

Agreements for the Transfer of Research Materials, Confidential Information and Data

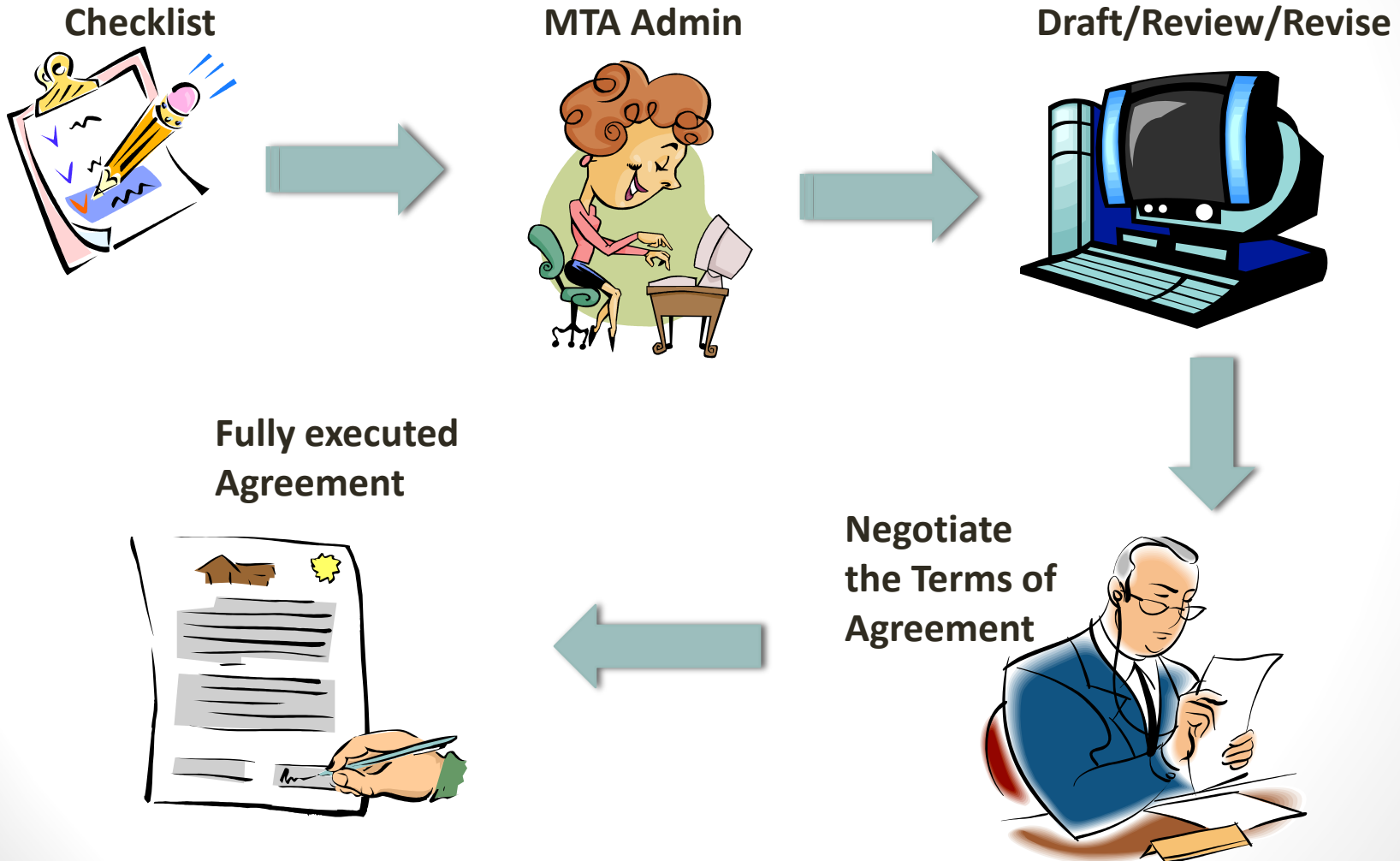
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Types of agreements handled by the Material Transfer Administrator

1. Material Transfer Agreement (MTA)
2. Confidential Disclosure Agreement / Non Disclosure Agreement (CDA / NDA)
3. Data Use Agreement (DUA)

Process for obtaining a fully executed MTA, CDA or DUA



An agreement may involve the following parties

Incoming Agreements

Industry to UR

Academic to UR

Non-Profit to UR

Outgoing Agreements

UR to Industry

UR to Academic

UR to Non-profit

MTA

- An material transfer agreement is a contract used to define the terms and conditions for the exchange of research materials.
- An MTA sets forth rights to use the materials and allocates the rights that result from their use.

