Data Use Agreements

Overview

A Data Use Agreement (DUA) is a written contract used to govern the transfer and use of data between organizations, which has been developed by nonprofit, government or private industry, where the data is nonpublic or is otherwise subject to some restrictions on its use and will be used for research purposes. Often, this data is a necessary component of a research project and it may or may not be human subject data from a clinical trial, or a Limited Data Set as defined in HIPAA. Universities want to ensure that DUA terms protect confidentiality when necessary, but permit appropriate publication and sharing of research results in accordance with University policies, applicable laws and regulations, and federal requirements.

In general, a DUA includes:

- What data will be released or shared
- Who has ownership of the data
- What, if any, identifiers will be included
- The purposes for which that data may be used
- With whom, if anyone, the data may be shared
- Data security safeguards
- To whom violations of the agreement should be reported
- The term of the agreement
- The disposition of the data at the end of the agreement
- Any indemnification or insurance requirements

When is a Data Use Agreement Required?

A Data Use Agreement (or applicable provisions in another agreement) is required when either:

1. The Data has some sort of proprietary status (information or data is, related to, or could be related to, a patent, invention, commercial product, or some other good); Or
2. The Data is considered sensitive (information about a person(s), patient information, government programs, health information or has some sort of confidentiality or security requirements, or needed by IRB); Or
3. The Data is covered by 1 and 2 above;

If the Data falls outside those areas of concern, data may be transferred without the formal need of a DUA. However, the Office of Research & Sponsored Programs recommends utilizing a DUA for studies involving de-identified data since there are still risks. The PI may utilize a DUA and build in protections as appropriate.

Ferris State University investigators cannot sign DUAs on behalf of the University. The agreement needs to be set up as a contract between institutions and signed by an Authorized Official who is capable of binding the University to the terms.

PIs are often required to sign DUAs as Read and Understood. **Ferris encourages its PIs to thoroughly read through DUAs before signing.** Not all DUAs are the same and it is very important that PIs and Key Personnel understand and abide by the terms and conditions outlined in the agreement.

For information on obtaining a DUA, contact The Office of Research & Sponsored Programs at research@ferris.edu.

Types of Data

These agreements can be set up between academic institutions, government agencies and/or corporate entities. DUAs can be classified into two different categories depending on the nature of the data being transferred:

1. Non-human subject data or completely de-identified human subject data (Only if determined by the Rutgers' IRB Office).
2. Human subject data which includes Protected Health Information. This includes data which constitutes a Limited Data Set as defined by HIPAA.

Data Transfers which fall into category #2 are subject to HIPAA regulations and may require IRB approval.

Data Use Agreements and Human Subjects Research

DUAs are commonly used when a researcher wishes to access archives or restricted data sets that may contain identifiable information about individuals for the purpose of conducting such projects. The IRB must be contacted if the use of the archived protected health data falls under the IRB's definition of "research". Research dealing directly with data with personal identifiers may require a HIPAA Authorization to use and/or disclose PHI (for individual authorizations to access PHI) or a HIPAA Waiver of authorization (for request of large sample size where individual authorizations are impractical and the request meets privacy rule specifications). IRB application forms must address the protective mechanisms planned to protect the identity of persons and to evaluate the security of procedures to safeguard these identities.

When a DUA is a part of the project submitted to the IRB, a draft or final signed version should be included in the protocol application**. Final IRB approval will not be granted until a copy of the signed DUA is received from the Office of Sponsored Programs and submitted with the IRB application**.