Data Use Agreements
Best Practice

General Description

Category:
Data Sharing - External

Purpose of this best practice:
A Data Use Agreement (DUA) is required when sharing data outside of the Johns Hopkins Covered Entity of Johns Hopkins Medicine ((School of Medicine (SOM), School of Nursing (SON), Kennedy Krieger Institute (KKI)). It can be used in both research and non-research data sharing. DUA's should not be confused with Use of Data Agreements (UDA), which address "how" data shared may be used.

Categories

Best Practice
Data Security
Data Sharing - External

Recommendations and Considerations

1. Johns Hopkins University (JHU) approved data use agreements are required PRIOR to sharing data with outside entities or JHU personnel not currently on the Institutional Review Board (IRB) application.

2. Data use agreements (DUA) are specific for limited use versus identifiable datasets.

3. When sharing data external to Johns Hopkins, the PI must submit the DUA to the Office of Research Administration (ORA). For additional information/guidance and the most current forms, contact the ORA directly.

4. When Johns Hopkins is providing the limited data set, if any material change is to be made to the Johns Hopkins template form, or if another party's version of a data use agreement is to be used, the Johns Hopkins Office of Research Administration must review and approve the terms of the agreement.

5. For data sharing within Johns Hopkins, a DUA is generally not required for team members who are on the Institutional Review Board (IRB) application.
The PI may, however, wish to use a "Use of Data" agreement to address specific concerns.

Considerations:

6.1. All parties involved should know what is in the DUA and the appropriate compliance requirements for their position within the project.

6.2. The Johns Hopkins Medicine (JHM) IRB must be notified if you plan to share a limited data set with a person not named in the original IRB application. If you disclose a Limited Data Set to another JHM researcher, that person must sign the one page Data Use Agreement on the JHM IRB website.

6.3. A covered entity (Johns Hopkins Medicine) may use one of its own workforce to create the "limited data set". The Department of Health and Human Services (DHHS) also has indicated that a covered entity may allow a person requesting a "limited data set" to create it, so long as the person is acting as a business associate of the covered entity. A business associate is someone who is not part of the covered entity's workforce but who will use the covered entity's PHI to perform some task on behalf of the covered entity. (Examples of business associates are lawyers, accountants, firms that analyze patient data, etc.) The covered entity (Hopkins) must enter into a separate business associate agreement with the entity and the agreement must meet the requirements of the Privacy Regulations. Once the limited data set is created under the business associate agreement, all of the PHI, other than the PHI qualifying as the limited data set under the data use agreement, must be returned to the covered entity.

6.4. It is possible that a recipient will act as the covered entity's business associate to create the "limited data set" from a broader set of PHI. In such a case, the recipient will need to sign both the data use agreement and the business associate agreement.

Resources and Examples

Useful Links:
JHM Template for Limited Dataset
JHM Definition of Limited Data Set
HIPAA Questions and Answers Relating to Research
Johns Hopkins Privacy Office - General Forms
### Responsibilities

<table>
<thead>
<tr>
<th>Position</th>
<th>Responsibility</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>The Principal Investigator (PI) is responsible for signing and enforcing the terms of the Data Use Agreement (DUA). If the PI is not allowed to sign the DUA, due to departmental policies, the PI is responsible for ensuring the proper channels are followed in having the DUA signed by the appropriate party.</td>
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<tr>
<td>Study Coordinator, Data Manager, Data Analyst/Biostatistician</td>
<td>The Study Coordinator, Data Manager, and Data Analyst/Biostatistician should be aware of all data use agreements in effect for the study.</td>
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