

Yale Policies on Incoming Material Transfer Agreements (MTAs)

The Grants and Contracts office ("G&C") is the office designated by Yale University ("Yale") to review all academic MTAs and all commercial MTAs for incoming material, and to obtain the authorized signature on behalf of Yale for agreements that are acceptable under Yale's policies and consistent with Yale's academic mission. G&C strives to review MTAs in a timely fashion to minimize any potential delays in research involving the requested materials or information. MTAs are reviewed by G&C (sometimes in consultation with the Office of Cooperative Research ("OCR")) and are then signed by an authorized University official to protect certain interests of Yale and its faculty. It is important that faculty investigators also review MTAs to make sure that they personally agree to comply with the terms and that the terms of the MTA are consistent with the objectives of their research.

The single most significant delay in finalizing these agreements is in negotiating acceptable terms with companies, and in some cases with other universities. While the majority of MTAs require little negotiation, the ones that do require negotiation, often involve material or information that is being transferred from entities outside the university to Yale's faculty. In particular, the majority of negotiations involve a company's desire to own intellectual property and to control publications related to their Material. Yale needs to preserve freedom to publish in a timely manner and seeks to retain rights to Yale inventions until the providing company or an alternative entity takes license and commits to actively commercialize them. Without these rights, Yale would lose its ability to ensure Yale inventions reach the marketplace and benefit society. The following guidelines are used by G&C to review agreements and are provided so that both Yale faculty and the providers of material can understand Yale's position on certain terms typically included in MTAs.

Definition of "Materials"

MTAs typically define "Materials" to be those materials that the Provider is supplying. In addition to the original materials being provided, the defined term "Materials," may include other items. Typical and acceptable additions include: portions, purebred progeny, and unmodified derivatives of the original material. The definition of Materials is important because the MTA contains a number of terms directed to the Materials. Materials usually can not be provided to another party, be used for commercial purposes, and are owned by the Provider. On occasion, MTAs will broaden the definition of Materials to include derivatives, modifications, and improvements of the materials and similar terms that could be construed to be new Inventions. Yale can not agree to include in the definition of Materials any subject matter that has the potential to be an Invention.

Publications

Providers sometimes seek terms that would place restrictions on publications resulting from Yale's use of the materials. In such cases, the Provider is interested in protecting confidential information related to the materials and new information generated through Yale's use of the materials. On the other hand, Yale needs to preserve its ability to publish its research.

Terms at issue:

A. Restrictions on publication or publication only with Provider's prior approval

Some MTAs include terms that explicitly restrict any publication of data obtained through the use of the materials. In other cases, Providers seek terms that would make any publication of data obtained through the use of the Material subject to the approval of the Provider. As an academic institution, Yale can not accept MTAs that place a restriction, or have the potential to place a restriction, on publications.

B. Provider's prior review of publications

Although Yale can not agree to most restrictions on publications, it is customary for MTAs to require Yale to provide manuscripts or other types of written or oral disclosures involving the use of the Provider's materials to the Provider for review and comment prior to disclosure (e.g. submission to a journal for publication, presentation of a poster or lecture, etc). The Provider is typically afforded thirty (30) to sixty (60) days to review and comment on a manuscript prior to Yale's disclosure, (the "Pre-submission Period"). Yale may agree to such terms in an MTA. Faculty should review their MTAs to ensure that they agree with the term of the Pre-submission Period. Yale will not agree to periods greater than sixty (60) days without the prior approval of its requesting faculty member.

C. Delays in publication

In addition to the Pre-submission Period, the Providers' MTA may contain terms requiring a further delay in the submission of publications to a journal, or other disclosure, upon the request of the Provider in order to allow the Provider to file a patent application ("Delay Period"). Delay Periods range from thirty (30) days to sixty (60) days. While these Delay Periods may be acceptable to Yale, Faculty should review their MTAs to ensure that they agree with the term of the Delay Period. Yale's policy is that the combined Pre-submission and Delay periods can not exceed a total of ninety (90) days.

