Authorized Official:_____
Date: _____

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____ _____
Recipient Scientist Date

PUBLIC HEALTH SERVICE

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("**MTA**") has been adopted for use by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"), collectively referred to herein as the United States Public Health Service ("**PHS**") within the Department of Health and Human Services ("**DHHS**"), in all transfers of research material ("**Research Material**") whether **PHS** is identified below as its **Provider** or **Recipient**.

Provider:

_____

Recipient:

_____

1. **Provider** agrees to transfer to **Recipient**'s Investigator named below the following **Research Material**:

_____

2. THIS **RESEARCH MATERIAL** MAY NOT BE USED IN HUMAN SUBJECTS. The **Research Material** will only be used for research purposes by **Recipient**'s investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This **Research Material** will not be used by for-profit recipients for screening, production or sale, for which a commercialization license may be required. **Recipient** agrees to comply with all Federal rules and regulations applicable to the **Research Project** and the handling of the **Research Material**.

2(a). Were **Research Materials** collected according to 45 CFR Part 46, "Protection of Human Subjects"?

____ Yes (Please provide Assurance Number:_____)
____ No
____ Not Applicable (Materials not collected from humans)

3. This **Research Material** will be used by **Recipient**'s investigator solely in connection with the following research project ("**Research Project**") described with specificity as follows (use an attachment page if necessary):

_____

_____

_____

4. In all oral presentations or written publications concerning the **Research Project**, **Recipient** will acknowledge **Provider**'s contribution of this **Research Material** unless requested otherwise. To the extent permitted by law, **Recipient** agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of **Provider**'s written information about this **Research Material** that is stamped **"CONFIDENTIAL"**, except for information that was previously known to **Recipient** or that is or becomes publicly available or which is disclosed to **Recipient** without a confidentiality obligation. Any oral disclosures from **Provider** to **Recipient** shall be identified as being **CONFIDENTIAL** by written notice delivered to **Recipient** within thirty (30) days after the date of the oral disclosure. **Recipient** may publish or otherwise publicly disclose the results of the **Research Project**, but if **Provider** has given **CONFIDENTIAL** information to **Recipient** such public disclosure may be made only after **Provider** has had thirty (30) days to review the proposed disclosure to determine if it includes any **CONFIDENTIAL** information, except when a shortened time period under court order or the Freedom of Information Act pertains.

5. This **Research Material** represents a significant investment on the part of **Provider** and is considered proprietary to **Provider**. **Recipient**'s investigator therefore agrees to retain control over this **Research Material** and further agrees not to transfer the **Research Material** to other people not under her or his direct supervision without advance written approval of **Provider**. **Provider** reserves the right to distribute the **Research Material** to others and to use it for its own purposes. When the **Research Project** is completed, the **Research Material** will be disposed of, if directed by **Provider**.

6. This **Research Material** is provided as a service to the research community. IT IS BEING SUPPLIED TO **RECIPIENT** WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. **Provider** makes no representations that the use of the **Research Material** will not infringe any patent or proprietary rights of third parties.

7. When **Provider** is the **PHS**: **Recipient** shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the **Research Project**. **Recipient** agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "**Government**") of the **Research Project**, the institution or personnel conducting the **Research Project** or any resulting product(s). Unless prohibited by law from doing so, **Recipient** agrees to hold the **Government** harmless and to indemnify the **Government** for all liabilities, demands, damages, expenses and losses arising out of **Recipient**'s use for any purpose of the **Research Material**.

8. When **Recipient** is the **PHS**: The **PHS** shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the **Research Project**. The **PHS** is not authorized to promise rights in advance for inventions developed under this **Agreement**. **Provider** acquires no intellectual property rights under this **MTA**, but may apply for license rights to any patentable invention that might result from this **Research Project**. It is the intention of **PHS** that **Provider** not be liable to **PHS** for any claims or damages arising from **PHS**'s use of the **Research Material**; however, no indemnification is provided or intended.

9. The undersigned **Provider** and **Recipient** expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

10. This **MTA** shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

11. Any additional terms:

_____

_____

_____

_____ _____

Date **Recipient**'s Investigator and Title

_____ _____

Date Authorized Signature for **Recipient** and Title

Recipient's Official and Mailing Address:

_____

_____

_____

_____ _____

Date **Provider**'s Investigator and Title

_____ _____

Date Authorized Signature for **Provider** and Title

Provider's Official and Mailing Address:

_____

_____

_____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

Material Transfer Agreement for the Transfer of Organisms (MTA-TO)
to Academic/ Not-for-Profit Organizations

This is in response to RECIPIENT's request for the MATERIAL (specifically, the name of the gene or allele mutation that makes the organism(s) unique)_____

_____

_____

_____

_____, found within the _____ [organism strain, species], and any unmodified derivative and unmodified progeny, as well as any biological materials (including, without limitation: zygotes, embryos, cells, tissues, fluids, etc.) which contain or incorporate the MATERIAL and are derived directly from the original organism or its unmodified progeny, to be used for the purpose of:

_____

_____

_____

_____

_____

_____.

The PROVIDER requires that the RECIPIENT agree to and the RECIPIENT SCIENTIST acknowledge the following terms before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.

2. **THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.**

3. The MATERIAL will be used for teaching or not-for-profit research purposes only.

4. The MATERIAL will not be further distributed to others who are not under the RECIPIENT SCIENTIST's direct supervision without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Material Transfer Agreement for the Transfer of Organisms to other scientists for teaching or not-for-profit research purposes only.

5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from RECIPIENT's use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.

8. If the RECIPIENT anticipates that it will generate cross-bred or genetically-modified organisms incorporating the PROVIDER's modified allele(s), RECIPIENT may transfer such cross-bred or genetically-modified organism(s) to non-profit institutions under the terms of a material transfer agreement that notifies the not-for-profit institution of the existence of PROVIDER's rights to the modified allele(s) and restricts the use of the transferred organism(s) by the not-for-profit recipient to teaching or not-for-profit research purposes only. This Agreement does not transfer any of PROVIDER's patent, invention, or other intellectual property rights in the organism(s) to RECIPIENT. Additionally, to the extent that any other party has any patent, invention or other intellectual property rights in the organism(s), these rights are not transferred to RECIPIENT by PROVIDER.

9. If NIH is the PROVIDER, the following addenda may be attached (check all that apply):
[ ] Cre-Lox Addendum, [ ] OncoMouse® Addendum, [ ] Animal Transfer Addendum, *or* [ ] Animal Transfer

Agreement (not required for transfers within NIH), [ ] Other

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE:

Provider Scientist: _____
Provider Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____

_____ _____
Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE:

Recipient Scientist: _____
Recipient Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____

_____ _____
Signature of Authorized Official Date

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement, and I understand that I must abide by them to receive and use the MATERIAL.

_____ _____
Recipient Scientist Date

DUPONT ADDENDUM FOR USE IF NIH IS THE PROVIDER

NIH has entered into certain Memoranda of Understanding (MOUs) with DuPont, in which DuPont agrees that NIH may receive, use, and transfer mice containing Cre-Lox or OncoMouse® technologies to other entities for research purposes. The MOUs state that NIH provide the following respective notices when shipping such mice.

Cre-Lox Technology:

The above MATERIALS are provided to the RECIPIENT with the knowledge of "Dupont Patent Rights" (U.S. Patent 4,959,317 and any patents granted on any divisional and continuation applications thereof) that have been assigned to DuPont, under the following conditions:

a) The RECIPIENT may use the MATERIAL, and any progeny or derivatives containing cre DNA and/or lox DNA derived directly or indirectly therefrom, for its internal noncommercial research purposes only, provided however, that such research purposes specifically excludes (i) any activity associated with higher plants or agricultural applications and (ii) the alteration of mouse embryonic stem cells or other pluripotential mouse cells for the purpose of preparing a library of such mouse embryonic stem cells or other pluripotential mouse cells containing cre DNA and/or lox DNA. The MATERIAL, and any progeny or derivatives containing cre DNA and/or lox DNA derived directly or indirectly therefrom, will not be used for any commercial purpose or for the direct benefit of any for-profit institution (except as may be permitted under a written agreement between the non-profit institution and DuPont).

b) The MATERIAL, and any progeny or derivatives containing cre DNA and/or lox DNA derived directly or indirectly therefrom, may not be transferred by the RECIPIENT to any third parties (except as may be permitted under a written agreement between the RECIPIENT and DuPont).

c) With respect to further license rights under U.S. patent number 4,959,317, the RECIPIENT should contact:

Debra Desmond
Bristol Myers Squibb Company
Route 206 & Province Line Road
EST&L, Mail Stop B24-05
Princeton, NH 08543-4000
Tel: 302-467-9431
Fax: 609-252-7337
Email: debra.desmond@bms.com

OR Greg Townsend
DuPont Intellectual Assets and Licensing
Chestnut Run Plaza 708/179
Wilmington, DE 19880-0708 USA
Tel: 877-881-9787
Fax: 302-999-4149
Email: j-gregory.townsend@usa.dupont.com

Oncomouse® Technology:

The above MATERIALS are provided to RECIPIENT with knowledge of "Dupont Patent Rights" (U.S. Patent 4,736,866, and 5,087,571, and 5,925,803 and corresponding foreign patents, and any patents granted on any divisional and continuation applications thereof (collectively known as "Harvard Patent Rights")), and that have been exclusively licensed to Dupont by Harvard University, under the following conditions:

a) The RECIPIENT institution may use the MATERIAL for its internal noncommercial research purposes only. The MATERIAL will not be used for any commercial purpose or for the direct benefit of any for-profit institution (except as may be permitted under a written agreement between the RECIPIENT and DuPont). Accordingly and without limitation, the RECIPIENT is not permitted under this Material Transfer Agreement to use any MATERIAL to test compounds for any commercial purpose or for the direct benefit of any for-profit institution or use the MATERIAL for the production of products for any commercial purpose or for the direct benefit of any for-profit institution.

(b) The MATERIAL may not be transferred by the RECIPIENT to any third parties (except as may be permitted under a written agreement between the RECIPIENT and DuPont).

c) The RECIPIENT is notified by PHS of the existence of Harvard Patent Rights and the exclusive license thereof to DuPont, and that the restrictions set forth under (a) and (b) above shall exist only during the term of the Harvard Patent Rights.

d) With respect to further license rights under the Harvard Patent Rights, the RECIPIENT should contact:
Greg Townsend
DuPont Intellectual Assets and Licensing
Chestnut Run Plaza 708/179
Wilmington, DE 19880-0708 USA
Tel: 877-881-9787
Fax: 302-999-4149
Email: j-gregory.townsend@usa.dupont.com

ANIMAL TRANSFER ADDENDUM FOR USE IF NIH IS THE PROVIDER

The terms of this Addendum are directed to the use and transfer of the tangible animal(s).

For transfers of any live animals from NIH to outside laboratories, a fully signed National Institutes of Health Animal Transfer Agreement should be completed by the parties prior to the actual shipment of the requested animal. The Animal Transfer Agreement has been adopted for use by the National Institutes of Health (NIH) for use in transferring animals for research purposes pursuant to Section 301 of the Public Health Service Act.

The PROVIDER agrees to transfer the animal(s) described in this Agreement to the RECIPIENT.

RECIPIENT agrees to use the animal(s) solely in connection with biomedical or behavioral research.

Relevant documents concerning the medical history, health status, and research uses of the animal(s), including prior surgical procedures and any infectious disease (human or zoonotic) to which the animal(s) may have been exposed, will be provided in a separate document.

For domestic recipients, RECIPIENT agrees that it will comply with the Animal Welfare Act and its implementing regulations, as applicable. RECIPIENT agrees that it will adhere to all applicable national standards for humane care and use of the animal(s) and assures the PROVIDER that it has appropriate animal care and use policies in place. The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and "Guide for the Care and Use of Laboratory Animals" are examples of acceptable standards for humane care and use of research animals.

