FREQUENTLY ASKED QUESTIONS

Capitalized terms used herein are defined in the External Data Use Agreements policy.

1. What is an External Data Use Agreement?

An External Data Use Agreement (an “EDUA”) is a contractual agreement between the University and a third-party data provider that governs the transfer, use, and retention of External Data. EDUA’s may sometimes referred to as data licensing agreements, data sharing agreements, confidentiality agreements, business associate agreements, data access agreements, or similar. EDUA's must be developed, reviewed, approved, and implemented in accordance with the External Data Use Agreements policy. Once executed, they are binding upon the University. All faculty, staff, students and all others acting on behalf or under the auspices of the University must comply with valid EDUA requirements.

2. What types of data might be provided under an EDUA?

- Non-public records from governmental agencies, non-profits, or corporations
- Human Research Subject Data
- A “limited data set” (see below for additional information)
- Genetic sequences
- Modeling data
- Proprietary or valuable information or material that does not fit the profile of a tangible physical material

3. When do I need an EDUA?

For Human Subject Data

- Disclosure of data for research purposes and;
- Individual authorization for disclosure to this recipient is not/has not been obtained (from human subject, as through use of a subject-signed informed consent authorization) and;
- Disclosure is permitted under an IRB-approved protocol (for human subject research) or;
- The researcher is disclosing or receiving a “limited data set” of personal health information, as defined under HIPAA. For more information on “limited data sets” under HIPAA, contact the IRB if the use of archived protected health data falls under the definition of “research”.

For Non-Human Subjects Data

- When no other form of contract concerning the data transfer exists between the provider and the recipient, and;
- When data is not in the public domain, and the disclosing party wishes to limit the further use or distribution of the data, and;
- The recipient intends to use the data for research purposes

4. When don’t I need an EDUA?

- When the data resides in public domain
- When data is exchanged that is not subject to a legal or other restriction on its use
- When de-identified data is exchanged for research purposes under a subcontract or other form of agreement with the recipient. “de-identified data” as used here has the meaning attributed in HIPAA.
5. **What if my EDUA is for HIPAA-protected information?**

The Privacy Rule requires that an EDUA must be implemented before any use or disclosure of a “limited data set” to an outside institution or party may occur. A “limited data set” constitutes protected health information ("PHI"). For more information, please use the Data Use Agreement Tool.

6. **Why should I enter into an EDUA?**

EDUA’s address important issues such as limitations on use of the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by the EDUA can help avoid later issues and will ensure the appropriate use of data for a specific research project, protecting both the provider and the recipient. Establishing an EDUA helps to achieve the following:

- Helps to shelter the investigator and University from any liability or loss arising from a recipient’s use of University data
- Protects the investment and reputation of both the investigator and the University
- Access to important data makes an investigator more competitive in publications and grants; sharing of this data helps to foster collaboration with other leading scientists
- Helps to ensure that the investigator and University receive academic credit for their work
- Appropriate acknowledgement of the data’s source in academic publications and presentations can be addressed in the EDUA, although any determination of appropriate authorship designation must be based on actual contribution to the research and cannot be agreed upon in a EDUA
- Prevents the inappropriate use of intellectual property or protected or confidential information that could cause harm to research subjects, the investigator or the University
- Assures that the recipients are using the data in accordance with applicable law
- Contractually obligates the recipient to use the data only for the purpose described in the EDUA
- Where data may be subject to HIPAA, ensures that appropriate restrictions on use are maintained

7. **How are EDUA’s executed on behalf of the University?**

Only University officials authorized by the University’s Contract Signature Authority Policy can enter into research agreements, including EDUAs, on behalf of the University. Researchers are not authorized to negotiate or sign agreements on behalf of the University. If a researcher signs such an agreement, the researcher could be subjected to legal and financial risks in addition to disciplinary action under applicable ABOR and University conduct policies. It is important for the researcher to read the terms of a EDUA before forwarding it to the OVPR for University signature. The University relies on the researcher receiving data under an EDUA to read, understand, and agree to conform to those terms, whether or not the researcher’s signature is required on the EDUA itself. The OVPR will confer with General Counsel and IRB or other pertinent compliance offices as required in the evaluation of EDUAs.

8. **How is a “limited data set” different from de-identified data?**

The HIPAA Privacy Rule (45 CFR, Parts 160 and 164(A) and (E)) specifies a process to make health data completely de-identified. This involves removing 18 elements that could be used to identify an individual or an individual’s relatives, employers, or household members; these elements are enumerated in the Privacy Rule. Investigators also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, **18 identifiers need to be removed.** Unlike de-identified data, PHI in “limited data sets” may include the following:

- 5-digit zip code (the 4-digit extension is not allowed)
- dates of birth, death, admission, discharge
- all geographic subdivisions other than street address
- Important: because limited data sets may contain identifiable information, they still contain PHI.

“Limited data sets” are not de-identified under HIPAA, even though names, addresses, ID numbers, and other direct identifiers are removed. “Limited data sets” are still protected health information.