D. Modifications to publications suggested by Provider

Some MTAs require Yale to include modifications to manuscripts that are suggested by the Provider. Yale considers such terms to restrict Yale's academic freedom regarding publications and can not agree to such terms. On the other hand, Yale will usually agree to consider any comments provided by the Provider and Yale will agree to remove from the manuscript any of the Provider's Confidential Information that Yale is under an obligation to keep confidential. Yale can not agree to allow the Faculty's data resulting from research using the Material to be considered the Provider's Confidential Information. Faculty members should also be aware that the deletion of the Provider's Confidential Information from a manuscript may render it unacceptable for publication in certain journals.

E. Co-Authorship with Provider's investigators

MTAs may include terms that require the Yale investigator to include the Providing scientist as a co-author on any publications resulting from the use of the Material. It is inappropriate for such terms to be included in an MTA unless there is a true collaboration between the Provider and Yale investigators. Manuscripts should conform to the principles of the "Uniform Requirements for Manuscripts Submitted to for Biomedical Journal" as published by the New England Journal of Medicine 324:424-8, 1991 "Journal" and to the standards outlined in the Guide to the Responsible Conduct of Research at the Yale School of Medicine (Guide) (linked to on our G&C website...check exact title). Credit for authorship shall conform to the standards of the Journal and the Guide. One or more of Provider's scientific personnel may be designated as co-authors on a publication related to such Study if such personnel meet the standards of intellectual contribution as detailed in the Journal and the Guide.

Confidential and proprietary information may be provided along with the requested Material. MTAs often contain terms requiring Yale to maintain such information as confidential. It is important for faculty investigators to review confidentiality terms in MTAs to ensure that any information, such as sequence information or the molecular structure of a compound, which is required to be kept confidential under the MTA will not be required for the publication of research results.

Terms at issue:

A. Defining confidential information

Because of Yale's concerns regarding the ability of its Faculty to publish the results of their research and because of a customary requirement to keep certain proprietary information as confidential, it is necessary for MTAs to carefully define that information which is required to be kept as confidential by Yale (the "Confidential Information"), if any. As stated above, Yale can not agree to keep as confidential any information (e.g., data) generated by the Faculty through the use of the Material. For this reason, it is necessary for Yale to require that Confidential Information be narrowly defined as information received from the Provider in the sole context of the subject of the MTA that is designated in writing as confidential. It is important for Confidential Information to be indicated as such in writing to eliminate any ambiguities regarding that which is Confidential Information and that which is not, such as data generated by Yale.

B. Term of confidentiality obligation

It is customary for MTAs with confidentiality provisions to require that the Confidential Information be kept as confidential for as long as three (3) to five (5) years. Some Providers may request longer periods of confidentiality; Yale prefers shorter periods, but in any case the period must be defined. The period of confidentiality is limited due to the practicality of managing the confidential information.

Intellectual Property

The most frequent negotiations in MTAs are related to intellectual property/inventions resulting from the use of the Provider's materials by Yale. Since the Provider is often supplying the materials at no cost to Yale, it is customary for the Provider to request some access to intellectual property/inventions developed by Yale through the use of its materials.

Terms at issue:

A. Ownership of inventions

Provider MTAs at times seek terms that will require any inventions made through the use of the materials ("Inventions") be owned by, or assigned to, the Provider. In addition, some Providers may seek terms that would require Yale to assign

inventions to the Provider if Yale breaches the terms of the MTA, or if Yale uses the Material for research other than what is described in the MTA. It is onerous and inappropriate for the Provider to obtain ownership of inventions made through the use of their materials. Furthermore, such ownership is contrary to Yale's policy and the laws associated with federally-funded research. Yale can not accept such terms, and may replace any such terms regarding ownership or assignment with language that grants the Provider the opportunity to take a license to any such Inventions.

