Material and Data Transfer Agreements at Northwestern University

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What is an MTA?

- A written contract used to govern the transfer of research material between organizations.

- Established between the Provider institution and the Recipient institution to:
  - Document the transfer of material.
  - Define rights and responsibilities surrounding its use.
What is an MTA? (cont.)

“Material” can mean

- Biological materials (cell lines, tissues, transgenic animals, plasmids, vectors, etc.)
- Pharmaceutical drugs or compounds
- Chemicals
- Software
- Other physical material
Types of MTAs

- MTAs with Non-profit organizations
  - Universities, government agencies, other non-profit research institutes
  - Can use pre-negotiated MTAs: UBMTA, Simple Letter Agreement
- MTAs with For-profit organizations
  - Pharmaceutical companies, Biotech companies
  - More extensive agreements, slower turnaround
What do MTAs say?

- Permitted uses of material
- Further distribution
- Ownership
- Publication of data and results
- Possible inventions
- Compliance with applicable laws
- Liability
- Term
What is a DUA?

• A written contract used to govern the transfer of research data between organizations

• Set up between academic institutions, government agencies and/or corporate entities

• “Data” can mean:
  • Any type of research data
  • Lab notes, methods, experimental data
  • Human and non-human data
What do DUAs say?

- Document the data being transferred
- Ownership/stewardship of data
- Permitted uses and further distribution
- Publication of results
- Compliance with applicable laws
- Liability
- Term
DUAs: What’s in a name?

• DUA vs. DTA vs. DSA?

• HIPAA DUA:
  – Used by Covered Entities (not NU) or by researchers acting as a business associate of a covered entity with respect to the data
  • RARELY the case at Northwestern

• Generic DUA, aka:
  • Research Data Transfer Agreement
  • Data Transfer Agreement
  • Data Sharing Agreement, etc.
When and what type of agreement is needed?

• **Inbound** data transfers:
  – DUAs/DTAs used at discretion of Provider institution
  – OSR reviews and approves

• **Outbound** data transfers:
  – Depends on how the data was obtained
    • IRB approved protocol / HIPAA Authorization / Waiver of HIPAA Authorization / Authorization from research participant
  – PI can ask OSR for guidance, OSR will consult with the IRB and OGC as needed
Generic DUAs / Research Data Transfer Agreements

• These MAY be needed if:
  • The data was received from a 3rd party
  • The PI considers the data proprietary
  • The PI wishes to restrict the use of the data
  • There are other contractual obligations
  • The data is from a sponsored research project

• PIs should consult with OSR to determine whether or not a research data transfer agreement is needed

• Remember: HIPAA DUAs and BAAs are RARELY needed at Northwestern
How do I process an MTA or DTA at Northwestern?

• MTAs: All NU MTAs go through OSR-Chicago
• DTAs: Chicago Campus PIs only: use OSR-Chicago

• MTAs and Chicago campus DUAs need to be reviewed and approved by OSR Chicago before anyone signs
• Principal Investigators cannot sign on behalf of NU
  • (PIs may sign as “Read and Understood”)
• Authorized Institutional Official will sign to bind the University to the terms
Material or Data transfer: Inbound to NU

1. MTA or DTA received from Provider
2. NU investigator submits request to OSR-Chicago (Inbound Request Form or ESPR)
3. Agreement is reviewed for compliance with NU policies and business practices
4. Changes are negotiated with Provider’s legal office if necessary
5. NU investigator and Authorized Official sign
6. Final draft approved
7. Changes are negotiated with Provider’s legal office if necessary
8. Provider institution signs, sends a copy to all
9. Investigators arrange transfer of material and/or data
Material or Data transfer: Outbound from NU

1. NU PI submits request to OSR-Chicago (Outbound Request Form or ESPR)
2. OSR drafts agreement and sends to Recipient
3. Recipient’s legal office reviews agreement & changes are negotiated if necessary
4. NU PI and Authorized Official sign, sends a copy to all
5. Recipient PI and Authorized Official sign
6. Final draft approved
7. Investigators arrange transfer of material and/or data
Frequently Asked Questions

• Why should the IRB care about MTAs and DTAs?

• Where should the IRB direct questions about DTAs?

• If human material and its associated data are being transferred to a collaborator, are both an MTA and DTA necessary?
Thank you!

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http://osr.northwestern.edu/agreements/mta
http://osr.northwestern.edu/agreements/dua