RECIPIENT agrees that it will adhere to appropriate biosafety practices and use the animals in a safe and responsible manner. The National Institutes of Health/Centers for Disease Control publication, "Biosafety in Microbiological and Biomedical Laboratories" is an example of acceptable standards for biosafety practices. RECIPIENT agrees that it will comply with applicable import/export regulations.

In accepting the animal(s), RECIPIENT accepts full ownership, custody, and control of the animal(s), except that to the extent the Government has any patent, invention or any other intellectual property rights in the animal(s), the Government retains these rights, as described in the attached Material Transfer Agreement for the Transfer of Organisms.

PROVIDER is transferring the animal(s) as a service to the research community. The animal(s) is transferred to the RECIPIENT with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Unless prohibited by law from doing so, RECIPIENT agrees to hold the United States Government harmless and to indemnify the Government from all liabilities, demands, damages, expenses and losses arising out of the RECIPIENT's care, use or treatment of the animal(s).

RECIPIENT agrees not to claim, infer, or imply Governmental endorsement of the RECIPIENT, the research project, the institution or personnel conducting the research, or any resulting product(s).

IOWA STATE UNIVERSITY

Taken from http://www.ospa.iastate.edu/
http://www.ospa.iastate.edu/StandardAgr/docs/MtaSampleExtended.pdf

BIOLOGICAL MATERIAL TRANSFER AGREEMENT

Between <RECIPIENT ORGANIZATION> and <PROVIDER ORGANIZATION>

THIS AGREEMENT is made by and between <RECIPIENT ORGANIZATION> ("Recipient"), and
<PROVIDER ORGANIZATION> ("Provider"); together the "Parties".

WHEREAS, this Agreement shall govern the conditions of disclosure by Provider to Recipient of certain biological materials identified below (Materials).

NOW THEREFORE, in consideration of the mutual covenants and promises herein contained, the Parties agree as follows:

1.0 Definitions. The following definitions shall apply to this Agreement:
1.1 Biological Sample: <SAMPLE DESCRIPTION>

1.2 Progeny: Unmodified descendant from the Material, such as virus from virus, cell from cell,
or organism from organism.

1.3 Unmodified Derivatives: Substances created by Recipient that constitute an unmodified functional sub-unit or product expressed by the Biological Sample. Some examples include, but are not limited to: subclones of unmodified cell lines, purified or fractionated sub-sets of
Materials, proteins expressed by DNA/RNA supplied by Provider, monoclonal antibodies secreted by a hybridoma cell line, or sub-sets of Materials such as novel plasmids or vectors.

1.4 Materials: The Biological Sample plus Progeny and Unmodified Derivatives.

1.5 Modifications: Substances created by Recipient that contain or incorporate Materials.

1.6 Commercial Purposes: The sale, lease, license, or other transfer of Materials or Modifications to a for-profit organization. Commercial Purposes shall also include uses of Materials or Modifications by any organization, including Recipient, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale,
or to conduct research activities that result in any sale, lease, license or transfer of Materials
or Modifications to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of Materials or Modifications for Commercial Purposes per se, unless any of the above conditions of this definition are met.

1.7 Information: Results of any study of Materials or information relating to Materials received
by Recipient from Provider.

2.0 Effective Date. The effective date of this Agreement is <ENTER DATE> ("Effective Date").

3.0 Ownership and Use of Materials.

3.1 All Information and Materials, including any Materials contained or incorporated in Modifications, supplied by Provider shall be deemed to belong to Provider and to have been disclosed or provided to Recipient in confidence. Except as may be authorized in advance in writing by Provider, Recipient shall not transfer Materials or Modifications to any others (except to its employees who are bound to Recipient by like obligations governing and restricting access, use, and continued use of Materials).

3.2 Recipient shall receive and use Materials for the sole purpose of research and evaluation and NOT for any Commercial Purposes. Materials will be used only in Recipient's laboratories
and only by laboratory personnel under Recipient's immediate and direct control. Recipient shall receive, handle, store, use and dispose of Materials in compliance with all applicable laws, regulations and guidelines, and in accordance with safe and prudent practices. Recipient acknowledges that it has adequate systems, procedures and personnel to review and oversee arrangements for the receipt, handling, storage, use and disposal of experimental materials of the nature of Materials and that it will ensure that all persons involved in receiving, handling storing, using or disposing of Materials are adequately qualified by training and experience to do so safely and legally.

3.3 Recipient agrees that the Information will not be used by Recipient or its employees or agents as the basis for any patent application disclosing or claiming any of the same without
Provider's written consent. If the Recipient's research involving Materials results in an invention or Modification that may be commercially useful, Recipient may file patent applications claiming inventions made solely by Recipient through the use of Materials but agrees to notify Provider upon filing a patent application claiming Modifications or methods of manufacture or use(s) of Materials.

3.4 The furnishing of Materials to Recipient shall not constitute any implied or expressed license to Recipient under any legal rights now or later held by Provider. The provision of Materials to Recipient shall not alter any pre-existing right of Provider to Materials. It is recognized by Recipient that any Commercial Purposes may require a commercial license from Provider and Provider has no obligation to grant a commercial license to its ownership interest in Materials incorporated in any Modifications.

3.5 Recipient shall acknowledge the source of Materials in any descriptions of experiments and/or results involving Materials. However, neither Recipient nor its personnel will otherwise use, or authorize or permit the use of, the name of Provider, or any of its personnel in connection with any commercial or promotional activities relating to Materials, nor in such a way as to imply any endorsement by Provider or its personnel of any Material, product or method.

4.0 Compensation. In consideration of making the Biological Sample available to Recipient under this Agreement:

4.1 Recipient shall pay a <INSERT FEE, IF APPLICABLE> fee to cover the cost of replicating and sending Materials. Despite the payment of any such fee, the transfer of the Biological Sample shall not be construed as a sale of Materials to Recipient.

4.2 Recipient will inform Provider of research results related to Materials by providing copies of
manuscripts describing the results of such research at the time the manuscripts are submitted for publication.

5.0 Notices.

<PROVIDER ORGANIZATION>
For Technical matters
Name:
Address:
Phone:
Fax:
Email:

For Business matters
Name:
Address:
Phone:
Fax:
Email:

For Intellectual Property matters
Name:
Address:
Phone:
Fax:
Email:

<RECIPIENT ORGANIZATION>
For Technical matters
Name:
Address:
Phone:
Fax:
Email:

For Business matters
Name:
Address:
Phone:
Fax:
Email:

For Intellectual Property matters
Name:
Address:
Phone:
Fax:
Email:

6.0 Warranty.

6.1 Recipient acknowledges that Materials are experimental products of research that may not
have been fully characterized, and will accept Materials as is and entirely at its own risk.

6.2 PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK OR OTHER PROPRIETARY RIGHT.

7.0 Indemnification. Except to the extent prohibited by law, Recipient shall indemnify Provider, its employees, members, boards, and agents against any claims, costs, or other liabilities which may arise as a result of Recipient's use of Materials, except to the extent caused by the gross negligence or willful misconduct of Provider.

8.0 Term and Termination. Provider may terminate this Agreement for material breach and require return or destruction of Materials by Recipient upon thirty (30) days written notice. Recipient shall otherwise, upon request from Provider, destroy all copies of Materials within three (3) years of the effective date of this Agreement, unless:

8.1 This deadline is extended by Provider in writing; or

8.2 Recipient has indicated to Provider in writing its desire to obtain a license to Materials and
negotiations to that end have begun.

9.0 Entire Agreement. This Agreement reflects the entire agreement between Provider and Recipient, and the Agreement may be modified or altered only in writing.

10.0 Interpretation and Jurisdiction. The interpretation and validity of this Agreement and the rights of the parties shall be governed by the laws of the State of Iowa.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of Effective Date written above.

<RECIPIENT ORGANIZATION>
Agreed and Understood
/
Name:
Date
Title:
Approved
/
Name:
Date
Title:

<PROVIDER ORGANIZATION>
Agreed and Understood
/
Name:
Date
Title:
Approved
/
Name:
Date
Title:

UW TechTransfer Invention Licensing
UBMTA Implementing Letter

Thank you for downloading this UBMTA Implementing Letter from UW TechTransfer Invention Licensing. To process your request, please follow the steps below. If you have any questions about this process, please send an email to mta-group@u.washington.edu and someone will respond to your inquiry.

1. Complete the Implementing Letter below with the following specific information:

    a. Insert a description of the ORIGINAL MATERIAL you are requesting. This should include names and quantities.
    b. Provide the RECIPIENT information.
    c. Provide the name of the RECIPIENT SCIENTIST as well as the PROVIDER SCIENTIST.

2. Print two (2) copies of this Agreement.

3. Obtain the appropriate signatures:
    a. The RECIPIENT SCIENTIST; and
    b. The RECIPIENT ORGANIZATION

4. Mail both copies to:

    Agreements Group
    UW TechTransfer Invention Licensing
    4311 11th Avenue N.E., Suite 500
    Seattle, Washington 98105-4608

    The Materials will be shipped to you as soon as possible and based on availability. (**Please note that you may require a different form based on the material you are requesting or the affiliations of the researchers who produced the materials. If that is the case, we will contact you and provide you with the appropriate form**.)

5. Additional contact/shipping information (**required**):
    a. E-mail address: _____
    b. Shipping Method (check one):
        World Courier _____
        BAX Global _____
        UPS _____
        FedEx _____
        Other (please specify) _____
    c. Shipping Account Number: _____

    Please include your name, contact information and shipping information along with the name of the UW contact that you have been in touch with regarding the

Agreement in your cover letter. **Please note that in order to process the request, the above information is required.**

UBMTA Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL:

   Organization: University of Washington

   Address: UW TechTransfer 4311 11th Avenue, N.E. Suite 500

   Seattle, Washington 98105

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL:

   Organization: _____

   Address: _____

   _____

3. ORIGINAL MATERIAL (Enter description):

   _____

   _____

   _____

4. Termination date for this letter (optional): _____.

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional). Amount: _____.

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

RECIPIENT SCIENTIST

Name: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

RECIPIENT ORGANIZATION CERTIFICATION

Certification: I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized Official: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

UBMTA Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer [[Page 12775]] Agreement ("UBMTA") March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL:

   Organization: _____

   Address: _____

   _____

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL:

   Organization: _____

   Address: _____

   _____

3. ORIGINAL MATERIAL (Enter description):

_____

_____

_____

4. Termination date for this letter (optional):

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional). Amount:_____.

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

RECIPIENT SCIENTIST

Name: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

RECIPIENT ORGANIZATION CERTIFICATION

Certification: I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized Official: _____

Title: _____

Address: _____

_____

Signature: _____

Date: _____

UW TechTransfer Invention Licensing
Materials Transfer Agreement (Not-for-profit Institutions)

Thank you for downloading this Material Transfer Agreement (MTA) from UW TechTransfer Invention Licensing. To process your request, please follow the steps below. If you have any questions about this process, please send an email to mta-group@u.washington.edu and someone will respond to your inquiry.

1. Complete the MTA below with the following specific information (look for blue typeface):
    a. Insert a description about the Material you are requesting. This should include names and quantities (first section).
    b. Provide the Recipient name and address (preamble)
    c. Provide the name of the UW Investigator/lab (in section 7) whose material you are requesting, as well as Recipient investigator name (in section 8)

2. Print two (2) copies of this Agreement.

3. Obtain the appropriate signatures:
    a. The Recipient Investigator; and
    b. The Recipient Authorized Representative

4. Mail both copies to:

    Agreements Group
    UW TechTransfer Invention Licensing
    4311 11th Avenue N.E., Suite 500
    Seattle, Washington 98105-4608

    The Materials will be shipped to you as soon as possible and subject to availability. (**Please note that you may require a different form based on the material you are requesting or the affiliations of the researchers who provided the materials. If that is the case, we will contact you and provide you with the appropriate form**.)

