**Request to Establish a Data/Tissue Repository**

**Note:** This form should be used when the investigator intends to establish a collection of tissue samples or data with the intent of establishing a relatively large collection of data or tissue that will be accessed by other investigators who may or may not be located at the University.

**PI Name:**       **IRB Protocol Number:**

1. Name of the Repository:

1. Location of the repository:

1. Describe the purpose(s) of the repository.

1. What type of repository is being established?

Data  Tissues/Specimens  Both

1. Describe the data/specimens that will be in the repository; be specific regarding the type of information/material, the source of the information/material and any other pertinent detail.

1. The Repository will include:

Existing Data/Specimens\*  Prospectively Collected Data/Specimens  Both

*\* Data/specimens are in existence at the time of this application.*

1. Will the repository include data/specimens from children, adults with impaired decision-making capacity, or other vulnerable populations.  Yes  No

If Yes, provide justification:

1. Identify how long will an individual’s data/specimens be retained in the repository and explain the reason for the intended duration.

1. Will informed consent be obtained from the donors of the data/tissue?  Yes  No

If Yes, describe the procedure for obtaining informed consent/assent, including who will be responsible for obtaining consent/assent, in the eProtocol application and upload a copy(ies) of the informed consent/assent forms.

If No, is a waiver of consent being requested?  Yes  No

If Yes, provide complete and upload into the eProtocol application a “Request for Waiver of Consent” form found on the Research Compliance web site.

1. Will data/specimens be associated with any information about the subjects, either directly by labeling or through a code? YES   NO

If No, describe the procedure for de-identifying and labeling the specimens; identify who will carry out the procedure.

If Yes,describe information that will be associated with the data/specimens: be specific regarding the type of information, the source of information, and if a coding system is to be used, the basis for the system.

1. Identify the person(s) who will be primarily responsible for ensuring the integrity and security of the repository.

1. Describe in detail the security measures that will be used to ensure the privacy of subjects and the confidentiality of data (e.g., password protected computer, data on protected server, locked cabinets). If the data/tissue is to be coded, describe the coding methodology, who is responsible for assigning the code, and how the code will be protected.

1. In accordance with the requirements delineated in Section 22.4.6 of the *University of Notre Dame Standard Operating Procedures for the Human Research Protection Program (SOPs)*, located on the Research Compliance web site, describe in detail the procedures you will utilize for collection, storage and release of data/samples from the repository. Include the procedures for requesting data/specimens and the person(s) responsible for retrieving and releasing the data/tissue to requesting investigators. Note: In accordance federal regulations and local SOPs, identifying information associated with the data/tissue in the repository cannot be released to investigators who obtain the data/tissue.