Agreements for Transfers of Data and Materials Relating to Human Subjects

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Office of Corporate Research Collaborations

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Types of Agreements

MTA – Material Transfer Agreement
» Often used generically for transfers of both data and materials
Data Transfer Agreement
Data Use Agreement
» Defined HIPAA term
» Specific to transfers of Limited Data Sets
Business Associate Agreement
» Defined HIPAA term
» Rarely allowed or appropriate for research

Considerations for When and What Type of Agreement Needed

HIPAA
IRB
Contractual
Business
Other Regulatory (e.g. Safety)
Specifics of what will be transferred and what purpose (Data or Materials or both)
**Business/Contractual Considerations**

Do we need or want to restrict use of data or materials?
- Proprietary Intellectual Property interests
- Safety issues
- Potential liability issues
- Restrict further disclosure, transfer, use or sale of data or materials
- Access to results of recipient’s research
- Acknowledgement / Authorship of Publications

Any third party contractual constraints?
Any third party intellectual property issues?
Payments to or from Duke?
Does recipient/provider require agreement?
Is recipient a commercial organization?

**IRB Considerations**

IRB review required for all incoming and outgoing transfers of human subjects data and materials for research purposes.
- Informed Consent and Authorization.
- Waiver of Consent and Authorization.
- Declaration of Not Human Subjects Research
  - Exempted from review.
**HIPAA and Common Rule Considerations**

Need Consent/Authorization from subjects unless:
- Waiver of Consent/Authorization has been granted by Duke IRB.
- Limited Data Set (remains PHI).
- Fully Deidentified (not PHI).
- Anonymized (not PHI, not Human Subjects).
- Determination from IRB of Not Human Subjects Research.

**Anonymous Human Subjects Data**

Fully HIPAA Deidentified with no link field or aggregated so no longer relating to an individual.

Transfer from Duke Requires
- Duke IRB review.
- Statement from PI to IRB that data is deidentified and anonymized.
- Statement from PI to IRB that use is consistent with informed consent, or collection circumstances if no consent.
- Formal agreement not required, unless other considerations apply.

Receipt by Duke Requires
- Duke IRB review.
- Statement from provider that data was collected with informed consent, or IRB determination that no consent required and planned use is consistent with approvals.
- Formal agreement not required, unless other considerations apply. Statements above may be by email.
**Fully Deidentified, but not Anonymous Human Subjects Data**

Fully HIPAA Deidentified, but includes Link Field.

**Transfer from Duke Requires**
- Same as anonymized data except statement will be that data is fully HIPAA deidentified and that key to link will not be provided to recipient.

**Receipt by Duke Requires**
- Same as anonymized data except statement from Provider will be that data is fully HIPAA deidentified and that key to link will not be provided to Duke.

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**Limited Data Set of Human Subjects Data**

Data includes HIPAA identifiers and remains PHI, but does not include direct identifiers.

**Transfer from Duke Requires**
- Duke IRB review.
- Data Use Agreement for specified research use consistent with HIPAA (unless IRB grants waiver).
- Use must be consistent with informed consent/authorization or terms of IRB waiver of consent/authorization.
- Only minimal necessary data to be supplied.
- Other terms based upon any other considerations.

**Receipt by Duke Requires**
- Same as for transfer from Duke if Provider is a Covered Entity.
- If Provider is not a Covered Entity:
  - IRB will need to grant a waiver of consent/authorization or declaration of not human subjects research.
  - A Data Transfer Agreement will usually be needed with terms based on particular circumstances.

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  - A Data Transfer Agreement will usually be needed with terms based on particular circumstances.
Data with Direct Identifiers

IRB approval required, usually with informed consent and authorization of subjects

Transfer from Duke Requires

» Data Transfer Agreement assuring use consistent with informed consent/authorization, maintaining confidentiality of identifiers and identified data, and approval by recipient’s IRB.
» If release is subject to a waiver of consent/authorization then data must be logged into the Duke Medicine Disclosure Accounting System.

Receipt by Duke Requires

» Data Transfer Agreement usually required limiting Duke’s use to specified project consistent with informed consent/authorization, maintaining confidentiality of identifiers and identified data.
» If data was collected without valid informed consent and authorization, the Duke IRB will need to grant a waiver of consent/authorization prior to receipt.

Additional Considerations for Materials (Human-Derived Samples)

Meaning of “Identified” may be ambiguous.

Usually safety considerations.

» Use and shipping in accordance with regulations.
» Blood and tissue are ≥BSL-2.

Agreement (MTA) usually needed if not governed by another agreement.

Non-HIPAA and IRB considerations often apply.
When Do I Need an Agreement, and What Type?

It depends.
Refer to guidance.
When in doubt, ask.

OCRC Contacts

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