DEVELOPMENT AND IMPLEMENTATION OF EXTERNAL DATA USE AGREEMENTS

The Office of the Vice President for Research ("OVPR") and the External Data Use Advisory Committee (the "Committee") provide primary support for researchers and all University projects that receive External Data from Data Providers to help ensure full compliance with all applicable law, regulation, and policy requirements and best business practices. This is primarily accomplished by providing guidance regarding the development and execution of External Data Use Agreements ("EDUA's") and any related data sharing and management plans. Appointed by the Vice President for Research and the Chief Information Officer, the Committee's members possess expertise in compliance, human research, data security, and applicable scientific research areas. The guidance provided is intended to help protect the University and its researchers and the security of the External Data with which the University and its personnel may be entrusted.

The relevant Principal Investigator ("PI") is typically responsible for a) complying with all applicable requirements of law and project sponsors; b) complying with the terms of relevant sponsored research agreements; c) ensuring the protection of any human subjects, the appropriate use of animals, and the proper use of tangible research materials; d) protecting the rights of faculty, students, postdoctoral scholars, and staff including all rights of access to, and credit for, data from research in which they participated; e) securing and protecting intellectual property rights; and f) adopting an orderly system of data organization and communicating the chosen system to all research group members and the appropriate administrative personnel.

Requests to develop and implement a new EDUA should first be forwarded to OVPR for processing. The Committee will maintain copies of all approved and implemented EDUAs. Depending on the project's needs and the External Data third-party provider, the following outlines the general process for EDUA development, approval, and implementation.

1. **PI contacts external agency to explore potential for data sharing.** All written contact should include a) a description of the data base; b) a description of the research project and why the data is necessary; c) identification of data safety and security requirements for the EDUA; d) identification of data sharing arrangement elements; and e) Identification of signature authority at the external data provider.

2. **PI requests the Committee's review of potential EDUA.** The material provided by the PI should include a) a description of the research project; b) a description of the External Data; c) identification of data safety and security requirements for the EDUA; and d) the responsible PI and the names of other NAU authorized users.

2. **The Committee reviews the data sharing request.** This includes a review of the draft EDUA including a) consideration of appropriate database security measures; b) review of IRB approvals as appropriate; and c) a recommendation for approval/disapproval of the data sharing project. Complex agreements (for example, EDUAs requiring special monitoring or enhanced reporting or security measures) must be reviewed by the full Committee while the Committee's chair alone may review basic or standard EDUAs.

4. **The EDUA is approved and implemented**: The approved EDUA is signed and executed by the appropriate authorized University official and the authorized representative of the external partner. The PI may then work with the Committee and ITS to ensure secure acquisition, use, storage, and destruction of data as specified in the EDUA. All External Data must be is transferred using the appropriate means and an appropriate plan for data dissemination and disposition must be developed and recorded.

For questions regarding compliance with these procedures or the External Data Use Agreements policy, contact the Office of Research Compliance. For questions regarding procedures for data use and sharing, contact the External Data Use Advisory Committee via the Office of the Vice President for Research.