5. Additional contact/shipping information (**required**):
    a. E-mail address: _____
    b. Shipping Method (check one):
        World Courier _____
        BAX Global _____
        UPS _____
        FedEx _____
        Other (please specify) _____
    c. Shipping Account Number: _____

Please include your name, contact information and shipping information along with the name of the UW contact that you have been in touch with regarding the Agreement in your cover letter. **Please note that in order to process the request, the above information is required.**

Outgoing Materials Transfer Agreement (Not-for-profit Institutions)

The University of Washington, acting through UW TechTransfer Invention Licensing, a public institution of higher education and agency of the state of Washington, with administrative offices at 4311 - 11th Ave NE, Suite 500, Seattle, WA 98105-4608 ("Provider") will provide to the (insert Recipient Institution name here) ("Recipient"), with administrative offices at (insert address here) the (insert the name of material) including any progeny and unmodified derivatives ("Material"). The Material is available to Recipient on non-exclusive basis. The terms are as follows:

1. Recipient agrees to utilize the Material solely for the purpose of academic research and will not distribute the Material to any person external to the Recipient without the prior written permission of the Provider.

2. THE MATERIAL DELIVERED HEREBY IS EXPERIMENTAL IN NATURE. THE PROVIDER MAKES NO WARRANTIES, REPRESENTATION, OR UNDERTAKING WITH RESPECT TO THE UTILITY, EFFICACY, NONTOXICITY, SAFETY, OR APPROPRIATENESS OF USING THE MATERIAL. THE PROVIDER MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.

3. None of the Material provided may be used for any commercial development directly or indirectly unless a license granting same is executed between the Provider and Recipient through UW TechTransfer Invention Licensing. Recipient agrees not to sell or otherwise transfer the Material, or any other material that could not have been made but for the Material, to any other party, whether with or without consideration, for any purpose or use.

4. The Material provided will not be used on any human subjects and in so far as it is administered to animals, no animal to which the Material is administered, or animal products derived therefrom, will be used for food, therapeutic or diagnostic purposes, or kept as a domestic pet or livestock. Any cells which are treated with the Material will not be used for therapeutic or diagnostic purposes.

5. Recipient will use the Material in compliance with all laws, governmental regulations, and guidelines that may be applicable to the Material, including, without limitation, export laws, current NIH guidelines, and any regulations or guidelines pertaining to research with recombinant DNA. Recipient agrees to abide by all U.S. export laws and regulations. Accordingly, Recipient is solely responsible for securing any necessary permission or license.

6. Recipient agrees that any person with the Recipient utilizing the Material will be advised of, and is subject to, the conditions in this Agreement ("Agreement").

7. The Provider scientific contact shall be: **(insert name here)**

8. The Recipient scientific contact shall be: **(insert name here)**

9. To the extent allowed by law, Recipient assumes all liability for damages that may arise from its use, storage, or disposal of the Material, and will indemnify, defend, and hold harmless Provider and its employees, students, and agents from any loss, claim, damage, or liability of any kind that may arise from or in connection with this Agreement or the use and handling of the Material. In no case will Provider or its employees, students, or agents be liable for any claim, loss, or demand made by Recipient, or made against Recipient by any other party, including any incidental, special, or consequential damages resulting from the use or handling of the Material.

10. Articles 2 (Warranty) and 9 (Indemnification) and other provisions which by their context would survive, shall survive the termination of this Agreement.

11. The term of this Agreement shall commence on the last date of signature and shall continue until completion of research or for a period of seven (7) years, whichever comes first. Upon expiration of this Agreement, Recipient agrees to provide to Provider a written statement warranting that all samples of Material have been destroyed.

12. This Agreement and all rights and obligations hereunder will not be assigned, licensed, sub-licensed, mortgaged, pledged, or otherwise transferred, encumbered, or disposed of, including by operation of law, in whole or in part, by either party unless agreed to in writing by an authorized representative of both parties. This Agreement will be binding upon any such permitted assigns.

13. Recipient shall not use the name of Provider in any public announcements, publicity, or advertising with respect to the subject matter of this Agreement without the prior written approval of Provider.

If the foregoing terms are acceptable, please have a representative of the Recipient sign in the space indicated for signature. **Please return two signed copies of this Agreement to UW TechTransfer Invention Licensing, University of Washington, 4311 - 11th Ave NE, Suite 500, Seattle, WA 98105-4608.**

This Agreement may be executed by facsimile or duplicate originals. This Agreement may be executed in several counterparts, all of which taken together will constitute effective execution.

The undersigned agrees with and accepts the foregoing:

Recipient:

Signature of Authorized Representative	Signature of Recipient Investigator
Print/Type Name	Print/Type Name
Title Date	Title Date
Phone: (insert phone #) Fax: (insert fax #) E-mail: (insert e-mail)	Phone: (insert phone #) Fax: (insert fax #) E-mail: (insert e-mail)

University of Washington:

UW TechTransfer Invention Licensing
University of Washington
4311 - 11th Ave NE, Suite 500
Seattle, WA 98105-4608
P: 206/543-3970
F: 206/685-4767

Date

MATERIAL TRANSFER AGREEMENT

This agreement governs the transfer of certain substances from time to time from Biogen, Inc. and its affiliates (collectively, "Biogen") to the institution referred to below and its personnel (collectively, the "Institution"). Each such substance will be identified in a letter substantially in the form attached hereto (a "Request Letter") and is referred to herein, together with any of its progeny or derivatives, as the "Material." The Institution agrees with Biogen as follows:

1) Material will be used only for the purpose stated in the Request Letter; will be used only for research, in a safe manner and in compliance with applicable law; will not be used in humans or anything destined for human consumption; and will not be given to any person not associated with the Institution.

2) Biogen makes *NO WARRANTY, EXPRESS OR IMPLIED*, as to the Material, expressly *DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE*, and will have no other liability in connection with the Material. The Institution will, to the extent allowable under the laws and constitution of the State of Texas, indemnify Biogen against any claims arising out of the Institution's use of the Material that are not caused by Biogen's negligence or willful misconduct.

3) Biogen will be informed of the results of the Institution's use of the Material before they are revealed to anyone else not associated with the Institution, and Biogen will be free to use such results subject to paragraph 4 below. Before disclosing its results to the public, orally or in writing, the Institution will give Biogen a copy of the proposed disclosure, with reference to this agreement, at least 21 (twenty-one) days in advance of disclosure. If Biogen determines that one or more patent applications should be filed before disclosure, the Institution will cooperate in doing so and will delay disclosure up to an additional 90 (ninety) days to permit such filing. In no event will the Institution disclose, or use for any purpose not set forth in the Request Letter, any confidential or proprietary information of Biogen that may be provided in connection with the Material. Any publication of results will duly acknowledge Biogen's role unless Biogen requests otherwise.

4) The Institution irrevocably grants to Biogen (a) a royalty-free, nonexclusive, worldwide license (provided that Biogen may grant sublicenses under any such license only on a royalty-free basis) under any patent or other intellectual property rights covering (i) any improvement to the Material resulting from the Institution's use of the Material or (ii) any new use of the Material resulting from the Institution's use of any Material if, prior to disclosure by the Institution of such new use, Biogen was conducting or had taken affirmative steps to conduct research in such area of new use and (b) an option to obtain a royalty-bearing exclusive license on commercially reasonable terms of intellectual property rights covering any inventions or technology resulting from the Institution's use of the Material, to be exercised within 45 (forty-five) days after the Institution gives Biogen notice thereof. The Institution will notify Biogen promptly of any such inventions or technology, with reference to this Agreement, and will provide such information as Biogen may reasonably request from time to time to enable Biogen to exercise its rights hereunder. The Institution represents and warrants that no other person will have any prior right to ownership of or a license under such inventions or technology by reason of any action or agreement by the Institution. Except as set forth above, no license or other rights are granted hereby by either party with respect to any inventions or technology.

Institution: THE UNIVERSITY OF TEXAS AT
_____

Location:
_____

University of Texas _____ Licensee:

By: _____ By: _____
Name Name

Title: _____ Title: _____

Date:_____ Date:_____

[Form of Request Letter under Biogen Material Transfer]

_____,1994

Biogen, Inc.
14 Cambridge Center
Cambridge, Massachusetts 02142

Attention: _____

Dear _____:

I am writing to request a sample of _____ under the terms of the Material Transfer Agreement dated _____,1994 between Biogen, Inc. and the undersigned Institution.

Our purpose is to perform the following research:

We will comply with the Material Transfer Agreement referred to above in connection with this request. As stated therein, no third party will have any prior right to ownership of or a license under any inventions resulting from this research by reason of any action or agreement by us. [List any exceptions].

Sincerely,

Name:_____

Title:_____

On behalf of the following Institution:

THE UNIVERSITY OF TEXAS AT _____
Location:_____

GHARPER\AGREEMNT\UNIVRSAL\BIOGNMTA.707
Revised 7/7/94

Excerpted from
http://www.utsystem.edu/OGC/intellectualProperty/contract/Wyeth%20Master%20MTA.htm

EFFECTIVE AUGUST 2005, WYETH IS NO LONGGR HONORING THIS MASTER MTA

MASTER MATERIAL TRANSFER AGREEMENT

THIS MATERIAL TRANSFER AGREEMENT (together with its Exhibit, the "Agreement") is between Wyeth Pharmaceuticals Inc., acting through its Wyeth Research Division (External Research Department, 87 Cambridge Park Drive, Cambridge, MA 02140, (617) 876-1170, Telecopier (617) 665-8708), together with its affiliates and subsidiaries (collectively, "Wyeth"), and The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Houston, The University of Texas M. D. Anderson Cancer Center, The University of Texas Health Center at Tyler, The University of Texas Medical Branch at Galveston, The University of Texas Southwestern Medical Center at Dallas, The University of Texas at San Antonio, The University of Texas at Dallas, The University of Texas at El Paso, and The University of Texas at Austin ("Recipient"), each with an office and place of business as set forth on the attached Exhibit A, and each a component institution of The University of Texas System having an address at 201 West 7th Street, Austin, TX 78701, on behalf of the Investigators identified on the Project Orders that may be issued from time to time under this Agreement ("Investigators").

1. Background. Investigators desire to obtain samples of the material described in attached Project Orders (together with all derivatives and improvements, collectively defined as the "Material") from Wyeth for use in the research described in the Project Orders (the "Research") under the terms and conditions of this Agreement.

2. The Material and the Research. Investigator and Recipient acknowledge that Wyeth owns the Material. Wyeth will use commercially reasonable efforts to provide Investigator with the Material described in the Project Orders. Recipient agrees to pay directly or to reimburse Wyeth for the cost of sending the Material to Investigator. Investigator will use the Material solely in the Research and for no other purpose. The Research will be conducted solely by Investigator at Recipient's research facilities, or by those employees at Recipient directly supervised by Investigator. None of the Material will be transferred or sold to third parties. Investigator will not use the Material for testing in or treatment of human subjects. Investigator acknowledges that the Material is experimental and will comply with all laws and regulations applicable to its handling and use. Any Material remaining upon completion of the Research will be returned to Wyeth.

3. Project Orders.

3.1 Description. All Research performed hereunder shall be in accordance with this Agreement and the applicable Project Order. Each Project Order shall set forth a description of the specific Research to be performed, the Research Materials being provided by Wyeth, and name of the Recipient and the Investigators responsible for performing and/or supervising the Research.

3.2 Separate Agreement. Each Project Order shall reflect a separate agreement of the parties, and, unless otherwise clearly stated in writing, the terms of each Project Order shall be independent of, and shall have no impact upon, the terms of any other Project Order.

