

AGREEMENTS FOR RESEARCH

*When Receiving or Sharing Confidential Information,
Data, or Materials*

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TEAM**

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"Sharing [of materials and data] facilitates new scientific and commercial advances, eliminates duplicative efforts by others to recreate materials [or data], and speeds the progress of science."

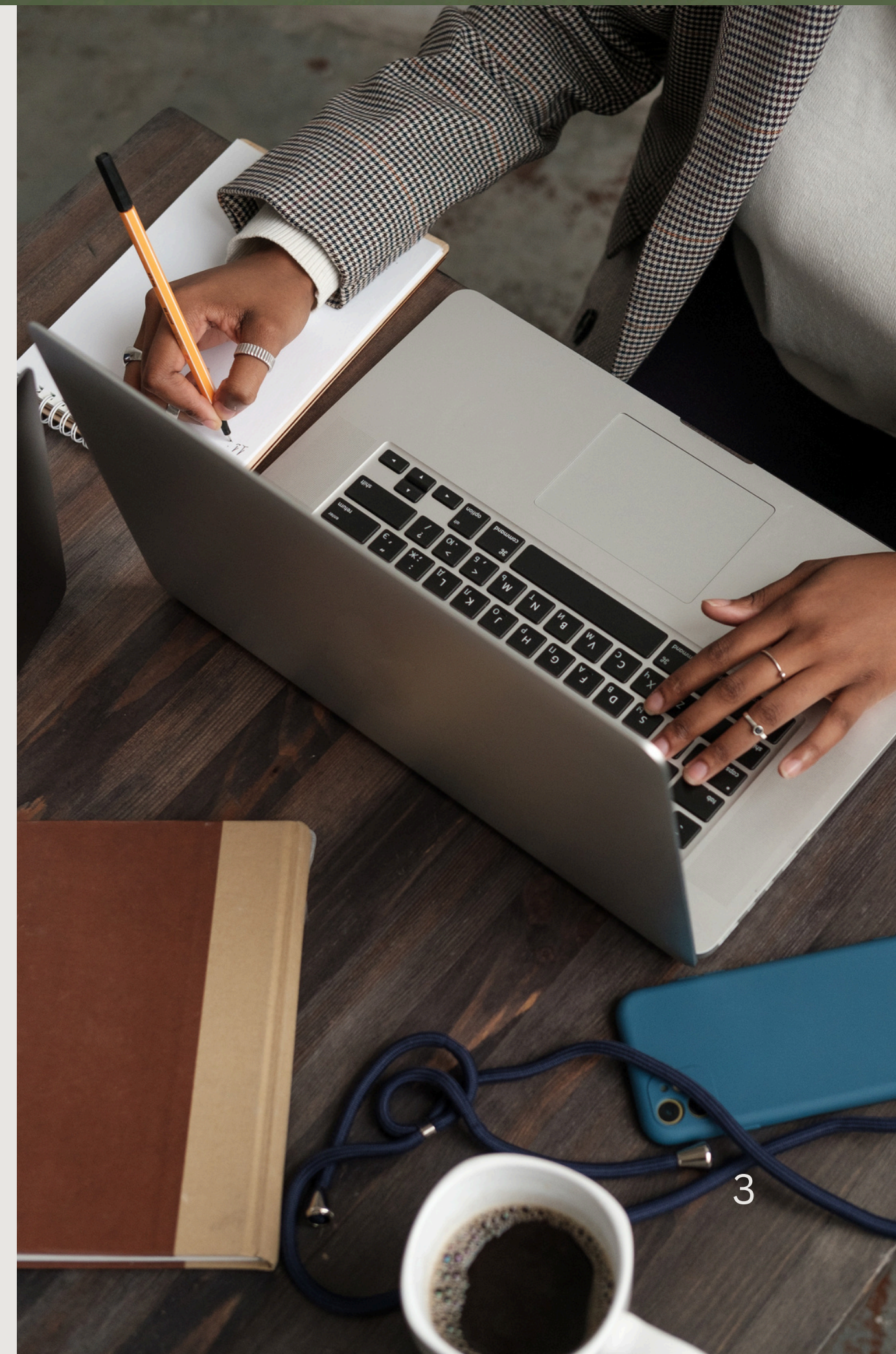
- National Research Council (US)
Committee on Responsibilities of
Authorship in the Biological Sciences

