Material Transfer Agreements (MTA)

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Transforming Ideas into Opportunities

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Outline

1. Why MTAs are important
2. Factors to consider for academic MTA's
3. Commonly negotiated terms
4. Tactics for successful negotiations
5. Special Issues: Regulated and Proprietary Materials
6. Special Issues: Label licenses
7. Special Issues: Transfer of human material
8. Q & A

Why MTAs are important?

1. Enables researcher to acquire material they need to move their research forward.
2. Helps in defining ownership of any research results generated with the use of material
3. To protect any proprietary material
4. To facilitate researcher's rights to publish
5. To inform recipient when material being transferred may be infectious, hazardous or subject to special regulations
6. To address any potential issues like liability/ indemnification
7. To transfer human samples, an MTA is required to ensure compliance with laws and regulations

Factors to Consider for Academic MTAs

1. What material is being transferred?
2. Rights to publish? Important factor for academic institutions
3. Authorship matter?
4. Who will own the intellectual property?
5. Does MTA grant's any ownership rights or royalty-free license to the provider for university invention created with use of material?
6. Is material export controlled?

Commonly Negotiated Terms

Ownership and IP – Provider remains owner of materials and may address ownership of any new material created through use of Provider material.

Publication – Provider may wish to limit whereas university researchers must be able to publish.

Confidentiality – Providers of proprietary materials may include confidentiality obligations that impact publication and dissemination of research results.

Limitations on Use- For research purposes only. Limited to PI and not allowed to provide to third parties. Export controls and human subject research.

Liability – Who is liable for any damages resulting from the transfer or use of the material?

Special Concerns for Regulated and Proprietary Materials

Hazardous Materials
Export Controlled Materials
Proprietary Materials
Materials Limiting Transfer Rights

Tactics for Successful Negotiations

1. Have a general idea of what the material is, where it's coming from (university or for profit entity), and how the researcher will be using the materials.
2. Start with standard templates (common sources- UBMTA, AUTM MTA resources, institutional template)
3. With non-standard terms:
    1. Pay attention to definitions
    2. Review the IP potential for inventions and other forms of IP taking to consideration institutions intellectual property policy
    3. Consult appropriate offices for assistance (export controls, intellectual property, IRB/IACUC, biosafety)
    4. Always have researcher on board before agreeing to any non-standard terms

Limited Use Label Licenses

What is Limited Use Label License?

A license of limited scope granted to a purchaser of a product by a notice on the label of a patented product or a product used in a patented process.

Example of a Label License Provision

This product and/or its derivatives are subject to one or more U.S. and foreign Patents (for a complete list, please click here. By purchasing the product, the purchaser agrees to comply with the terms of this Limited Use Label License. **The product is provided to purchaser for research use only**. Purchaser may not transfer or otherwise sell this product or its derivatives to a third party without the express written permission of Company, Inc. No rights are given to the purchaser to use the product or its derivatives for commercial use or purposes as defined below.

"Commercial Use" shall mean, but not be limited to: (a) providing a service, information, or data to a person or entity not party to this Agreement for financial gain; (b) production or manufacture of products for general sale or products for use in the manufacture of products ultimately intended for general sale; (c) use in the development of products for sale to third parties; (d) use of the product for therapeutic, diagnostic, or prophylactic purposes; or (e) use in connection with proficiency testing service(s), including but not limited to, calibrations or tests on the same or similar items or materials in accordance with predetermined conditions.

Why Should We Be Worried About Label Licenses?

Any inventions developed by university researchers using a research tool subject to a label license may be subject to the label license term limitations.

Limitations on materials made using the transferred material, not just incorporating the material.

Limitations on modifying materials or using components, and limitations on quantity or amount purchased.

Example

"Company will not assert claim against recipient or buyer of infringement of the above patents based upon the manufacture, use, or sale of a therapeutic, clinical diagnostic, vaccine or other product developed in research by recipient or buyer in which this product was employed provided that neither this product or its components was used in the manufacture of such product"

Special Issues: Transfer of Human Material

- Privacy issues- strict restrictions on personally identifiable information
- Compliance with all applicable federal regulations, if required, have protocol(s) reviewed and approved by the Institutional Review Board (IRB)
- General term that transferred material may not be used in humans for any diagnostic, prognostic or treatment purposes

"14. Provider ensures that the Original Material provided pursuant to this Agreement was collected or will be collected in accordance with the standard patient informed consent procedures of Provider in effect at the time of collection and subject to approval or an exemption determination by the Provider Institutional Review Board ("IRB") or equivalent. Recipient may review the consent form used in collection of Original Material as well as any subsequent revisions thereof. The Original Material provided to Recipient will not be accompanied by personally identifiable patient information and for Original Material subject to U.S. laws, will not be accompanied by "Protected Health Information" ("PHI") as defined in 45 CFR 164.501 or personally identifiable information as described in 5 USC Section 522. However, if de-identified information ("Information") is provided that nevertheless could be used to identify an individual at a later time, a Recipient in the U.S. hereby agrees to treat Information as PHI or personally identifiable information, as applicable. If Information is provided, it will be described in Exhibit C. In any circumstances, the Recipient agrees to use the Information only for the research purpose as set forth in Exhibit C and to the extent necessary for that specific research, and will not contact or make any effort to identify human subjects from whom the Original Material was obtained without specific written approval from the Provider."

(AUTM MTA Template for Human Tissues)

THANK YOU!

Q & A