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Taming the MTA Beast: Tips for Successfully Negotiating and Managing Material Transfer Agreements

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The formal presentation will begin at Noon Eastern

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Taming the MTA Beast: Tips for Successfully Negotiating and Managing Material Transfer Agreements

Speakers:

Victoria M. Malia, J.D., Associate Director and Senior Contracts Officer, Columbia Technology Ventures, Columbia University

Erika R. Carmean, J.D., Contracts Counsel, Office of the General Counsel, Howard Hughes Medical Institute

November 13, 2013

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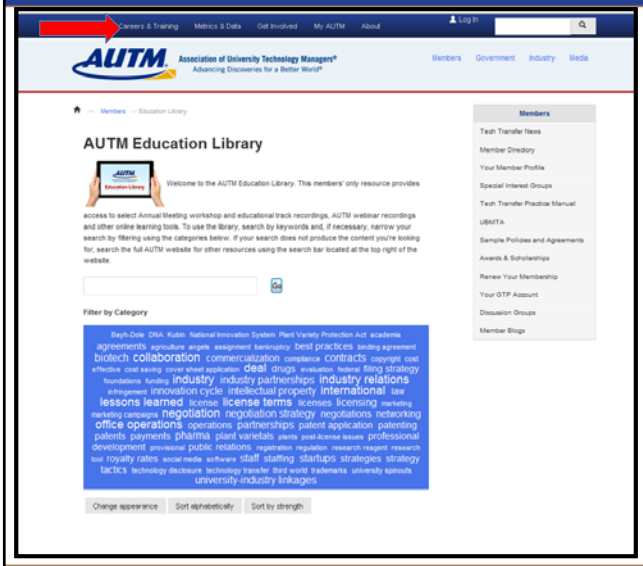

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Taming the MTA Beast: Tips for Successfully Negotiating and Managing Material Transfer Agreements

Victoria M. Malia, J.D.
Columbia Technology Ventures

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Practical Tips for Efficiently Managing MTAs

Educating your institution's researchers and administration about why MTAs matter is time well-spent

1. **Improved cooperation from PIs & their labs**
2. **Increased support for the administration of MTAs from administration.**
3. **Increased efficiency in the administration of MTAs and increased likelihood of having appropriate agreement terms.**

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Why MTAs Matter

- **Although MTAs do not generate revenue, there can be no output without input.**
- **If the researcher can't get the materials s/he needs to do a project, the research doesn't get done, competitors get ahead.**
- **If the research doesn't get done, society loses:**
  - Research that isn't done can't be published, and thus is not shared with others working on the same problem.
  - Research that isn't done can't lead to a commercial product or improvement to a process, etc., that will address a critical problem, benefit humanity, and possibly generate some revenue for your institution.

Why MTAs Matter

- **MTAs are agreements, not forms!**
- **Forms collect information**
- **MTAs are agreements that may be legally enforceable**

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Researchers' Priorities"*

1. What do we expect to get out of this?
2. Who is going to do what and by when?
3. Who will have access to our data?
4. Who will give public presentations and how much data will they reveal?
5. How will we assign authorship?
6. How will we decide when to publish?
7. Who owns the intellectual property?
8. Will we share our reagents with other labs?
9. What happens if one of us leaves the project?
10. What happens if one of us wants to form a separate, but related, collaboration with another lab?

*"Collaborator's Pre-Nup" excerpted from, "With All Good Intentions," Heidi Ledford, 452 Nature 682 (2008)

Organizational Priorities

Commonly-Negotiated Provisions:

Confidentiality

Publication

Ownership & Control of IP

Liability

Non-Profit Corporation

- Doesn't issue stock & uses any surplus funds to pursue its goals
- Exempt from income tax and other taxes*
- ***Pursuing goals while maintaining non-profit status***

**Provided non-profit adheres to various laws & regulations*

For-Profit Corporation

- Issues stock and distributes any profit as dividends to employees & shareholders
- ***Maximizing return to shareholders***

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Triage & Prioritize

- **Take 5 minutes when an MTA is received to separate the "routine" from the "exceptional"**
  - Identify "higher risk" vs. "lower risk" MTAs based on provider/recipient, materials, research plan
  - Review all correspondence submitted with the MTA
- **USE A STANDARD FORM WHENEVER POSSIBLE**
- **Set realistic expectations for the lab**

What is a "Routine" MTA?