Reason for MTA

- The material and/or information is proprietary or confidential.
- The provider wants to restrict how the material is to be used.
- The material is infectious, hazardous or subject to special regulations.
- The provider wishes to protect against any potential liability.
- The provider wishes to obtain rights to the results of the research for which the material or information is to be used.
- The provider wishes to ensure that correct and appropriate acknowledgement is included in any publication regarding the use of the material.

Publication

- Enable the Recipient of the Materials to publish or present results of the Recipient's research using the Materials without the approval of the Provider. The University of Rochester requires that there is no restriction or unreasonable delay to publish.
- Send Provider a copy of any proposed publication for review of confidential information and/or for filing of a patent application based on intellectual property of the Provider.
- Acknowledge the Provider in publications as scientifically and academically appropriate, based on their contribution.

Intellectual Property

- MTA may contain overreaching IP language which may claim ownership rights to results of the research and any developed intellectual property.
 - Usually occurs with incoming MTAs from industry
- For complex intellectual property issues, we contact IP attorneys in UR Ventures.

Types of MTAs

- Simple Letter Agreement (SLA)
- Uniform Biological Material Transfer Agreement (UBMTA)
- Institutional based MTA (drafted by the providing institution)

How to get started

How to get started:

A request must be submitted by the Principal Investigator (PI) using one of the following checklists:

- Checklist for Sending Materials
 - De-identified material requires HIPAA form 25.5.1
- Checklist for Receiving Materials

The checklist and word version of the agreement are requirements for the MTA Administrator to handle a request.

CDA/NDA

- A Confidential Disclosure Agreement / Non Disclosure Agreement) is an agreement under which one or both parties agree to maintain confidentiality regarding proprietary information that one party receives from the other party.

Reasons for a CDA

- A company may wish to share information for the purpose of determining whether an academic institution might be interested in establishing a clinical trial to test the company's drug / biologic / device.
- A company, academic institution or non-profit may wish to discuss a possible research collaboration.

Types of CDAs

One-way CDA:

- Only one party is bound by obligations of confidentiality

Two-way (Mutual):

- Both parties are bound by obligations of confidentiality

How to get started

- A CDA Checklist should be completed and a word version of the CDA should be sent to the MTA Administrator
- The MTA administrator will negotiate the terms of the agreement
- Once both parties have agreed upon the terms, the MTA Administrator will contact the department administrator and/or PI

DUA

- A data use agreement is a contract that is used to define the terms and conditions upon which data is transferred between organizations.

Reason for DUA

- Used when transferring proprietary or sensitive data, to control the use of the data
 - Proprietary data: research results
 - Sensitive data: protected health information (PHI)
 - ❖ Required under HIPAA

Types of DUAs

- Data Transfer Agreement
 - Used when transferring de-identified data
- Data Use Agreement
 - Used when transferring a Limited Data Set (LDS)
 - Research, public health or healthcare purposes
 - Information that may remain in the data:
 - Dates
 - City, state, zip code

How to get started

- A DUA Checklist should be completed and a word version of the DUA should be sent to the MTA Administrator.
 - De-identified: HIPAA form 25.5.1
 - Limited data set (LDS): HIPAA form 25.6.1
- The MTA administrator will negotiate the terms of the agreement.
- Once both parties have agreed upon the terms, the MTA Administrator will contact the department administrator and/or PI.

When a PI Leaves the University of Rochester

When a principal investigator leaves the University of Rochester, it is suggested that the department administrator or PI contact our office to see whether or not there are any active MTAs/CDAs/DUAs involving the PI.

The PI should notify us whether or not they plan to:

- 1) continue using materials/data they received from another institution at their new place of employment;
- 2) transfer material or data made/developed/obtained while at the University of Rochester to their new place of employment;
- 3) no longer use materials or data in existing agreement(s).