



Introduction to IIAs/MTAs/ CDAs from the University Perspective

AUTM Webinar
June 6, 2017

Presented by:
Laura Savatski, BloodCenter of Wisconsin
Pamela L. Cox, Marshall, Gerstein & Borun, LLP



The following presentation reflects the personal views and thoughts of Pamela L. Cox and Laura Savatski, and is not to be construed as representing in any way the corporate views or advice of Marshall, Gerstein & Borun LLP or BloodCenter of Wisconsin and their affiliates, subsidiaries or divisions, nor the views or advice of the Association of University Technology Managers (AUTM).

The content is solely for purposes of discussion and illustration, and is not to be considered legal advice.

Overview of Acronyms

- Confidential Disclosure Agreements (CDAs) / Non-disclosure Agreements (NDAs)
- Material Transfer Agreements (MTAs)
- Inter-Institutional Agreements (IIAs)

Confidentiality Agreements

Purpose from university perspective:

- Prevent bar to patentability
- Disincentivize companies from using university's ideas without a license
- May be required for contractual/statutory compliance

Confidentiality Agreement Terms

University to university:

- There may be no need for an agreement

University to industry:

- Often depends on the “Purpose” (tied to narrow scope of subject matter) vs (framework agreement) and Permitted Use (evaluate license interest) vs (collaboration)

Resource: LES Model CDA in the works

What is Confidential Information

- Confidential or proprietary information provided by one party (disclosing party) to the other party (receiving party)
- May include tangible materials
- Marked?
- Receiving party may be restricted to certain individuals or functions (e.g. TTO not faculty)

Exceptions to Definition of Confidential Information

- Publically available
- Known prior to disclosure (shown by competent evidence)
- Lawfully received from third party without restriction
- Independently developed by personnel without knowledge of the confidential information (shown by contemporaneously written records)

Disclosures required by law should be addressed separately from an exception if you intend all other uses to remain prohibited.

Common Terms in CDA

- Maintain in confidence and not disclose to third party without consent
- Use limited to Permitted Use
- Return or destruction upon termination/request (state who decides)
- Surviving obligation of confidentiality and non-use for certain period of time (e.g. 1-5 years) *note*, this is different than the term of the discloser period
- Typically no trade secret protection addressed
- May or may not provide for injunctive relief
- Disclaimer of all warranties

How Does a CDA Differ from a MTA?

- Intangible vs tangible property rights
- Bailment
- Discussion of derived materials and use
- Safety or regulations regarding materials

MTAs

- Basic considerations
- Terms covered and general best practice
- Tracking and administration

MTA: General Considerations

- Likely the most common agreement
- To protect commercial aspects of the material
- Identify who owns the agreement
 - This is a business transaction
 - The agreement does not belong to the legal department
 - The people using the material need to understand their responsibilities
 - Keeping a database or an agreement listing is helpful
 - Departments that typically negotiate MTA's vary

MTA: General Considerations

- Often MTAs live in perpetuity or until material is destroyed so your owners need to be periodically reminded of their agreements
- Be sure you can comply with all of the terms
- Walk-away point
- Complexity of terms should match complexity of the deal

MTA: General Considerations

Protect the expected and unexpected outcomes

- Project delayed
- Publication of results
- Filing of patents or regulatory documents
- Generation of intellectual property with materials
- Relationship damaged

MTAs: Terms Covered

- Parties
- Description of the materials
- Ownership of material
- Purpose and allowed uses & restrictions on uses
- Money or other consideration
- Warranty and representations
- Reporting, confidentiality, notice provisions, future IP
- Term or termination
- Shipment particulars

MTA Toolkit from AUTM

- Uniform Biologic Material Transfer Agreement
- Genetically Modified Organisms
- Human Tissues and Specimens
- Biologic Materials
- Chemicals

UBMTA

- Promulgated in 1995 by AUTM to help harmonize terms and make administration of MTAs easier
- An official listing of signatories to the UBMTA is kept by AUTM and published on-line
- Your institution can be a signatory and choose to use the UBMTA terms for specific transactions
- You do not need to use the UBMTA exclusively
- Use an Implementing Letter to put the UBMTA into use for a transaction