Introduction

Agreements by Type

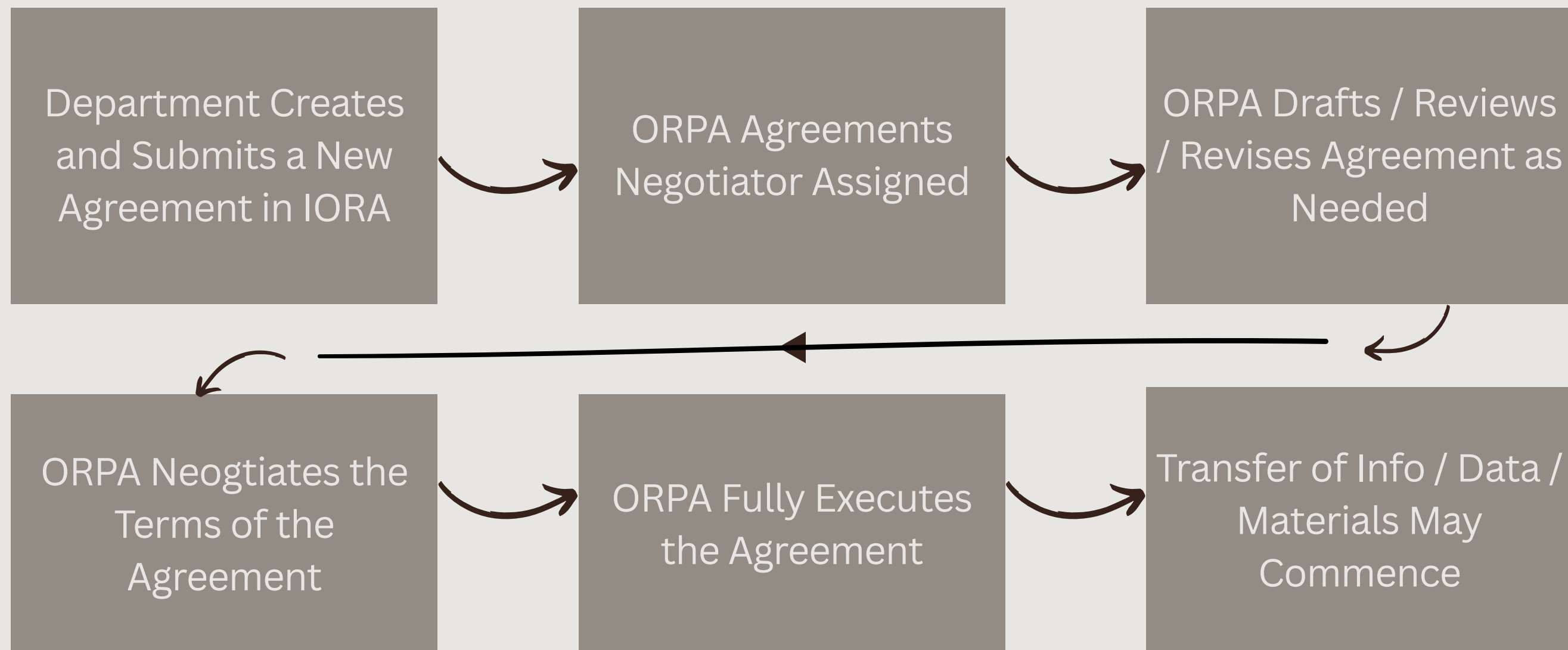
- Confidential Information:
 - CDAs / NDAs (Confidentiality / Non-Disclosure Agreements)
 - For example, CDA0000XXXX in IORA
- Data:
 - DUAs / DTAs (Data Use / Data Transfer Agreements) ***
 - For example, DUA0000XXXX in IORA
- Materials:
 - MTAs (Material Transfer Agreements) ***
 - For example, MTA0000XXXX in IORA

*** May include Data Registries, Consortium, or Biobank Agreements



Processing

Obtaining a Fully-Executed CDA, DUA, or MTA



What is a CDA?



An agreement under which one or both parties agree to maintain confidentiality regarding proprietary information that one party receives from the other party.

Why Do We Need It?

Clinical Trial:

- 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.

Other Research Collaboration:

- A company, academic institution, or non-profit may wish to discuss a possible research collaboration that would involve sharing intellectual property of one or both institutions.

DUA / DTA

What is a DUA?



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

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Why Do We Need It?

Used when sharing proprietary or sensitive data, to control the use of the data, including:

- Proprietary data: research results, intellectual property
- Sensitive data: Human Subject Data
 - protected health information (PHI) ***
 - genomic data

Things to consider:

- Privacy Laws (HIPAA, GDPR - EU Countries, various state laws)
- FERPA
- Intellectual Property

** It is always best practice to have a DUA when sharing data.

*** DUA required under HIPAA

MTA

What is an MTA?



A material transfer agreement is a contract used to define the terms and conditions for the sharing of research materials.

Why Do We Need It?

An MTA sets forth the rights of the provider and the recipient of the materials, including:

- To Protect Proprietary and/or Confidential Materials (protect intellectual property rights)
- Restrict Use, to a specific PI or Project
- Hazardous Material / Special Regulations
- Potential Liability
- Obtain rights to the results of the research for which the material or information is to be used
- Ensure correct and appropriate acknowledgement is included in any publication regarding the use of the material

MTA Continued

What if there is no MTA? Issues to consider...

1

Further sharing

An investigator wishes to share the same material with another internal OR external collaborator. Do we have the right?

2

Affiliation changes

An investigator moves to another institution and wishes to take the material with them. Are they allowed to continue using them outside of the University?

3

Publication issues

An investigator seeks to publish research utilizing the materials. What if the publication is blocked by a materials provider claiming no knowledge of the research or the investigator's use?

Importance

Help us protect the University of Rochester's information, data, and materials



Comply with laws and regulations



Protect intellectual property



Ensure appropriate use and handling



Maintain the University's reputation

Friendly Reminders

Help us process
your agreements
as efficiently as
possible

1. PIs and Department Chairs are not authorized signatories on Agreements.
2. All CDAs, DUAs, MTAs require entry in IORA before review, negotiation, and signature by ORPA admin.
3. It is always Best Practice to get an agreement before sharing Confidential Information, Data, or Materials.
4. If your PI received the Confidential Information, Data, or Materials from an outside source it is always best to review the agreement before sharing with others.
5. While only those questions marked with an asterisk (*) are required fields in IORA SmartForms, the more information you provide upfront the less questions we ask and the faster your agreement can be processed.
6. Please do not submit pre-signed agreements.
7. Review your contracting party information for accuracy, make sure it matches the entity identified in the drafted agreement.
8. If you have questions the Agreements team is here to help.

Contact Us

The Agreements Team has departmental assignments just like your ORPA Research Administrators:

https://www.rochester.edu/orpa/_assets/pdf/orpa_MTADeptList.pdf

Please keep in mind just like your ORPA RAs this list is subject to change as our staff changes.

If your department is not listed, please contact anyone on the team for assistance.

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General Inquiries

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Q&A

Please feel free to ask us any questions.

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THANK YOU

For Listening

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