4. In vivo Studies. If Investigator is using the Material for non-human in vivo studies, Investigator will (a) consider alternative in vitro approaches, (b) comply with all applicable federal, state and local laws and regulations and (c) provide Wyeth with copies of the applicable in vivo protocols. If Investigator observes unexpected adverse events, including but not limited to mortalities (especially in non-rodent species such as non-human primates or dogs), evidence of mutagenicity, carcinogenicity, or adverse effects on

reproductive parameters, Investigator will inform Wyeth in writing within five (5) business days of the original observation.

5. Inventions.

5.1 Disclosure. Recipient and Investigator will promptly and fully disclose in writing to Wyeth any and all inventions, know-how and other rights (whether or not protectible under state, federal, or foreign intellectual property laws) related to the Material or its use, or developed using the Material, which are conceived and/or reduced to practice by Investigator, alone or jointly with others, in the course of the Research (the "Inventions").

5.2 License and Option. Recipient and Investigator grant to Wyeth (a) a non-exclusive, worldwide, royalty-free license, with the right to grant sublicenses for internal research use only, to make, use, and have made any Inventions related to or derived from the Material or its use (for example, antibodies, tissue or cells, cell lines, genes, proteins, diagnostics, assays, new therapeutic indications, and new methods of manufacture and administration of therapeutics developed from Investigator's or Recipient's use of the Material) and (b) a first option to obtain an exclusive, worldwide, royalty-bearing license to any or all of Recipient's and Investigator's interests in the Inventions, with the right to grant sublicenses. For each Invention, Wyeth's first option must be exercised within ninety (90) days of full written disclosure of that Invention to Wyeth by Recipient and/or Investigator. The royalty payable to Recipient or Investigator and other terms of the exclusive license will be negotiated by the parties in good faith.

5.3 Patent Applications. Any patent applications necessary to protect the proprietary positions of the parties in any of the Inventions will, in Wyeth's sole discretion, be prepared and filed by Wyeth (jointly in Wyeth's and Recipients/Investigator's names, if jointly invented, or solely in Recipient's and/or Investigator's name, if solely invented), with expenses borne by Wyeth. Inventorship will be determined according to U.S. patent law.

5.4 Reports. At Wyeth's written request, Investigator will advise and update Wyeth on the progress and results of the Research.

6. Confidentiality. Except as provided in Section 7, Investigator will not publish or disclose any of Wyeth's confidential or proprietary information to third parties. Confidential information of Wyeth includes, without limitation, any scientific, technical, trade or business information disclosed by Wyeth to Investigator which is treated by Wyeth as confidential or proprietary, whether or not such information is labeled or identified as "Confidential". This confidentiality obligation does not apply to information which is available to Investigator from an independent source, is already published, is required by law to be disclosed or is/was known by Investigator independent of Wyeth's disclosure. Such confidentiality obligations will end five (5) years after the respective Project Order ends.

7. Publication. Investigator will have the right to publish and disclose the results of the Research. In order to balance this right with Wyeth's proprietary interests, Investigator will submit the proposed disclosure to Wyeth for its review at least thirty (30) days prior to the scheduled disclosure of the results to any third party (including, without limitation, to any journal for review). Wyeth will complete its review within thirty (30) days of receipt of the submitted documents. Wyeth may request that Investigator delete from the documents any reference to Wyeth's confidential information. If, during its thirty (30) day review period, Wyeth notifies Recipient and/or Investigator that it desires to file patent application on any Inventions disclosed in the documents, Investigator will defer publication/disclosure for up to sixty (60) additional days from the date of submission of the document to Wyeth.

8. NO WARRANTY. THE MATERIAL IS PROVIDED TO RECIPIENT AND INVESTIGATOR AS-IS AND WITHOUT WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, TITLE OR FITNESS FOR A PARTICULAR PURPOSE. Additionally, Wyeth does not warrant that any Material supplied hereunder is free from disease or pathogen or

other contaminant which may affect the supplied Material or any animals, cells or tissues with which the Material comes in contact.

9. Indemnification. To the extent authorized under the Constitution and the laws of the State of Texas, Recipient will indemnify and hold Wyeth harmless from any claims or liability resulting from Recipient's and Investigator's negligent use of the Material, except insofar as such claims or liability result from Wyeth's negligence or wrongdoing.

10. Termination. Either Wyeth or Recipient may terminate this Agreement or any Project Order (s) on thirty (30) days prior written notice to the other party. Upon termination, Investigator shall immediately return to Wyeth its confidential information, and any unused samples of the Material, and all of Recipient's and Investigator's rights to use the Material shall end. Following termination, neither Wyeth nor Recipient shall have any further obligations under this Agreement, except that Sections 5 through 8 shall survive.

REMAINDER OF THIS PAGE IS BLANK

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by proper duly authorized persons.

WYETH RESEARCH DIVISION	**The University of Texas M. D. Anderson Cancer Center**
By: _____ Print Name: _____ Title: _____ (Duly Authorized) Date: _____	By: _____ Leonard A. Zwelling, M.D., M.B.A. Vice President for Research Administration Date: _____

PROJECT ORDER ATTACHED HERE

Simple Biomaterials License Agreement

This Agreement, made between the _____ ("UNIVERSITY"), and _____ ("COMPANY") having an office at _____, is effective as of _____ (hereinafter the Effective Date).

1. THE UNIVERSITY represents that it presently has custody of and has the authority to license the following biological materials: *description of material* (the "MATERIALS").

2. COMPANY, as a pharmaceutical research and product development company, wishes to obtain a non-exclusive license to the MATERIALS.

3. THE UNIVERSITY hereby grants to COMPANY, effective as of the date of the last signator to sign this Agreement, a non-exclusive license to make and use but not to sell products and processes encompassed within or incorporating the MATERIALS.

4. COMPANY agrees to utilize the MATERIAL solely for the purpose of COMPANY's own internal research. It is understood that COMPANY will be using the MATERIALS as a research tool. UNIVERSITY shall acquire no rights of any kind in any of COMPANY's proprietary compounds, their compositions or uses, identified as a result of the use of the the MATERIALS. COMPANY shall have the sole and unrestricted right to use all data developed as a result of utilizing the MATERIALS.

5. THE UNIVERSITY agrees to provide COMPANY with samples of the MATERIALS, as available, and to make good faith efforts to replace the MATERIALS at a nominal fee in the event of their unintentional destruction, providing that THE UNIVERSITY shall be under no obligation to replace the MATERIALS more than once per calendar year.

6. The MATERIALS delivered hereby are experimental in nature. The UNIVERSITY makes no warranties, representation or undertaking with respect to the utility, efficacy, nontoxicity, safety or appropriateness of using the MATERIALS or with respect to the non-infringement of patent or other proprietary rights not licensed hereunder.

7. COMPANY agrees to retain control over the MATERIALS, and agrees that it shall not sell or otherwise transfer the MATERIALS, or any derivative of the MATERIALS to any other party, whether with or without consideration, for any purpose or use, without the prior express written permission of the UNIVERSITY.

8. COMPANY agrees that any person with the COMPANY utilizing the MATERIALS will be advised of, and is subject to, the conditions in this Agreement.

9. COMPANY agrees that this Agreement does not preclude THE UNIVERSITY from distributing the MATERIALS to third parties for research or commercial purposes.

10. COMPANY agrees to notify THE UNIVERSITY promptly of any commercial products and processes incorporating the MATERIALS.

11. The UNIVERSITY shall not be liable for any use of the MATERIALS or related know-how, and COMPANY hereby agrees to defend, indemnify and hold the UNIVERSITY and its employees harmless from any loss, claim, damage or liability, of whatsoever kind of nature, which may arise from, or in connection with this Agreement, or the use of the MATERIALS or related know-how hereunder.

12. COMPANY is encouraged to publish the results of its research projects using the MATERIALS. In all oral presentations or written publications concerning these MATERIALS, COMPANY will acknowledge the contribution of the named inventor, Dr. William Catterall, of the MATERIALS, unless requested otherwise by THE UNIVERSITY or the named inventor.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO COMPANY UNDER THIS AGREEMENT OR THAT THE MATERIALS DO NOT INFRINGE PATENT OR OTHER PROPRIETARY RIGHTS NOT LICENSED HEREUNDER. COMPANY accepts license rights to the MATERIALS "as is," and THE UNIVERSITY does not offer any guarantee as to its patentability.

14. COMPANY agrees in its use of the MATERIALS to comply with all applicable statutes, regulations and guidelines, including Public Health Service regulations and guidelines.

15. This Agreement shall be construed in accordance with the laws of the United States as interpreted and applied by the courts in the State _____.

16. This Agreement constitutes the entire understanding of THE UNIVERSITY and COMPANY and supersedes all prior agreements and understandings with respect to the MATERIALS.

17. In consideration of the grant in Paragraph 3, COMPANY hereby agrees to pay the sum of _____ as a non-refundable licensing fee for the MATERIALS, due in full within thirty (30) Days of the Effective Date of this Agreement.

18. COMPANY agrees to pay a late fee for any overdue licensing fee due the UNIVERSITY under terms of this Agreement. The late fee shall be computed as the prime rate plus Two Percent (2%), as set forth by the *Wall Street Journal* on the date on which such payment is due, of the outstanding, unpaid balance. The payment of such a late fee shall not foreclose or limit UW from exercising any other rights it may have as a consequence of the lateness of any payment.

19. In the event of material breach of this Agreement by COMPANY, the UNIVERSITY may, at its sole discretion, terminate this agreement by notifying COMPANY, in writing, that this Agreement is terminated as of the date of such written notification from UNIVERSITY (the "Termination Letter"). COMPANY shall then comply with the terms of Attachment A, execute such Attachment A, and return the fully signed Attachment A to UNIVERSITY within thirty (30) days of the date of the Termination Letter to COMPANY.

20. The provisions of this Agreement are severable, and in the event that any provision of this agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this agreement.

If the foregoing terms are acceptable, please have a representative of the COMPANY sign in the space indicated for signature. Please return a copy of this Agreement to _____ with payment. After receipt of the executed Agreement and payment of the distribution fee we will arrange to provide you with the MATERIALS.

The undersigned agrees with and accepts the foregoing.

_____	_____
UNIVERSITY	COMPANY
_____	_____
Date	Date

ATTACHMENT A

Letter of Termination

The Biomaterials License Agreement executed between _____ ("UNIVERSITY") and the _____ ("COMPANY") for *description of material* (the "MATERIALS") is terminated. In executing this Letter of Termination, COMPANY warrants that all MATERIALS provided under the Biomaterials License Agreement, including progeny, subclones and derivatives thereof, have been destroyed.

