Background
This guide applies to proposals for the collection, storage, and use of data, registries, and specimen repositories. The purpose of such data/specimen repositories may be for clinical or diagnostic needs, quality improvement, or for research purposes. Some repositories may serve more than one of these purposes. The terms database, registry, data bank, repository, and tissue bank are often used interchangeably.

If the repository is to be used for research purposes, Institutional Review Board (IRB) oversight is required. Research use with such data/specimen repositories are governed by federal human subject protection regulations, known as the Common Rule (45 CFR 46), the HIPAA Privacy Rule (45 CFR 160, 164), and the University of Louisville Human Subjects Protection Program (HSPPO) policies and procedures. Specific requirements of each proposal depend on how the data/specimens are collected, used, and whether or not the data/specimens are identifiable.

Institutional Review Board Requirements
Researchers who wish to develop or maintain a repository for current or future research must submit an application for IRB review. IRB approval is required before initiating the repository. Operators of the repository must implement physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens. These procedures must be reviewed by the IRB and must be sufficient to ensure the protection of subjects' privacy and the confidentiality of subjects' information.

Researchers who plan to use data and/or specimen from any repository, including their own, should consult with the IRB prior to the collection or analyzation of the data/specimen. IRB oversight is required for each research protocol that uses identifiable or re-identifiable information contained in the repository. Each research protocol requires its own separate submission to the IRB and may not proceed until IRB approval is obtained. The HIPAA Privacy Rule also requires a separate HIPAA Research Authorization for each use or disclosure from the data repository for a specific research activity.

Separate IRB review may not be required if the use is considered “Not Human Subjects Research” or NHSR. NHSR activity involves data/specimens in which the investigators cannot readily ascertain the identities of the data/specimens. The IRB encourages investigators to submit the Non-Human Subjects Research determination form in iRIS to receive an official determination from the IRB.

Developing and Maintaining a Research Data/Specimen Repository
Investigators should consider the following when developing a repository:

- Plan for data/specimen collection
- Safe storage and back-up
- Controlled access to the data/specimens
- Potential research uses (note: some uses may be anticipated at the time of collection but most cannot be specified at the time the repository is created)

A repository application and protocol submitted to the IRB must include the following information:
- The specific conditions under which data/specimens may be accepted into the repository
• Description of secure receipt, storage, and transmission of information and specimens to ensure the protection of subjects' privacy and the confidentiality of subjects' data/specimens

• Conditions under which data/specimens may be shared with other investigators

• Consent (where applicable) and HIPAA authorization (or waiver of authorization) or combined consent/authorization (following the UofL template) that include:
  o The general concept and purpose of repository;
  o The name and location of the repository(ies);
  o The nature and types of future research in as much specific detail as possible;
  o A summary of the physical and procedural mechanisms for protecting subjects' privacy and the confidentiality of data/specimens;
  o The conditions (if any) under which subject's may withdraw their consent/authorization to use of specimens;
  o The conditions and requirements under which data/specimens and materials derived from specimens may be shared with recipient-investigators;
  o The elements of PHI (if any) to be shared with recipient investigators;
  o Risks related to a breach of confidentiality
  o If applicable, where human genetic research is anticipated, information about the consequences of DNA typing (e.g., regarding possible paternity determinations, impact on insurability, etc.) and related confidentiality risks.

Sharing and Receiving Data Outside of UofL
Research involving sharing of data and/or specimens must be described in the protocol and the research consent form (as applicable) in order for data and/or specimens to be used for future research and/or shared with another institution. Without participant consent, data and specimens cannot be used without the IRB’s approval of a waiver of consent and a waiver of HIPAA authorization.

Additionally, an agreement may be required between the institution providing the data and/or samples and the entity receiving them such as a Material Transfer Agreement (MTA) or Data Transfer Agreement (DTA). For research under a Clinical Trials Agreement (CTA), the CTA may cover the future use and sharing without the need for another agreement. Contact the UofL Privacy Office (http://louisville.edu/privacy) or the UofL Commercialization EPI-Center (formerly the Office of Technology Transfer) (http://louisville.edu/research/epi-center/) to help determine what agreement is required.