B. Options

The grant of an opportunity to take a license is customary when the Provider is a for-profit entity and it is called an "Option". Options may include the right to take an exclusive or non-exclusive license on terms that will be negotiated between the parties. Yale sometimes accepts option terms in MTAs, particularly on Provider MTA's; however, the option must be a "first" option in which Yale gives the Provider the opportunity to reach agreement on the terms of a license prior to offering third parties a similar opportunity, or the option may be an "exclusive" option for a fixed period of time during which Yale can not offer a license to a third party (the "Option Period"). The Option Period is typically three (3) months from the time Yale notifies Provider of the making of an Invention. Yale will not agree to Option Periods longer than ninety (90) days. The reason for this is that the value of certain inventions may decrease over time (for example, the value of an invention may decrease after its publication). Option and negotiation periods can always be extended by mutual agreement between Yale and the Provider.

C. Pre-negotiated Royalty Rates

Provider MTAs sometimes propose pre-set royalty rates and other terms along with the grant of an option, stating the terms under which a license will be negotiated. Yale can not agree to pre-negotiated royalties in an MTA for a number of reasons. First, it is difficult to anticipate an appropriate royalty rate for an invention that has not yet been made. Second, depending on the Yale facility in which the research is conducted, certain tax laws [LINK to IRS rev. proc 97-14] may prohibit Yale, as a non-profit institution, from performing research in which Inventions are encumbered under terms with a pre-negotiated royalty.

D. Non-exclusive royalty-free licenses

A number of MTAs from for-profit Providers contain a requirement that Yale agree to grant the Provider a non-exclusive, royalty-free license for commercial purposes to any Inventions. Yale may agree to this language under certain very limited circumstances. However, Yale will not agree to granting a non-exclusive license with the right to sublicense, as this could potentially lead to a situation in which Yale and the Provider are competing with each other to commercialize any inventions resulting from the use of the Material. Furthermore, it is important for Yale investigators to understand that agreeing to

such language will make it unlikely that the Yale investigator and Yale will receive any royalties or other revenues from the commercialization of any Inventions resulting from research utilizing the materials. As opposed to a license for any commercial use, it may be appropriate for Yale to agree to grant a non-exclusive royalty-free license for the Provider's internal research purposes.

E. Exclusive royalty-free licenses

A few MTAs will contain language requiring Yale to grant to the Provider an exclusive, royalty-free license. This language basically gives the Provider the right to commercialize Inventions without making any payments to the Yale. Furthermore, such language prevents Yale from licensing Inventions to third parties. This language is unacceptable to Yale.

G. Right of first refusal

Providers' MTAs that contain the grant of an option may also contain language that grants to the Provider a right of first refusal. In the event that Yale and the Provider are unable to reach agreement on the terms of a license for an Invention that falls under an option and Yale subsequently negotiates a license with a third party, this language requires that Yale, prior to entering into a license agreement with the third party, offer Provider a license on the terms negotiated with the third party. If the Provider rejects the terms of the license, then Yale is then free to license the Invention to the third party. The right of first refusal language may make it very difficult to negotiate with a third party. Yale may accept such language, but only under certain very limited circumstances, and only provided that the right of first refusal be limited only to specific financial terms (such as royalty rate), and the time period for such a right be limited to no more than 6 months.

H. Definition of "Materials"

MTAs typically define "Materials" to be those materials that the Provider is supplying. In addition to the original materials being provided, the defined term, "Materials," may include other items. Typical and acceptable additions include, portions, purebred progeny, and unmodified derivatives of the original material. The definition of Materials is important because the MTA contains a number of terms directed to the Materials. Materials usually can not be provided to another party, can not be used for commercial purposes, and are owned by the Provider. On occasion, MTAs will broaden the definition of Materials to include derivatives, modifications, and improvements of the materials and similar terms that could be construed to be new Inventions. Yale can not agree to include in the definition of Materials any new material that has the potential to be an Invention.