_____
Signature

_____
Signator's Name

_____
Title

_____
Date

L#:

PUBLIC HEALTH SERVICE
BIOLOGICAL MATERIALS LICENSE AGREEMENT
INTERNAL USE ONLY

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:
   (a) "**Materials**" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof:
   _____,
   as described in
   _____
   _____ and developed in the laboratory of
   _____.
   (b) "**Licensed Products**" means _____.
2. **Licensee** desires to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** or the **Licensed Products** for commercial use or commercial research.
3. **PHS** hereby grants to **Licensee** a non-exclusive license, within its research facilities, to make, have made, use, but not to sell the **Materials** or the **Licensed Products**.
4. In consideration of the grant in Paragraph 3, **Licensee** agrees to make the following payments to **PHS**:
   (a) Within thirty (30) days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ dollars ($X).
   (b) A nonrefundable annual royalty of _____ dollars ($X) which shall be due and payable on January 1 of each calendar year. The annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
   (c) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix B. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.
      i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and
      ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty and the prorated first year annual royalty and verification of these royalties, **PHS** agrees to provide **Licensee** with samples of the **Materials**, as available, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** as specified in Appendix A.
6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days after the end of each calendar year. These reports shall include, but not be limited to, progress on the research and development involving the **Materials** or the **Licensed Products** and use of the **Materials** or the **Licensed Products**. **Licensee** shall submit each report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.
7. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 23 are not fulfilled, and shall expire _____ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 14 or 15.
8. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS**.
9. This **Agreement** does not preclude **PHS** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.
10. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.
11. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** "as is", and **PHS** does not offer any guarantee of any kind.
12. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials** or the **Licensed Products**.
13. **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
14. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.
15. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of the default.
16. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and the **Licensed Products** to **PHS**, or provide **PHS** with written certification of their destruction.
17. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.
18. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, **Licensee** shall acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.
19. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

20. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.
21. The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
22. Paragraphs 11, 12, and 18 of this **Agreement** shall survive termination or expiration of this **Agreement**.
23. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT
FOR LICENSEE'S INTERNAL USE ONLY
SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____
Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
Mailing Address for **Agreement** notices:
Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

_____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____
_____
_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title
Mailing Address

_____
_____
_____
_____

Email Address: _____
Phone: _____
Fax: _____

Any false or misleading statements made, presented, or submitted to the United States Government, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX B – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank
ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$
NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001
(412) 234-4381 (Customer Service)
Please make checks payable to: *NIH/Patent Licensing*
*The OTT Reference Number **MUST** appear on checks, reports and correspondence*

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PUBLIC HEALTH SERVICE
BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:
   (a) "**Materials**" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof:
   _____,
   as described in
   _____
   _____ and developed in the laboratory of
   _____.
   (b) "**Licensed Products**" means _____.
   (c) "**Net Sales**" means the total gross receipts by **Licensee** for sales of **Licensed Products** or from income from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions transferring title, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, or for the cost of collections.
   (d) **"Licensed Field of Use**" means
   _____.
2. **Licensee** desires to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** or the **Licensed Products** for commercial use or commercial research.
3. **PHS** hereby grants to **Licensee**:
   (a) a worldwide, non-exclusive license to make, have made, and use the **Materials** or the **Licensed Products**; and
   (b) a worldwide, non-exclusive license to sell and have sold, to offer to sell and to import the **Licensed Products** in the **Field(s) of Use**.
4. In consideration of the grant in Paragraph 3, **Licensee** hereby agrees to make the following payments to **PHS**:
   (a) Within thirty (30) days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ dollars ($X).
   (b) A nonrefundable minimum annual royalty of _____ dollars ($X) which shall be due and payable on January 1 of each calendar year and may be credited against earned royalties for sales made in that year. The minimum annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
   (c) An earned royalty of _____ percent (X%) of **Net Sales**, which shall be due and payable within sixty (60) days of the end of each calendar year.

(d) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix C. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and

ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty and the prorated first year minimum annual royalty and verification of these royalties, **PHS** agrees to provide **Licensee** with samples of the **Materials**, as available, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** as specified in Appendix A.

6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days of December 31 for each calendar year. This report shall state: the number, description, and aggregate **Net Sales** of **Licensed Products** made, sold, or otherwise disposed of; the total gross income received by **Licensee** from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due **PHS** pursuant to Paragraph 4(c) and as shown in the example in Appendix B. **Licensee** shall submit each report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

7. **Licensee** agrees to supply the laboratory of Dr. _____, at **PHS**, at no charge, reasonable quantities of **Materials** or the **Licensed Products** that **Licensee** makes, uses, sells, or offers for sale or otherwise makes available for public use. **Licensee** also agrees to supply, to the Mailing Address for **Agreement** notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with insert samples of the **Licensed Products** or their packaging for educational and display purposes only.

8. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 25 are not fulfilled, and shall expire _____ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17.

9. As part of **Licensee's** performance under this **Agreement**, **Licensee** agrees to make the **Licensed Products** available to the public within _____ (X) months from the effective date of this **Agreement**.

10. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS** except as provided in Paragraph 3.

11. This **Agreement** does not preclude **PHS** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.

12. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** and the **Licensed Products** "as is", and **PHS** does not offer any guarantee of any kind.

14. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials** or the **Licensed Products**.

15. **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
16. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.
17. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of the default.
18. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and the **Licensed Products** to **PHS**, or provide **PHS** with written certification of their destruction.
19. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.
20. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, **Licensee** shall acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.
21. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.
22. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.
23. The provisions of this **Agreement** are severable, and in the event that any provision of the **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
24. Paragraphs 13, 14, and 20 of this **Agreement** shall survive termination or expiration of this **Agreement**.
25. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT
SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____

Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
Mailing Address for **Agreement** notices:
Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

_____ _____

Signature of Authorized Official Date

_____

Printed Name

_____

Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____

Name

_____

Title
Mailing Address:

_____

_____

_____

_____

Email Address: _____
Phone: _____
Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX B – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX C – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank
ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$
NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001
(412) 234-4381 (Customer Service)
Please make checks payable to: *NIH/Patent Licensing*
*The OTT Reference Number **MUST** appear on checks, reports and correspondence*

PUBLIC HEALTH SERVICE
NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE
COVER PAGE

For PHS internal use only:

License Number:

License Application Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Licensee:

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Licensed Products, Processes, Territory, Field of Use and Termination), Appendix C (Royalties), Appendix D (Shipping Information) and Appendix E (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and
2) The person, corporation, or institution identified above and on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

PUBLIC HEALTH SERVICE
NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 U.S.A.; and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary for Health of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710a, and the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.4 **PHS** desires to transfer these inventions to the private sector through commercial research licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire the rights to use certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Government**" means the government of the United States of America.

2.2 "**Licensed Patent Rights**" shall mean:

(a) U.S. patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.2(a):

(i) continuations-in-part of 2.2(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations; and

(iv) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in 2.2(a): all counterpart foreign applications and patents to 2.2(a) and 2.2(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.2(b) or 2.2(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in 2.2(a).

2.3 "**Licensed Products**" means tangible materials, identified in Appendix B, which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.4 "**Licensed Processes**" means processes, identified in Appendix B, which, in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.5 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.6 "**Licensed Fields of Use**" means the field of use identified in Appendix B.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and to use, but not to sell the **Licensed Products** and **Licensed Processes** in the **Licensed Fields of Use** only.

3.2 **Licensee** has no right to sublicense.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether such patents are dominant or subordinate to the **Licensed Patent Rights**.

3.4 **PHS** acknowledges that information relating to the **Licensed Patent Rights** may be of assistance to **Licensee** in its commercialization efforts. Accordingly, **PHS** shall consider reasonable requests by **Licensee** for access to the inventors of the **Licensed Patent Rights**.

4. ROYALTIES

4.1 **Licensee** agrees to pay **PHS** a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.

4.2 **Licensee** agrees to pay **PHS** a nonrefundable annual royalty as set forth in Appendix C.

4.3 All royalties due under this **Agreement** shall be paid in U.S. dollars, net of all non-U.S. taxes, and payment options are listed in Appendix E. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

4.4 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. PERFORMANCE

5.1 Upon receipt and verification of the royalties due under Paragraphs 4.1 and 4.2, **PHS** agrees, if **Licensed Products** are available to **PHS**, to provide **Licensee** with samples of the **Licensed Products** to the individual and address listed in Appendix D and, at reasonable cost to **Licensee**, to replace them in the event of their unintentional destruction. **Licensee** agrees to retain control over the **Licensed Products** and shall not distribute or release them to others without the prior written consent of **PHS**.

5.2 **Licensee** shall expend reasonable efforts and resources to carry out the research development plan submitted with **Licensee's** application for a license and shall begin research within six (6) months of the effective date of this **Agreement**.

5.3 **Licensee** agrees in its use of any **Licensed Products** provided by **PHS** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of this research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of this research or trials.

5.4 **Licensee** shall provide written annual reports within sixty (60) days of the end of each calendar year detailing the current status of on-going research using **Licensed Products**.

5.5 All plans and reports required by this Article 5 shall be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential and, to the extent permitted under the research development plan by law, not subject to disclosure under the Freedom of Information Act, 5 U.S.C. §552.

6. NEGATION OF WARRANTIES AND INDEMNIFICATION

6.1 **PHS** offers no warranties other than those expressly specified in Article 1.

6.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

6.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR OF ANY **LICENSED PRODUCTS** PROVIDED TO **LICENSEE** UNDER PARAGRAPH 5.1.

6.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

6.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**, or

(b) the design, manufacture, distribution, or use of any **Licensed Products** or materials provided under Paragraph 5.1, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

6.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

7. TERM, TERMINATION AND MODIFICATION OF RIGHTS

7.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 8.8 are not fulfilled, and shall terminate at the time specified in Appendix B, unless previously terminated under the terms of this Article 7.

7.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 7.3 and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

7.3 **PHS** shall specifically have the right to terminate this **Agreement** by written notice if **Licensee**:

(a) has not demonstrated that it is executing the research plan submitted with its application for a license or that it has not taken or cannot be expected to take, within a reasonable time, effective steps to achieve the practical application of the **Licensed Patent Rights** as contemplated by this **Agreement**; or

(b) has willfully made a false statement of or willfully omitted a material fact in its application for a license or in any report required by this **Agreement**.

7.4 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by Federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

7.5 **Licensee** shall have a unilateral right to terminate this **Agreement** by giving **PHS** sixty (60) days written notice to that effect.

7.6 Within thirty (30) days of receipt of written notice of **PHS'** unilateral decision to terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the Director of **NIH** or designee. The decision of the **NIH** Director or designee shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

7.7 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

7.8 Within thirty (30) days of the termination of this **Agreement** under this Article 7 or expiration under Paragraph 7.1, **Licensee** shall submit payment of any royalties due and shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with certification of their destruction.

7.9 Paragraphs 4.3, 5.5, 6.1-6.5, 7.6, and 7.8 of this **Agreement** shall survive termination of this **Agreement**.

8. GENERAL PROVISIONS

8.1 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

8.2 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

8.3 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

8.4 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by such other party, and shall be effective as of the date of the postmark of such notice.

8.5 This **Agreement** shall not be assigned by **Licensee** except:

(a) with the prior written consent of **PHS**; or

(b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**; and

(c) **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**.

8.6 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by **Licensee** that it shall not export other items to certain foreign countries without prior approval of the agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

8.7 The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modification or termination decisions provided for in Article 7. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

8.8 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS NON-EXCLUSIVE PATENT LICENSE AGREEMENT
FOR INTERNAL COMMERCIAL USE

FOR **PHS**:
by: _____ _____
Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
Mailing Address for **Agreement** notices:
Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

FOR **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
Licensee
by: _____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title
Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.
II.
III.

APPENDIX B – LICENSED PRODUCTS, PROCESSES, TERRITORY, FIELD OF USE AND TERMINATION

I. **Licensed Products**:
   (a)

II. **Licensed Processes**:
   (a)

III. **Licensed Territory**:
   (a)

IV. **Licensed Fields of Use**:
   (a)

V. Termination:
   (a) This **Agreement** shall terminate _____ (X) years from the effective date as defined in Paragraph 7.1.

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of _____ dollars ($X) within thirty (30) days from the effective date of this **Agreement**.

II. **Licensee** agrees to pay to **PHS** a nonrefundable annual royalty in the amount of _____ dollars ($X) as follows:

(a) The first annual royalty is due within thirty (30) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(a) Subsequent annual royalty payments are due and payable on January 1 of each calendar year.

APPENDIX D – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX E – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank
ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$
NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001
(412) 234-4381 (Customer Service)
Please make checks payable to: *NIH/Patent Licensing*
*The OTT Reference Number **MUST** appear on checks, reports and correspondence*

PUBLIC HEALTH SERVICE
PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*
COVER PAGE

For PHS internal use only:

License Number:

License Application Number:
Serial Number(s) of Licensed Patent(s) or Patent Application(s):

Licensee:

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks:

Public Benefit(s):

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D ((Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and
2) The person, corporation, or institution identified above and on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

PHS PATENT LICENSE AGREEMENT--*NONEXCLUSIVE*

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.4 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.2 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.3 "**First Commercial Sale**" means the initial transfer by or on behalf of **Licensee** of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.4 "**Government**" means the Government of the United States of America.

