Research Professionals Network

sponsored by DOCR
Duke Office of Clinical Research
Office of Corporate Research Collaborations (OCRC)
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What Agreements are negotiated by OCRC?

- Clinical Agreements
- Confidential Disclosure Agreements
- Collaborative Research Agreements
- Consortium or Network Agreements
- Core Lab and Shared Resource Agreements
- **Data Transfer Agreements**
- Equipment Loan Agreements
- **Material Transfer Agreements**
- Sponsored Research Agreements
- Technology Use Agreements
- Others
Data Transfer Agreements

The term Data Transfer Agreement is a generic term for multiple types of transfers:

- De-identified data
- Limited Data Set
- Protected Health Information more than a Limited Data Set
- Data Sets (annotated, longitudinal, etc)
Data Transfer Agreements

• De-identified data - all 18 HIPAA identifiers removed

• A Limited Data Set - a class of Protected Health Information (PHI) that only includes indirect identifiers:
  • Dates of service (e.g. blood drawn on May 1, 2015)
  • Ages greater than 89
  • Geographical information (State, County, City, Zip Code)

• PHI - More than a Limited Data Set

• Data Sets - Proprietary
Data Transfer Agreement IRB Process

- Study team completes Intake Form
- OCRC sends Intake Form to the IRB
- IRB review to determine acceptability of transfer
- Upon IRB consideration and permission to move forward, OCRC drafts the appropriate Data Transfer Agreement and works with study team to send to the other party
- Study team uploads the fully executed DTA into the eIRB once signed by both parties
- IRB approved data can be transferred to the other party
Data Transfer Agreement OCRC Process

- **Incoming Data (only)**
  - Clinical and PHI
    - Susan
  - All Data Sets
    - Curtis

- **Outgoing Data (only)**
  - Clinical and PHI
    - Susan
  - For Data Sets (e.g. Cathgen, CALORIE)
    - Curtis

- **Data plus Materials**
  - Curtis
Material Transfer Agreement

Governs the Recipient’s use of a Provider’s Material.

- Non-use and non-distribution terms
- Publication rights
- Intellectual property rights
- Confidentiality
- Liability
Why a Material Transfer Agreement

• Protect the rights of both the Recipient and the Provider.
  • Publication rights
  • Intellectual Property rights

• Prevents unrestricted use of Materials
  • Necessary for compliance with ICF and IRB approval
    • Subject samples and clinical data

• Facilitates compliance with federal regulations
  • HIPAA
  • Export Control
Material Transfer Agreement

- Human samples (e.g. whole blood, plasma, fluids)
- Human tissues (e.g. whole organ, tissue biopsies)
- Human-derived samples (e.g. extracted RNA, DNA, proteins)

- Animal models and Animal tissues
- Proprietary materials (e.g. unique Abs)
- Research Tools (e.g. plasmids)
- Reagents (e.g. unique chemical compounds)

- Plus information (clinical, technical, confidential)
Material Transfer Agreement OCRC Process

- **Incoming Materials**
  - Provider usually provides the agreement

- **Outgoing Materials**
  - **Recipients**
    - Nonprofits
    - Service Providers
    - Industry
    - Intra-Duke
  - **Material type**
    - Human samples, tissues or human-derived materials
      - Generally, a MTA is required

- Other material transfers
  - Contact OCRC for determination
Material Transfer Agreement IRB Process

• **Incoming Materials**
  - Study team should enter an amendment to the relevant protocol
  - Uploaded the fully executed MTA into the eIRB

• **Outgoing Materials**
  - For completed studies (retrospective)
    - Enter an amendment to the relevant protocol
    - Upload the fully executed MTA into the eIRB
  - For active studies
    - Enter an amendment to the relevant protocol
    - IRB review of ICF to determine acceptability of transfer
    - Upload the fully executed MTA into the eIRB
When should I contact OCRC

• Receipt of a research agreement from a Sponsor or Provider

• Intend to transfer Data or Materials.

• Initiation of a federal subaward in which the subawardee will receive Data or Materials from Duke. OCRC will work with ORA to facilitate

• Initiation of a procurement request that includes the transfer of Data, Technology or Materials
  • Purchase order
  • Research Support Services Agreement (RSSA)-Rider C only
When should I contact OCRC

• Anytime you have a question about a research situation

• We are here to help;
  • Facilitate your research
  • Protect you and Duke
  • Draft your agreement
What to expect during the negotiations

• You and the team members you indicate will be copied on email exchanges with the other contracting party

• Negotiation time
  • Complexity of the agreement
  • Promptness of providing information
  • Responsiveness of the other contracting party
  • Responsiveness of other Duke offices

• You or members of your study team (including the PI) are not authorized to sign on behalf of Duke
OCRC Contacts

Research Programs Collaborations  
(Data Transfers)

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Preclinical and Basic Research  
(Material and Data Set Transfers)

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Confidential Disclosure Agreement

• Disclosures related to clinical research
  • Intervention – behavioral, drug, device
    • Contact Marti Salguero, marti.salguero@duke.edu

• Prospective collection
  • Contact Curtis Bradney, curtis.bradney@duke.edu

• Disclosures related to other research arrangements
  • Contact Curtis Bradney, curtis.bradney@duke.edu
Clinical Agreements

Industry or foundation funded clinical research agreements, usually provided by the sponsor

• Duke site based

  • Intervention – behavioral, drug, device
    • Contact Marti Salguero, marti.salguero@duke.edu

  • Prospective collection
    • Contact Curtis Bradney, curtis.bradney@duke.edu