Secondary Analysis of Previously-Collected Research Data

The Human Research Protection Program (HRPP) must approve an investigator's plans to conduct a secondary analysis of data that were collected in a previous IRB-approved human research project. The purpose of HRPP review is to ensure that:

1. The original data were ethically collected; and
2. The objectives of the secondary analysis are compatible with the uses for which the original research participants provided their consent; and
3. The identity of research participants remains protected.

The process to request approval for a secondary analysis will depend on the type of data being obtained for the new use.

De-identified data

If the data for the newly proposed project are being provided to the investigator as a HIPAA- compliant de-identified data set, then the investigator should submit a "Request for Determination of Not Human Subjects Research" form.

Please accompany your request with the following documentation:

- Protocol for the new analysis
- IRB approval letter and the approved consent form from the original project
- Letter of support/permission from the current holder of the data.

If the data meet HIPAA standards for de-identification (i.e., all eighteen HIPAA identifiers have been removed), if the purpose of the new analysis generally aligns with the original consent, and if the holder of the data supports the secondary analysis, then the request will be approved administratively with no requirement for further IRB review.

Partially-identifiable data

Certain secondary analyses require a limited number of the eighteen HIPAA identifiers to be retained. Examples include the pairing of diagnosis with zip code or an analysis that involves dates of hospitalization and discharge. Investigators should submit the "Request for Determination of Not Human Subjects Research" and the materials listed above under "De-identified data." If investigators cannot readily ascertain the identity of research participants, then the project does not involve human subjects and IRB approval is not required. However, the project must still comply with HIPAA standards because *some* of the eighteen identifiers (i.e., zip code and dates) are being used. Permission for the secondary analysis may involve a data use agreement or a waiver of privacy authorization. The HIPAA Compliance Office will advise the investigator based upon the specifics of the data set.

Merging data sets

IRB approval is required if existing de-identified data are merged with other data that could potentially lead to research participants being identified. For example, if the investigator adds community, neighborhood, census track, or other geographic data to an existing de-identified data set, the probability of discerning individual identities would increase. In these instances, IRB and HIPAA requirements are case-specific. Review will be through an expedited process or by the convened committee, depending on any risks to participants. Investigators are encouraged to consult with IRB staff if their project involves merging existing and new data.

Re-analysis of identifiable data

Additional analyses of identifiable data must have IRB approval before they are undertaken. Depending on the nature of the new analysis, the investigator may either amend the existing protocol or submit a new IRB application. If the new analysis aligns with the specific aims of the original approval, then a protocol amendment is most likely appropriate. A new, separate IRB application may be required if the new analysis differs substantially from the intent of the original IRB approved protocol or if there is a new funding source. The requirement for additional informed consent will depend on whether the new analysis involves further interaction with research participants, whether the new analysis increases risk to participants, and whether the new analysis could reasonably impact participants' willingness to continue in the study.

IRB staff can provide guidance for specific circumstances.

Secondary analysis involving specimens

In general, secondary use of specimens will be evaluated similarly to data. However, new uses of specimens may increase risk to participants, particularly if individual codes or identities are retained or if genetic analyses reflect new purposes that were not anticipated when specimens were donated.

The IRB will evaluate the purposes of the new analysis as to the original consent and the possibility of increased risk. If specimens are coded or identified and the new analysis increases risk or could impact the clinical care of participants, re-consent will be required.