2.5 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.6 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a):

(i) continuations-in-part of 2.6(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.6(a); and

(v) any reissues, reexaminations, and extensions of all these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.6(a): all counterpart foreign and U.S. patent applications and patents to 2.6(a) and 2.6(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.6(b) or 2.6(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.6(a).

2.7 "**Licensed Processes**" means processes, which in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.8 "**Licensed Products**" means tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.9 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.10 "**Net Sales**" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee**, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee**, and on its payroll, or for the cost of collections.

2.11 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 **Licensee** has no right to sublicense.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.

5.2 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

6. ROYALTIES AND REIMBURSEMENT

6.1 **Licensee** agrees to pay **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 **Licensee** agrees to pay **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.

6.4 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.

6.5 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses; or

(c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.6 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.7 On sales of **Licensed Products** by **Licensee** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.8 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and incurred by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay **PHS**, as an additional royalty, within sixty (60) days of **PHS'** submission of a statement and request for payment to **Licensee**, an amount equivalent to such patent expenses previously incurred by **PHS**.

6.9 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and incurred by **PHS** on or after the effective date of this **Agreement**, **PHS**, at its sole option, may require **Licensee**:

(a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS'** submission of a statement and request for payment, a royalty amount equivalent to all patent expenses incurred during the previous calendar year(s);

(b) to pay these expenses directly to the law firm employed by **PHS** to handle these functions. However, in this event, **PHS** and not **Licensee** shall be the client of the law firm; or

(c) under exceptional circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide **PHS** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.10 **PHS** agrees, upon written request, to provide **Licensee** with summaries of patent prosecution invoices for which **PHS** has requested payment from the **Licensee** under Paragraphs 6.8 and 6.9.

6.11 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to **PHS** and owe no payment obligation under Paragraph 6.9 for patent-related expenses incurred in that country after the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 **PHS** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

8. RECORD KEEPING

8.1 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of **PHS**, by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.

8.2 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Products** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalties owed to the **Government** under this **Agreement**, and whether the royalties owed have been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, **Licensee** has provided **PHS** with the **Commercial Development Plan** in Appendix E, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written approval by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

9.3 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 **Licensee** shall submit to **PHS**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to **PHS** at its address for **Agreement** Notices indicated on the Signature Page.

9.6 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

9.7 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.8 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 CFR §5.65(d).

10. PERFORMANCE

10.1 **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available on a compassionate use basis to patients, either through the patient's physician(s) or the medical center treating the patient.

10.4 **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.

11.2 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against **PHS**, **PHS** agrees to notify **Licensee** that an action alleging invalidity has been brought. **PHS** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. Should the **Government** be made a party to any suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. Upon **Licensee's** payment of all costs incurred by the **Government** as a result of **Licensee's** joinder motion or other action, these actions by **Licensee** shall not be considered a default in the performance of any material obligation under this **Agreement**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 **PHS** offers no warranties other than those specified in Article 1.

12.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**. **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

12.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.15 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee's** receipt of written notice.

13.4 **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving **PHS** sixty (60) days written notice to that effect.

13.5 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS'** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived.

13.6 In making the determination referenced in Paragraph 13.5, **PHS** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g). If **Licensee** fails to alleviate **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to **PHS'** satisfaction, **PHS** may terminate this **Agreement**.

13.7 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

13.8 Within thirty (30) days of receipt of written notice of **PHS'** unilateral decision to modify or terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with written certification of the destruction thereof.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned by **Licensee** except:

(a) with the prior written consent of **PHS**, this consent shall not to be withheld unreasonably; or

(b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**; and

(c) **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**, and **Licensee** shall pay **PHS**, as an additional royalty, one (1) percent of the fair market value of any consideration received for any assignment of this **Agreement** within thirty (30) days of the assignment.

14.8 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve **PHS** patent rights in those countries.

14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of **NIH**, **PHS**, **FDA** or **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of **PHS**.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 8.1, 9.6-9.8, 12.1-12.5, 13.8, 13.9, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.15 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*
SIGNATURE PAGE

For **PHS**:

_____ _____
Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
Mailing Address for **Agreement** notices:
Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

_____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____
_____
_____
_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title
Mailing Address:

_____
_____
_____
_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.
II.
III.
IV.
V.
VI.

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**
(a)

II. **Licensed Territory:**
(a)

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of _____ Dollars ($X) within thirty (30) days from the effective date of this **Agreement.**

II. **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty in the amount of _____ Dollars ($X) as follows:

(a) The first minimum annual royalty is due within thirty (30) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. **Licensee** agrees to pay **PHS** earned royalties of ___ percent (X%) on **Net Sales** by or on behalf of **Licensee**.

IV. **Licensee** agrees to pay **PHS Benchmark** royalties within thirty (30) days of achieving each **Benchmark**:

(a)
(b)
(c)
(d)
(e)
(f)

APPENDIX D – BENCHMARKS AND PERFORMANCE

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

I.
II.
III.
IV.
V.
VI.
VII.

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank
ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$
NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001
(412) 234-4381 (Customer Service)
Please make checks payable to: *NIH/Patent Licensing*
*The OTT Reference Number **MUST** appear on checks, reports and correspondence*

Appendix 24

Sample Grant Language

An example of a grant where the licensee is only permitted to evaluate the material for a particular use, perhaps to see if the material would be useful in the licensee's internal testing program or if it is suitable to help make or be incorporated in a commercial product, is as follows.

- Licensor hereby grants, and Licensee accepts, a worldwide non-exclusive license for evaluation purposes ***only*** to make, have made, use and have used, but not to sell, offer for sale, or have sold, the Material and processes using the Material. Licensee agrees that any use of the Material, other than for evaluation purposes, will be made only pursuant to the terms of the Non-Exclusive BioMaterials License (Exhibit A). Licensee agrees that the Material will be provided to Licensee for the ***evaluation of commercial applications only and not for commercial use***. This grant does not include the right to file patent applications for or the use of the Material without Licensor's express prior written approval, which approval will be in Licensor's sole discretion.
- Licensee agrees to retain control over the Material, and not to distribute them to third party for any reason, with or without consideration, without the express prior written consent of the Licensor.
- Licensee agrees in its use of the Material to comply with all applicable statutes, regulations and guidelines, including those of the Public Health Service and the Licensor regulations and guidelines.
- Licensee agrees that this Agreement does not preclude the Licensor from distributing the Material to third parties for research or commercial purposes.

An example of a grant where the licensee is obtaining a license to use the material commercially, is as follows. In this example, the words in all capital letters would be defined in a preceding section of the license.

- Subject to Licensee's compliance with Articles 3 (License Fees) and 6 (Payments and Reports), and all other provisions of this Agreement, Licensor hereby grants to Licensee, and Licensee accepts, an exclusive, royalty-bearing license, with the right to SUBLICENSE, under the LICENSED PATENTS to import, make, use, sell, and offer for sale LICENSED SUBJECT MATTER in the TERRITORY.
- The license granted above is subject to a reserved non-exclusive license, with the right to non-exclusively SUBLICENSE to non-profit institutions for research purposes only, in Licensor and Licensor INVENTORS to make, have made, and use, but not to sell or have sold, products, processes, or other subject matter covered by LICENSED PATENTS or included in the LICENSED SUBJECT MATTER.
- **Paragraph 3.1** notwithstanding, Licensee acknowledges that the LICENSED PATENTS may involve federal research funding. In the case of federal research funding, Licensee acknowledges that Licensor has obligations ("Obligations") under federal law, and actions taken by Licensor to fulfill such Obligations shall not be deemed inconsistent with Licensor's obligations under this Agreement. Licensee acknowledges that Obligations include, without limitation, the granting of a worldwide non-exclusive, royalty-free license for any such INVENTION, LICENSED PATENTS and/or TECHNICAL INFORMATION, by Licensor to the United States Government, and a statement of United States Government patent rights on all the patents and patent applications within the LICENSED PATENTS. Licensee acknowledges that any and all determinations of federal funding involvement shall be made solely by Licensor and Licensor's determination shall be honored by Licensee. LICENSED SUBJECT MATTER Sold in the United States must be manufactured substantially in the United States so long as this license remains exclusive.
- During the term of this Agreement Licensor agrees to make TECHNICAL INFORMATION in the Field of Use reasonably available to, and as may be requested by, Licensee, providing that such obligation does not unreasonably interfere with the academic responsibilities of the Licensor INVENTORS.

Appendix 25: Sample Payment Language

Payment language can vary from the simple to the complex, depending on factors such as on the nature of the material being licensed, whether it is patented, and how the licensee plans to use it.

Simple payment language.

All payments to University must be made in U.S. dollars; for conversion of foreign currency to U.S. dollars, the conversion rate will be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars must be paid entirely by Lic

Complex payment language. In this example, the words in all capital letters would be defined in a preceding section of the license.

1.0 Licensing Fees and Royalty

1.1 License Issue Fee. Licensee agrees to pay to Licensor a one-time, non-refundable, non-creditable license issue fee of _____ Dollars ($____) due and payable in full within thirty (30) days of the Effective Date of this Agreement.

1.2 Annual Maintenance Fee. Licensee agrees to pay to Licensor a non-refundable, non-creditable annual license maintenance fee due and payable within thirty (30) days of the end of each calendar quarter during the term of this Agreement. Prior to first commercial use or sale of LICENSED SUBJECT MATTER, this license maintenance fee must be ____ Dollars ($____), and thereafter must be ____ Dollars ($ _____).

1.3 Minimum Annual Royalties. During the Licensed Term of this Agreement, Licensee must pay minimum annual royalties according to the following schedule, such minimum annual royalties to be creditable against earned royalties on a non-cumulative basis and to be due in full and payable no later than **(Effective Date of Agreement)** of each year during the term of this Agreement..

- Years 1 and 2: **XXXXX** Dollars ($**XXXXX** USD) per year
- Years 3 and 4: **XXXXX** Dollars ($**XXXXX** USD) per year
- Years 5 and 6: **XXXXX** Dollars ($**XXXXX** USD) per year
- Years 7, 8 and 9: **XXXXX** Dollars ($**XXXXX** USD) per year
- Years 10 and each year thereafter: **XXXXX** Dollars ($**XXXXX** USD) per year

1.4 Earned Royalties. Licensee agrees to pay to Licensor an earned royalty of **XX** percent (**XX**%), due and payable within thirty (30) days of the end of each calendar quarter, of NET SALES REVENUE.

1.4.1 In the case of COMBINATION SUBJECT MATTER for which the component constituting a LICENSED SUBJECT MATTER and each component not constituting a LICENSED SUBJECT MATTER have established market prices in a particular country when sold separately, NET SALES REVENUE in that country will be determined by multiplying the net sales for each such COMBINATION SUBJECT

MATTER by a fraction, the numerator of which fraction will be the established stand-alone market price for the LICENSED SUBJECT MATTER contained in the COMBINATION SUBJECT MATTER and the denominator of which fraction will be the sum of the established stand-alone market price for the LICENSED SUBJECT MATTER plus the established stand-alone market price of the other components contained in the COMBINATION SUBJECT MATTER. When such separate stand-alone market prices are not established in that particular country, the parties will negotiate in good faith to determine a fair and equitable method of calculating NET SALES REVENUE in that country for the COMBINATION SUBJECT MATTER in question.

1.4.2 If Licensee is required to pay royalties to a third party(ies) for a license(s) to a patent(s) or patent application directly related to sales of that LICENSED SUBJECT MATTER for which payments are also due to Licensor ("Third Party Royalties"), then the royalties to be paid by Licensee to Licensor for that LICENSED SUBJECT MATTER will be reduced by the amount of one half of the Third Party Royalties, but in no event will the royalties paid by Licensee to Licensor on NET SALES of that LICENSED SUBJECT MATTER be less than fifty percent (50%) of what they would otherwise have been without accounting for Third Party Royalties.

