Using human subject data for research generally requires IRB approval prior to collecting the data. The level of IRB review will depend on the specific circumstances of the project. The following information describes various levels of IRB review for data collection projects. For additional guidance on how to submit your project, please contact an IRB Analyst.

1) Data collection research that could be considered Exempt Category 4:
   - Secondary use of data in research that have been collected or will be collected solely for research purposes (such as medical treatment or diagnosis) in which informed consent is not required.
   - Identifiers may be collected as part of the research data collection only if it is Protected Health Information (PHI) that is regulated by HIPAA.
   - Note that HIPAA does not apply to biospecimens, so this category applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).

2) Data collection research that could be considered Expedited Category 5:
   Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) and does not meet the criteria above for exempt.

   **#1 & #2 IRB Submission Instructions**
   - An IRB Application must be submitted in iRIS, along with a written protocol, data collection sheet, and HIPAA waiver of authorization when applicable. A “waiver of informed consent” must also be requested in the IRB application to provide justification for all criteria for a waiver of consent.
   - **Study Team Requirements:** All study personnel must have CVs loaded in iRIS, completed ADF form, and have current CITI Human Subjects & HIPAA Research Training (training not required for Exempt research).

3) Data collection research that could be considered Non-Human Subjects Research (NHSR):
   - Secondary use of data in research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) in which informed consent is not required.
   - The researchers will not view or collect any of the 18 HIPAA identifiers (i.e. the data is completely de-identified before the researcher is given access).
   - The researchers cannot link the data back to the subject identities (e.g. if the data is coded, the researcher cannot access the link to the subject identities).

   **Submission Instructions:** The NHSR application along with a written description of the project may be submitted in iRIS for the IRB to formally make this determination.

4) Data Collection that may be considered a Case Report:
   - University of Louisville defines a case report as medical information collected and presented on up to five patients to highlight an interesting treatment, presentation, or outcome.
   - If an author develops a case report with no prior research intent, IRB review is still required prior to publication to confirm the case report determination.

   **IRB Submission Instructions:** The Case Report Application must be submitted in iRIS with the written case report.