- **MTAs that can be signed "as is"**
  - Standard Forms (UBMTA; SLA; NIH-TO)
  - Repositories (MMRRC; Addgene; KOMP)\
  - Specifically identified providers
  - After flagging specific issues for PI
- **MTAs requiring changes routinely requested/accepted**
- **Materials are published, non-hazardous, not of human origin, unpatented, not subject to third party rights**

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Handling Routine MTAs

- **Identify "buckets" of MTAs to be handled as routine**
- **Route to entry level or administrative personnel**
- **Designate personnel to handle specific categories of MTAs**
- **Use template emails**
  - To communicate with other parties
  - To flag issues for PI
- **Maintain central file of standard redlines**
- **Consider delegating signing authority and utilizing signature stamp/electronic signature**

Focus on MTA Process

- **Establish standard processes for handling MTAs**
  - Document processes for all team members
  - Re-examine processes periodically
- **Allocate resources appropriately to increase efficiency**
- **Use checklists, precedent and templates**
- **Actively manage process**
  - Use ticklers
  - Set rules for when to follow up on or abandon an MTA

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The Big Payoff

- **Streamlining processing of routine MTAs will pay huge dividends!**
- **HHMI's Incoming MTAs for FY 2012**
  - 1249 MTAs received; 1180 completed
  - 601 (51%) completed in 0-1 days
  - 816 (69%) completed in less than 2 weeks

Determining what is an "Exceptional" MTA

- **Do we have the right to transfer this material?**
  - Was this material made at our institution?
  - Does this material incorporate material that was obtained from an external party under an MTA or other agreement?
  - Was this material derived from humans?
- **Do we have the right to transfer this material for the proposed end use?**
- **Is this material hazardous?**
- **Is this material export controlled?**
- **Will this material be used in humans?**
- **Has this material been published / patented?**

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Recognizing Exceptional Circumstances

- **Need to ask questions!**
- **"Expediting" forms are helpful – see course materials for an example**
- **Not intended to be a hurdle**
- **For your institution's materials, keep good records so you don't ask the PI the same questions every time s/he wants to transfer the same material**

MTAs Are Not Administered in a Vacuum

- While researchers "should" be familiar with their institution's policies & the offices that administer these policies, the reality is quite different.
  - New researchers
  - In large labs, there may be a disconnect between the post-doc, graduate student, or technician actually doing the experiment and the PI, as well as the PI's administrator.
- The MTA administrator can serve as the hub, bringing everyone together

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Examples

- Our office sends an e-mail to the Principal Investigator ("PI"), so s/he is aware that a request has been made in her/his name. We also copy the PI's office and individual who made the request.
- Columbia's expediting form for incoming material informs the PI that s/he needs to work with the animal facility when requesting animals. Our office also informs the PI of this obligation via e-mail and copies the animal facility.

Examples, cont'd

- **Our Compliance Officer screens all agreements (not just MTAs) for export control issues using Visual Compliance software.**
  - Export control is not administered by the Contracts Group
  - Columbia has a separate Compliance office that administered all compliance matters, including export control matters, as well as attorneys in Columbia's General Counsel's Office.
  - PIs are brought into the process as soon as possible if there are any questions.

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Examples, cont'd

- **Agreements involving the routine purchase of materials are directed to Columbia's Purchasing Office.**
- **Most agreements involving human material are directed to Columbia's Clinical Trials Office.**
- **Agreements involving PI's affiliated with Howard Hughes Medical Institute ("HHMI") are reviewed and sent to HHMI's legal group for their comments and jointly negotiated.**
- **Attorneys in Columbia's General Counsel's Office are consulted any time we encounter non-standard agreement terms or unusual circumstances.**

Know the people in these offices, understand what their baseline positions are on issues that affect them, and bring them into the situation as early as possible if you anticipate any issues!

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Communicating with the Lab

- **Avoid "legalese"**
- **Communicate directly with PI**
- **Identify problematic terms for PI early in review process**
- **Frame issues in terms that the PI cares about**
  - How will it impact his/her ability to publish and meet journal requirements?
  - How will it impact his/her future research?
  - How will it impact dissemination of his/her discoveries?

Sample Email to PI

"If you create any derivatives, you cannot distribute them outside of your lab. Will you make any derivatives and if so, will you need to be able to distribute them (e.g., to other researchers after you publish, in order to meet your sharing requirements under the journal and NIH and HHMI policies)?"