1.5 Licensee agrees to pay to Licensor a percentage of non-royalty, cash and non-cash, consideration derived from SUBLICENSES granted by Licensee in and to LICENSED PATENTS, due and payable within thirty (30) days of the end of each calendar quarter in which such licensing fees and other income is received by Licensee, according to the following schedule:

In the event that the LICENSED PATENTS are SUBLICENSED as a "bundle" with other technologies, the value attributable to the LICENSED PATENTS must be a commercially reasonable value as determined by Licensee, providing that (a) proper supporting documentation supporting that valuation is provided by Licensee to Licensor, and (b) if Licensor reasonably disputes that valuation, then in any dispute resolution the burden will be Licensee's to support its valuation.

1.5.1 If Licensee receives consideration in any form other than cash in connection with the use or sale of LICENSED SUBJECT MATTER, or in connection with the grant of any SUBLICENSE, Licensee must, in the applicable report pursuant to Article X (Payment and Reports) of this Agreement, state the cash value to Licensee of such non-cash consideration. Licensor may either (a) accept Licensee's statement of cash value, in which case such stated cash value will be shared with Licensor in accordance with the provisions in Article 1 (Licensing Fees and Royalty) of this Agreement; or (b) elect to have such non-cash consideration appraised by a third party appraiser acceptable to Licensor, in which case the appraised cash value will be shared with Licensor in accordance with the provisions in Article 1 (Licensing Fees and Royalty) of this Agreement. If the appraised cash value is greater than Licensee's stated value, then Licensee must pay for the appraisal, up to a maximum amount of twenty percent (20%) of the difference between the appraised value and Licensee's stated value. If the appraised value is less than Licensee's stated value, then Licensor must pay for the appraisal.

1.5.2 If Licensee receives consideration in the form of equity, all provisions of Paragraph 1.4.1 of this Agreement will apply, except that Licensor may, at its sole discretion, elect to receive Licensor's share of such equity as either equity or the cash equivalent of such equity.

1.5.3 If under the provisions of Paragraph 1.4.2 of this Agreement Licensor elects to receive the equity, such equity must be in the name " XXXXX University".

1.6 Licensee will be responsible for the payment of all taxes, duties, levies, and other charges, including but not limited to, sales, use, gross receipts, excise, VAT, ad valorem and any other taxes, any withholdings or deductions, import and custom taxes, any duties, or any other charges imposed by any taxing authority with respect to the royalties payable to Licensor under this Agreement. Should Licensee be required under any law or regulation of any government entity or authority, domestic or foreign, to withhold or deduct any portion of the payments on royalties due to Licensor, then the sum payable to Licensor will be increased by the amount necessary to yield to Licensor an amount equal to the sum it would have received had no withholdings or deductions been made. Licensor must cooperate with Licensee in the event Licensee elects to assert, at its own expense, Licensor's exemption from any such tax or deduction.

1.7 No multiple royalties will be payable to Licensor because any LICENSED SUBJECT MATTER, its manufacture, use, or sale are or will be covered by more than one patent application or issued patent included as part of LICENSED PATENTS.

For interest, a definition of "COMBINATION SUBJECT MATTER" is included here:

"COMBINATION SUBJECT MATTER" means any subject matter, including but not limited to products and processes, containing both a component that constitutes a LICENSED SUBJECT MATTER and one or more other active components that do not constitute LICENSED SUBJECT MATTER and which is/are reasonably necessary for the imputed function of such subject matter.

Appendix 26
Sample language for Representations and Warranties

1. Licensor represents and warrants that it has the right to grant the license in and to LICENSED PATENTS and disclose the TECHNICAL INFORMATION set forth in this Agreement.

2. NOTHING IN THIS AGREEMENT MAY OR WILL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY LICENSOR AS TO THE PATENTABILITY, VALIDITY, SCOPE, OR USEFULNESS OF LICENSED PATENTS; OR, A REPRESENTATION OR WARRANTY BY LICENSOR THAT ANYTHING MADE, USED, SOLD, OR OTHERWISE DISPOSED OF UNDER ANY LICENSE GRANTED IN THIS AGREEMENT IS OR WILL BE FREE FROM INFRINGEMENT OF PATENTS OR OTHER PROPRIETARY RIGHTS NOT INCLUDED IN LICENSED PATENTS.

3. LICENSOR EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, PERTAINING TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE INVENTION, LICENSED SUBJECT MATTER, TECHNICAL INFORMATION, OR ANYTHING ELSE LICENSED, DISCLOSED, OR OTHERWISE PROVIDED TO LICENSEE UNDER THIS AGREEMENT. LICENSOR'S TOTAL LIABILITY UNDER THIS AGREEMENT IS LIMITED TO THE COSTS AND FEES PAID TO LICENSOR UNDER THIS AGREEMENT.

Another example.

1. Licensor represents and warrants that all right, title, and interest in the patent applications or patents comprising the Licensed Patent Rights and Optioned Patent Rights have been assigned to it and that Licensor has the right and authority to issue licenses under said Licensed Patent Rights and options under the Optioned Patent Rights . LICENSOR DISCLAIMS ALL IMPLIED OR EXPRESS WARRANTIES OF ANY NATURE WHATSOEVER CONCERNING THE VALIDITY, PATENTABILITY, SCOPE OR USEFULNESS OF THE LICENSED PATENT RIGHTS LICENSED HEREUNDER AND THE AND OPTIONED PATENT RIGHTS OPTIONED HEREUNDER. LICENSEE ACKNOWLEDGES AND AGREES THAT NEITHER LICENSOR NOR ANYONE ACTING ON ITS BEHALF HAS MADE ANY REPRESENTATIONS OR WARRANTIES WHATSOEVER WITH REGARD TO THE SCOPE OF THE LICENSED PATENT RIGHTS OR THAT SUCH LICENSED PATENT RIGHTS MAY BE EXPLOITED BY LICENSEE, AN AFFILIATE, OR SUBLICENSEE WITHOUT INFRINGING PATENTS OR OTHER PROPRIETARY RIGHTS NOT INCLUDED IN THE LICENSED PATENT RIGHTS.

2. Licensor expressly disclaims any and all warranties, whether express or implied, pertaining to the merchantability or fitness for a particular purpose of the Licensed PATENT RIGHTS, KNOW-HOW, or anything else licensed, disclosed, or otherwise Provided to LICENSEE under this Agreement. LICENSOR'S TOTAL LIABILITY UNDER THIS AGREEMENT IS LIMITED TO THE COSTS AND FEES PAID TO LICENSOR UNDER THIS AGREEMENT.

Appendix 27
Useful Clauses in Defining "The Materials"

From the UBMTA:

"Progeny: unmodified descendants from the original material, such as virus from virus, cell from cell, or organism from organism."

"Unmodified Derivatives: an unmodified functional subunit or product expressed by the original material, e.g., subclones of unmodified cell lines, proteins expressed by DNA or RNA supplied by the provider, or monoclonal antibodies secreted by a hybridoma cell line."

Source: A session by Heidi Henning, J.D., at the National Association of College and University Attorneys, November 2004.

If the materials are mice that will be cross-bred to a strain proprietary to the recipient, cross-bred progeny should be jointly owned rather than the sole property of the provider. However, most company providers will not allow cross-bred progeny that incorporates the genetic modifications of their parent strain to be distributed without their prior written consent. This is understandable but not entirely consistent with the (the NIH's) Research Tool Guidelines. An alternative here is to define the materials to include "any immediate or remote progeny or descendant from organisms or cell lines containing the same genetic mutation or lesion as the original Biological Material", and include the following in the agreement's ownership provisions:

> "The Mice may be bred solely for the purpose of maintaining the strain. If the Mice are bred with mice of another strain or which contain a different or additional genetic mutation or lesion ("Cross-Bred Mice"), Provider and Recipient shall jointly own such Cross-Bred Mice. Recipient shall notify Provider of Cross-Bred Mice and their characteristics and provide Provider with a breeding pair of such mice upon Provider's request and subject to availability.

"Human embryonic stem cells" means human embryonic stem cell line materials and their unmodified and undifferentiated progeny or derivatives.

"Progeny" means unmodified descendants from the original material, such as virus from virus, cell from cell, or organism from organism.

"Unmodified derivatives" means an unmodified functional subunit or product expressed by the original material, for examples, subclones of unmodified cell lines, proteins expressed by DNA or RNA supplied by the provider, or monoclonal antibodies secreted by a hybridoma cell line.

(*Note*: If the provider will not accept the limitation of covered derivatives to "unmodified", other possibilities for language are "direct" or "non-novel and obvious.")

Appendix 28

Useful Language in Negotiating MTA License Issues

Source: A session by Heidi Henning, J.D., at the National Association of College and University Attorneys, November 2004.

"The project covered by this agreement is supported with funding from the National Institutes of Health. Provider agrees that upon publication, unpatented unique research resources arising out of this project may be freely distributed."

"In the event an invention is primarily useful as a research tool, any option granted shall either be limited to a non-exclusive license or the terms of any resulting exclusive license shall include provisions that ensure that the research tool will be available to the academic research community on reasonable terms."
"Provider agrees that Recipient shall have the right to make any materials and inventions developed by Recipient in the course of the collaboration (including materials and inventions developed jointly with Provider, but not including any Provider materials (or parts thereof) or Provider sole inventions available to other scientists at not-for-profit organizations for use in research, subject to Provider's independent intellectual property rights."

"Subject to Recipient's obligations to the U.S. government, including 37 CFR Part 401, the NIH Grants Policy Statement, and the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, Recipient grants to Sponsor the following rights, such grant *subject to any obligations the Recipient may have to third parties*:..."

- In the above grant, the phrase *"subject to any obligations the Recipient may have to third parties"* might be replaced by the phrase "subject to the recipient's pre-existing contractual obligations."
- In the above grant, the recipient may want to add language that the provider (the optionee, in this case) will pay all patent costs incurred by the recipient during the time period that the option is being exercised and negotiated.

"Recipient hereby grants Provider an option to negotiate for an exclusive, royalty-bearing license to use any such Invention on terms that are commercially reasonable. The option to negotiate shall be valid and exercisable for a period of 60 days after Recipient notifies Provider of an Invention and, if Provider exercises the option within that period, then Provider shall have 120 days after exercise of the option within which to execute a license. The 120-day period may be extended by mutual agreement of Recipient and Provider. If the parties are unable to reach agreement within the negotiation period, Recipient will be free to offer rights in the Invention to third parties."

"Provider's review must be limited to identifying provider's Confidential Information (and removal of such information may be required) and/or identifying any patentable inventions disclosed in the publication (and patent filings prior to publication/submission may be required). Otherwise, provider must not have any right to edit or veto the content of the publication. Provider may "comment" on the content."

"If Investigator publishes Modifications, Provider agrees to negotiate in good faith the terms of a material transfer agreement under which Investigator may share Modifications with other academic researchers for non-profit research purposes."

Appendix 29

Useful Confidentiality Clauses

Source: A session by Heidi Henning, J.D., at the National Association of College and University Attorneys, November 2004.

"If Company wishes to provide Institutions with Confidential Information, Institution may accept that information provided it is background in nature, i.e., the Confidential Information would not be necessary to include in any publication of the results of the Research Project nor necessary for other scholars to verify those results. Before providing any Confidential Information to Institution, Company shall provide Institution with a non-confidential summary of such Confidential Information, and Institution shall, at its sole discretion, accept or decline to receive the Confidential Information or any portion thereof."

"For purposes of this Agreement, "Confidential Information" is (i) information disclosed by Provider in written, electronic or other tangible form and marked as confidential at the time of disclosure or designated as confidential by written notice to Recipient within thirty (30) days after disclosure to Recipient, and (ii) information disclosed in oral, visual or other non-tangible form if such information is designed as confidential by confirmatory written summary or description of such information sent to Recipient within thirty (30) days after disclosure of such information to Recipient."