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:
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:

UBMTA Terms

1. Provider owns the Material
2. Recipient owns Modifications (not progeny, unmodified derivatives)
3. Restrict to research use only
- 4&5. Recipient will not distribute Material except to non-profits with approval
6. No license for commercial use granted
7. Recipient will negotiate a license in advance of commercial use
8. Recipient will notify if filing patents claiming modifications or use of material
9. No warranty of any kind
10. Recipient assumes all liability for use
11. Proper acknowledgment of Material
12. Comply with laws regarding particular material (animals, DNA, etc.)
13. Termination on 30 days written notice by either party
14. Material supplied at no cost unless indicated in Implementing Letter

Administration

- The party who owns the material starts the process and provides the MTA to the receiving party
- If changes are needed, a redline copy is provided
- Typically a discussion with the scientist occurs on all incoming MTAs describing the terms and suggested edits
- Be sure to ask for Authorized Signatures from inexperienced parties
- Communicate the final document to all parties so the transfer can be started
- Reminding scientists of materials received from others is good practice

Negotiating Perspective Matters

- Parties may be looking for different outcomes
- Negotiating University to University is generally easy
- Differences or distance apart in perspectives impacts speed of negotiation
- Understanding the perspective of the other side and having experience with similar parties can speed negotiation
- Dealing with an inexperienced party like a biotech start-up can be challenging

IAs

Purpose of an Inter-Institutional Agreement:

- Address IP management and commercialization efforts regarding jointly-owned IP or in anticipation of an inventor leaving your institution and going to another
- To collaborate to create IP to commercialize jointly
- Funding of multi-parties requires an agreement
- See AUTM's Model IIA at: <http://www.modeliia.org/model-agreements.html>

IP Management in an IIA

- What forms of IP are covered – define scope of intellectual property and tangible property included
- Address how background rights or sideground rights will be handled. May they be included in a license with the covered rights?
- Who has primary responsibility for outside counsel and what role do the other party(ies) have in review/comment?
- How do the parties intend to address defense and enforcement with and without licensee?
- Who pays and for what? Is a party entitled to stop supporting and if so, what happens?

Marketing Efforts Under the IIA

- Typically one party is the lead with responsibility and authority to market and negotiate IP transfers
- What are the IP transfers authorized e.g. are MTAs and research agreements included?
- Ensure clear understanding of authority, proof may be required by potential licensee in due diligence
- Lead may or may not be an agent of the other(s)
- Address what happens if lead needs/wants to be replaced

Accounting for Consideration & Expenses

- Define amounts receivable, what expenses may be deducted, whether there is an administrative fee (if so, whether capped) and percentage of sharing
- Describe any variations to financial scheme that may occur, e.g. change in lead party
- What happens to non-cash consideration?
- What frequency will payments and reports be made? Will interest be charged?
- What records are required and may they be audited?

IP Transfers & Administration

- Typically the IIA will address minimum terms required by each party to be included in any IP Transfer (e.g., retained research right, disclaimer of liability, indemnification and third party beneficiary designation for non-signing party(ies))
- Administration of the agreement and the relationship could include terms such as reporting to non-lead institutions and what steps will be taken if licensee is in breach
- Typically each entity will be responsible for its governmental compliance and will cooperate with each other to provide the necessary information
- Some IIAs provide for audit rights of the financial records

Other Common Terms in IIAs

- Confidentiality
- Termination
- Disclosures
- Prohibition on use of name obligations
- Compliance and other legal requirements



Other Optional Terms

- Representations/Warranties
- Indemnity
- Insurance
- Publication
- Choice of law and venue
- Dispute resolution procedures



Questions? Thank you!

Laura Savatski
BloodCenter of Wisconsin
8733 Watertown Plank Road
P.O. Box 2178
Milwaukee, WI 53226
414.937.3833
laura.savatski@bcw.edu

Pamela L. Cox
Marshall, Gerstein & Borun LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606
312.474.3451
pcox@marshallip.com