I. Patent prosecution

Patent prosecution for Inventions is something that should be managed by the owner of the patent rights to ensure that the

patent is prosecuted to the fullest extent. MTAs may contain terms that give the Provider the right to file and prosecute patent applications on Inventions. If such Inventions are solely owned by Yale, then Yale can not accept this language. When the Provider is granted an option to Inventions and is reimbursing Yale for patent expenses, Yale may give the Provider the right to review and comment on applications. MTAs may also include language requiring Yale to file on any Inventions made through the use of the materials. Yale evaluates inventions made by its faculty and files patents on inventions that meet certain criteria. Yale will not agree to language in an MTA that requires Yale to file patent applications on Inventions unless the Provider agrees to pay all patent expenses.

J. Conflicts between terms MTAs and other MTAs or sponsored research

Since MTAs can encumber Inventions by the grant of an option to Inventions or by Yale agreeing to grant to the Provider a license, it is important for Yale investigators to determine whether the encumbrances in an MTA conflict with the terms of other MTAs or with sponsored research agreements which may also contain encumbrances. Obviously, Yale can not agree to grant both the Provider of a Material and a sponsor of research using the Material an exclusive license to the same invention. Therefore, it is extremely important that Yale investigators inform G&C of any potential conflicts. In addition, Yale cannot represent and warrant that no such conflicts exist or may arise in the future, except by use of language specifically approved by Yale's General Counsel's office. Such language limits Yale's review of conflicting documents to only those that apply to the Scientist, and not Yale University as a whole. One example is the following: "Institution represents that, to the best of its knowledge after good faith review by its Grant and Contract Administration office, except for any prior agreements and grants between Institution and government organizations which provide funding to or for the Scientist using Materials under this Agreement, no agreement with any other person or body provides funding for or relates directly to the activities described in Appendix A which will result in obligations inconsistent with the terms of this Agreement. After the Effective Date, Institution will not enter into any agreement on behalf of Scientist with any other person or body which would result in obligations inconsistent with the terms of this Agreement without Provider's prior written consent".

Miscellaneous Provisions

In addition to the broad categories of terms described above which are typically included in incoming MTAs, there are a number of other issues related to both incoming and outgoing MTAs which must be reviewed and often require modification.

Terms at issue:

A. Parties to the agreement

Yale University, and not the Faculty member or a Department or School, is the party to all MTAs. Many MTAs are drafted with the faculty investigator as the party to the agreement. Yale will modify the agreement such that "Yale University, on behalf of Dr. _____, agrees..." Although Yale's faculty investigator is not a party to the agreement and although the faculty investigator does not have the authority to bind Yale to the agreement, Yale may require that the investigator sign a side letter to indicate that he or she has read the agreement and agrees to abide by its terms. The investigator's signature on the side letter may be required before Yale's authorized representative will sign the agreement. Any questions regarding the terms of the agreement may be directed to G&C.

B. Use of name

Yale is concerned with the use of its name in association with MTAs. For this reason, Yale may require the addition of certain language in MTAs that places a prohibition on the use of its name by the other party to an MTA without the prior written approval of the appropriate officer of Yale.

C. Human Materials

There are a number of issues to be considered when providing or receiving materials of human origin. G&C should be informed of any such transfers, so that the appropriate Institutional Review Board approvals, biosafety approvals, and other related issues can be addressed.

D. MTAs and Funding

The appropriate Grant and Contract Administration Office (e.g. main campus or Medical School) (G&C) needs to be informed by its faculty investigators when any MTA includes funding of any kind. Normally, funding will mean that this is a research program and should be handled with the appropriate research agreement or collaborative research agreement, rather than a MTA. Should a sponsor want to provide a gift, such gift should not be tied to MTA's, since gifts are considered to be unrestricted and terms in the MTA cannot apply to a gift. G&C/OCR needs to be notified when a gift is offered by a party with which Yale has already signed an MTA. It is inappropriate for a company to receive an option to inventions under an MTA from research which is funded by a gift from the same company. In cases where faculty need research funding in addition to material, a research agreement must be used and the appropriate budget should be submitted to the G&C Office.