"Subject to Section X [publication provisions], during the term of this Agreement and for a period of three years thereafter, Recipient shall cause all Confidential Information (as defined below) relating to the Materials that is disclosed to it by Provider to be used only for purposes of the Research Project and to be treated according to the same internal security procedures and with the same degree of care regarding its secrecy and confidentiality as Recipient treats similar information of its own within its organization."

Standard exclusions from confidentiality:
"Confidential Information" means information that is marked as confidential, or, if orally disclosed, is indicated at the time of disclosure as confidential and provided in written form within thirty days. Not withstanding the foregoing, the receiving party will have no obligation of confidentiality relating to any information of the disclosing party that:

(i) is or becomes part of the public domain through no fault of the receiving party;

(ii) is known to the receiving party prior to the disclosure by the disclosing party, as evidenced by documentation;

(iii) is independently developed by the receiving party without any breach of this Agreement as evidenced by documentation;

(iv) is subsequently obtained by the receiving party from a duly authorized third party;

(v) is publicly released as authorized under this Agreement by the disclosing party, its employees or agents, or;

(vi) is required to be disclosed by judicial or legislative action or government regulation.

Appendix 30

Useful Language for Simple Biomaterials License

Licensee agrees to retain control over the Material, and not to distribute them to third party for any reason, with or without consideration, without the express prior written consent of the University.

Licensee agrees to utilize the Material solely for the purpose of Licensee's own internal research and screening programs. It is understood that Licensee will be using the Material as a research tool. University will not acquire any rights of any kind in any of Licensee's proprietary compounds, their compositions or uses, identified as a result of Licensee's use of the Material as contemplated by this Agreement. Licensee will have the sole and unrestricted right to use all data developed as a result of its use of the Material.

Licensee agrees in its use of the Material to comply with all applicable statutes, regulations and guidelines, including those of the Public Health Service and the University regulations and guidelines.

Licensee agrees that this Agreement does not preclude the University from distributing the Material to third parties for research or commercial purposes.

Licensee acknowledges that it is in possession of the Material. University agrees to make good faith efforts to replace such Material, as available and at reasonable cost, in the event of its unintentional destruction, but will not be required to do so more than once per year nor more than five times total.

Licensee is encouraged to publish the results of its research projects using the Material. In all oral presentations or written publications concerning this Material, Licensee will acknowledge the contribution by the named inventors of this Material, (*insert inventor's name*) unless requested otherwise by the University or Drs. (*the inventors*).

By entering into this Agreement, University neither directly nor indirectly endorses any product or service provided, or to be provided, by Licensee, whether directly or indirectly related to this Agreement. Licensee will not state or imply that this Agreement is an endorsement by University or its employees. Licensee must not use the name "University of XXXX" without the express written permission of University.

Negation of Warranties and Indemnity

NOTHING IN THIS AGREEMENT WILL BE CONSTRUED A WARRANTY OR REPRESENTATION THAT THE MATERIAL, LICENSED PRODUCT, OR ANYTHING ELSE MADE, USED, SOLD, OR OTHERWISE DISPOSED OF UNDER ANY LICENSE GRANTED IN THIS AGREEMENT IS OR WILL BE FREE FROM INFRINGEMENT OF PATENTS, COPYRIGHTS, AND TRADEMARKS OF THIRD PARTIES.

UNIVERSITY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, PERTAINING TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE MATERIAL OR LICENSED PRODUCT OR ANYTHING ELSE LICENSED, DISCLOSED, OR OTHERWISE PROVIDED TO LICENSEE UNDER THIS AGREEMENT. UNIVERSITY'S TOTAL LIABILITY UNDER THIS AGREEMENT IS LIMITED TO THE COSTS AND FEES PAID TO UNIVERSITY UNDER THIS AGREEMENT.

LICENSEE AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS UNIVERSITY, ITS FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, OFFICERS, TRUSTEES AND AGENTS AND EACH OF THEM (THE "INDEMNIFIED PARTIES"), FROM AND AGAINST ANY AND ALL CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "CLAIMS") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE INDEMNIFIED PARTIES RELATED DIRECTLY OR INDIRECTLY TO OR ARISING OUT OF THE DESIGN, PROCESS, MANUFACTURE OR USE BY ANY PERSON OR PARTY OF THE LICENSED PRODUCTS AND ANY EMBODIMENT OF THE MATERIAL EVEN THOUGH SUCH CLAIMS AND THE COSTS (INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE) RELATED THERETO RESULT IN WHOLE OR IN PART FROM THE NEGLIGENCE OF ANY OF THE INDEMNIFIED PARTIES OR ARE BASED UPON DOCTRINES OF STRICT LIABILITY OR PRODUCT LIABILITY; PROVIDED, HOWEVER, THAT SUCH INDEMNITY WILL NOT APPLY TO ANY CLAIMS ARISING FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF ANY INDEMNIFIED PARTY. LICENSEE WILL ALSO ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE INDEMNIFIED PARTIES PURSUANT TO THIS PARAGRAPH ##, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.

Appendix 31

Useful BML Language

"Licensed Product(s)" means the Material and any product that contains the Material or any part thereof, which could not have been made but for the Material, or in whose development the Material was used.

“Field” means research reagents ***only*** and specifically ***excludes*** human therapeutics or any use in humans, including clinical trials.

“The University hereby grants, and the Licensee accepts, a worldwide non-exclusive license to make, have made, use, offer for sale and sell Licensed Product in the Field and in the Territory. Sublicensing is expressly ***prohibited***. This grant does not include the right to file patent applications for or the use of the Material or Licensed Product without University’s express prior written approval, which approval will be in University’s sole discretion.”

“Field” means research reagents ***only*** and specifically ***excludes*** human therapeutics or any use in humans, including clinical trials.

"Net Sales" means the gross amount of consideration that is paid by unrelated third parties to Licensee for Licensed Products by sale or other mode of transfer, less discounts and allowances given and actually taken and that are customary in Licensee’s trade, other than commissions paid to individuals whether they be with independent sales agencies or regularly employed by Licensee and on its payroll, or for the cost of collections.

If Licensed Product is sold in a combination product also containing component(s) that are not Licensed Product, then Net Sales for each combination product must be calculated by multiplying the net sales of that combination product by the fraction A/(A+B), where A is the gross selling price of the Licensed Product sold separately and B is the sum of the gross selling price(s) of the other active component(s) when sold separately.

Termination

Licensee may terminate this Agreement by giving University notice in writing at least ninety (90) days in advance of the effective date of termination, provided that Licensee will thereupon cease using any Material and Licensed Product.

This Agreement will terminate if Licensee: (a) is in default in payment of royalty or making of reports; (b) is in breach of any other contract provision; or, (c) makes any materially false report, and Licensee fails to remedy any such default, breach, or report within thirty (30) days after written notice thereof by University.

Upon termination of this Agreement for any reason Licensee must return to University all Material and Licensed Product then in Licensee’s possession or under Licensee’s control, or provide University with certification of their destruction.

Surviving any termination are: (a) Licensee's obligation of Paragraph XX to make the termination report; (b) Licensee's obligation to pay royalties accrued or

accruable; (c) Licensee's obligation of Paragraph XX to keep records and allow a final audit; (d) the provisions of Article XX (Negation of Warranties and Indemnity).

APPENDIX 32

ALTERNATIVE DISPUTE RESOLUTION

1. The parties must attempt to resolve through good faith discussions any dispute which arises under this Agreement. Any dispute may, at the election of either party, be referred to the chief executive officers, or their designated representative. If they are unable to resolve the dispute, except one having to do with the scope, enforceability, infringement or validity of a patent, within thirty (30) days after delivery of written notice of the dispute from one party to the other, either party may seek to resolve it by initiating Alternative Dispute Resolution ("ADR") in which the (*name of group, for example, the American Arbitration Association, and geographical location*) will select the arbitrator (the "Arbitrator"), as provided herein.

2. An ADR must be initiated by a party by sending written notice thereof to the other party and JAMS, which notice must state the issues to be resolved. Within ten (10) business days after receipt of such notice, the other party may, by sending written notice to the initiating party and JAMS, add issues to be resolved. Within twenty (20) business days after the date of the original ADR notice, JAMS must nominate to the parties at least five (5) qualified nominees from JAMS' panel. The parties must will five (5) business days after the receipt of such nominations to agree on an Arbitrator or, failing to agree, to rank-order their preferences with the most preferred being given the lowest number, and mail the rank-order to JAMS. JAMS will notify the parties of their selection. If all nominees are unacceptable to a party, the procedure must be repeated and, if the parties cannot select an Arbitrator the second time, JAMS must select the Arbitrator.

3. Each Arbitrator must be a lawyer and must have experience in the biopharmaceutical field and in intellectual property law matters, and must have no relationship with either party that would constitute a conflict-of-interest or otherwise prevent this Arbitrator from serving as a neutral arbitrator. In the event of a dispute between the parties relating to the calculation of any royalties or the amount of other consideration payable under this Agreement (including without limitation, the results of any audit conducted on behalf of a party pursuant to Article 8), then, notwithstanding the foregoing, the Arbitrators must be partners or full members of an internationally recognized certified public accounting firm which is not an auditing firm for either party and has not provided material services to either party during the last two (2) year period prior to the date of ADR initiation.

4. The Arbitrator must hold a hearing to resolve the issues within one hundred twenty (120) business days after selection. The location of the hearing must be (*geographical location*). Each party may be represented by counsel. Prior to the hearing, the parties will be entitled to engage in discovery under procedures of the Federal Rules of Civil Procedure; provided, however, that a party may not submit more than twenty five (25) written interrogatories or take more than seven (7) depositions. There may not be, and the Arbitrator must not permit, any discovery within thirty (30) days of the hearing. The Arbitrator will have sole discretion regarding the admissibility of evidence and conduct of the hearing. At least five (5) business days prior to the hearing, each party must submit to the other party and the Arbitrator a copy of all exhibits on which such party intends to rely at the hearing, a

pre-hearing brief (up to 15 pages) and a proposed disposition of the dispute (up to 5 pages). The proposed disposition must be limited to proposed rulings and remedies on each issue, and must contain no argument on or analysis of the facts or issues; provided, however, that the parties will not present proposed monetary remedies. Within five (5) business days after close of the hearing, each party may submit a post-hearing brief (up to 5 pages) to the Arbitrator. The parties must hold and will cause the Arbitrator to hold all information provided hereunder confidential.

5. The Arbitrator must render a disposition on the proposed rulings as expeditiously as possible after the hearing, but not later than fifteen (15) business days after the conclusion of the hearing. The Arbitrator must rule on each issue and must adopt in its entirety the proposed ruling of one of the parties on each issue. In the circumstances where the Arbitrator rules for a party on a claim in the form of a claim for monetary damages, the parties will then submit a proposed remedy within ten (10) days of notice of the ruling. The proposed remedy may be accompanied by a brief in support of the remedy not to exceed five (5) pages. The Arbitrator will rule on and adopt one of the proposed remedies within ten (10) days of their submission. The Arbitrator's disposition will be final and not be appealable, except that either party will have the right to appeal such disposition on the basis it was affected by fraud or bad faith in connection with the ADR proceedings. A judgment on the Arbitrator's disposition may be entered in any court having jurisdiction over the parties.

6. Except as otherwise provided in this Article 16, JAMS Rules must be used in connection with the ADR.

7. A party may not be prohibited from bringing a claim for resolution under this Article 16 on the ground that the claim could have been brought during an earlier proceeding under this Article 16.

8. The substantially prevailing party in arbitration or in any judicial or administrative action or proceeding arising under or in connection with this Agreement will be entitled to reimbursement from the other party for its reasonable costs and attorneys fees, including those on appeal, and including without limitation, the cost at the hourly charges routinely charged by the person providing the services, the time of legal assistants, secretarial and clerical overtime, and fees and expenses of experts retained by counsel.