



IRB Guidance: Identification & Protection Levels in Research

The purpose of this guidance is to describe the identification and protection levels of data collected for research purposes in sufficient detail to assist investigators in their classification and protection levels of their research data.

Levels of Identification refers to the use of identifiers in the collection, recording and storage of research materials.

A research may begin with one level of identification and during the course of the project change levels of identification. *For example, A researcher recruits potential subjects through a website. Potential participants provide their contact information(identified information) to the researcher and the researcher emails them a consent form and information regarding the research project before they come for their research visit. During the visit, the researcher collects information from the participants using a code (coded information) as the participants identifier. The key to the code is stored in a secure location accessible only by the researcher. After all data has been collected, the researcher then removes the code from the data and destroys the key to the code (de-identified information).*

Levels of “subject identification” are as follows:

1. **Identified Data:** Refers to data which utilizes one or more identifiers, including those defined by HIPAA privacy code but not using a “limited data set” or defined by FERPA regulation.
 - Audio/video or image recordings are considered identifiable.
 - Identified data contains the following subsets:
 - A. Coded Data, Key held by project team: Data is coded; and key code held by the person at Campbell whether or not they are part of the project team.
 - B. Coded Data, Key not held by project team: Data is coded; key code not held by a Campbell faculty member, employee, fellow, resident, or student; key code not held by a member of the project.
 - If any element of your records, data files, or administrative records contains an identifier, you should indicate that your initial level identification is identified.
 - If you plan to de-identify data at any time other than the first day you access the information, you should indicate that your data is identified.
2. **Limited Data Set:** Refers to PHI and the only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions. The use of a limited data set requires the PI to execute a “limited data set” data use agreement.
3. **De-identified or De-identification:** Refers to data that has undergone or will undergo a process of removing or obscuring any private health information (PHI) or personally identifiable information (PII).



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Specific steps for de-identification can vary, the following methods are approved by the IRB:

- A. Use of a Campbell University sanctioned “honest broker”. An honest broker is an individual, or system, acting on behalf of the researcher to collect and provide de-identified information/biospecimens to the research team. Please contact the IRB office regarding who at Campbell University can serve as an honest broker.
 - The honest broker access the desired recorded information and provides the research with de-identified data.
 - The honest broker can assign a code to the information provided the research does not have access to the information linking the code to the identities of the research subjects. The researcher can request, through the honest broker, additional information corresponding to a given subject for prospective/longitudinal research.
 - If the honest broker provides coded data to the researcher but not the method to de-code the data, then the information provided will be considered de-identified.
- B. Receiving coded data/biospecimens without identifiers and without a key code. No code key may be created or saved and the resulting dataset/biospecimens can never be re-identified. This method of de-identification is usually used when an external institution is providing data to the investigator.
- C. **Anonymized or Anonymization:** Refers to data/biospecimens that is received or undergone a process of de-identification which produces de-identified data, where individual information cannot be linked back to the subject, because a key code was never created or used. There is no possible method available to re-identify the subjects.

Protection level requirements

For specific information regarding Campbell University’s protection level requirements for labeling, sharing and storage please see IT policies located at:

https://cufind.campbell.edu/university_policies/.

If you have questions, please contact the [IRB Office](#).