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Roadblocks:
Successfully Negotiating "Sticky" MTA Terms

Definition of "Material"

- **"Material" shouldn't include new materials made by recipient**
  - Examples: derivatives, modifications, improvements, substances "which could not have been made but for the use of the material", information "embodied" in the material
- **MTA obligations attach to all "Material"**
  - Owned by provider
  - Limited scope of permitted use
  - Prohibitions on distribution and commercialization

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Negotiating Definition of Material

- **Pick your battles and be practical**
- **What is the material?**
  - Consumable or self-replicating?
  - Proprietary?
  - Subject to third party rights?
- **Will your PI make any derivatives, etc.?**
- **Is there an alternate source for the material?**

Negotiating Definition of Materials

- **Seek to understand other party's position**
- **Potential compromises**
  - Ownership to be negotiated or determined according to applicable law
  - Carve out new materials that involve an inventive step
  - Allow "non-novel and obvious derivatives" or "direct derivatives"
  - Grant provider "freedom to operate"
  - Limit commercial use or distribution
    - But preserve ability to distribute to non-profit researchers

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Material as "Confidential Information"

- **Potential to block publication**
- **May need to publish material for results to be reproducible**
- **Journal requirements**
  - Compound chemical structure, synthesis and characterization
  - Identity and properties of material
  - Sequence information

Sharing of Unpublished Material Among Non-profit Researchers

- Becoming more common for provider scientists to specify in an MTA their right of first publication.
- Not usually a problem, if the transfer is part of a collaboration and the scientists intend to jointly publish their work.
- Issues may arise if the recipient scientist has to wait for the provider scientist to publish before s/he can publish her/his work.
- MTA should specify that recipient won't be blocked from publishing her/his work if provider scientist doesn't publish within a reasonable time frame.

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"All inventions resulting from the research

- Overly-broad and vague – all research builds on previous research
- Difficult to determine when obligations concerning "inventions" end.
- Research will be published and everyone else will be free to use the results without any obligation to the provider*

  *Subject to dominating patents, of course.

- May be able to fix by adding the word, "directly"

  "All inventions resulting directly from the research"

"All inventions relating to the Material"

- **Overly-broad and vague**
- **How closely-related does it have to be?**
- **Does this include prior research? Future research?**
- **What about other research in the general field that doesn't even physically use the Material?**
- **What about other researchers working in the general field at your institution?**

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Make "Invention" a Defined Term

- **"Invention" means all patentable inventions and discoveries made* in the course of Recipient's use of the Material that are reported to Recipient's technology transfer office.**
- **"Material Inventions" means Inventions that necessarily contain or incorporate the Material and Inventions that necessarily use the Material.**

***18 USC 201(g), "The term 'made' when used in relation to any invention means the conception or first actual reduction to practice of such invention."**

What if the Provider Won't Budge?

- **Discuss the research with your licensing officer and researcher.**
  - **Are inventions likely to result from this work?**
  - **How will the terms affect the researcher's existing technology portfolio?**
- **Does your researcher have a "Champion" at the provider?**
- **Restrict the scope of the Research, if possible.**
- **Terminate MTA request.**

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Journal Policies on Availability of Materials

- **Authors must make materials available to other researchers**
  - Promptly upon request
  - "Reasonably"; "without undue qualifications"
- **Non-compliance may result in:**
  - **Retraction or formal statement of correction**
  - **Barred from future publication**
- **Complaints to journals made by the requesting PI**

Sample Journal Policy

- ***Nature* policy:**
  - "… a condition of publication in a Nature journal is that authors are required to make materials, data and associated protocols promptly available to readers without undue qualifications. Any restrictions on the availability of materials or information must be disclosed to the editors at the time of submission. Any restrictions must also be disclosed in the submitted manuscript, including details of how readers can obtain materials and information. If materials are to be distributed by a for-profit company, this must be stated in the paper"
  - "After publication, readers who encounter refusal by the authors to comply with these policies should contact the chief editor of the journal (or the chief biology/chief physical sciences editors in the case of Nature). In cases where editors are unable to resolve a complaint, the journal may refer the matter to the authors' funding institution and/or publish a formal statement of correction, attached online to the publication, stating that readers have been unable to obtain necessary materials to replicate the findings."

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Sample Email from PI to PI

I don't quite understand why you would want control over who gets [your reagent]. Most people consider sending reagents a pain -- not a privilege. Also note that [a colleague] already submitted his [plasmids] to Addgene. [Another colleague] gives out plasmids left and right. Your contributions are (and should be) acknowledged through citations to your papers, which laid the foundation of the field (especially the [journal] paper).

Best, [Requesting PI]

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Thank You!

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