OHRS Information Sheet
Coded, Deidentified, and Anonymous Specimens

This OHRS Information Sheet provides clarification regarding **important definitions** relevant to research involving data and specimens.

The DF/HCC IRB requires that research involving the use of tissue specimens clearly describes the specimen that is being collected; what use is planned for that specimen; what links will exist to the specimen; who will have access to it; where the information will be stored, and what will be done with it once the planned investigation is completed. In addition, the investigator, in the research protocol, must describe what safeguards are in place to assure that participation in the study and other confidential information is protected from inappropriate disclosure.

- Confidential and confidentiality refer to the researcher's plan to handle and disseminate private information about human subjects and the means used to protect that information from unauthorized disclosure. Confidential information may be obtained about a human subject without having a direct interaction with that person.

- Coded data are data that are linked to a unique code and individual subjects' identifiers such as name, medical record number, address, email, etc. Generally, the data are saved with a study ID and a separate file exists that links the ID to the participants' identifiers.

- Deidentified data do not contain any direct or indirect identifiers or codes that link data to the individual participant's identify. All codes linking the data to the individual are destroyed, or there is no means of reidentifying the individual. As an example, samples or data may be received from another researcher which are coded, but if the recipient does not have access to the code, then the data are deidentified to the recipient. **Please Note:** For secondary use studies, if the researcher was involved in the original collection of the data, and retains a code, this would be considered human subjects research.

- Anonymous means "without a name." Data are anonymous when no one, not even the researcher, can identify the individual. Therefore, anonymous data truly lack any ability to link the information back to the person from whom the information was originally obtained. Removing a subject's name from their study-related information does not offer reasonable protection if other means of identifying the subject, such as hospital numbers or social security numbers remain with the data.

- Unique identifier refers to a code that is substituted for some or all specific patient identifiers in the patient data. This term implies that the key to this code remains in a single location and is itself protected from disclosure in some systematic way (e.g. "stored in a locked file cabinet in the principal investigator's office.") **Please Note:** Information about a human subject that has a unique identifier is NOT ANONYMOUS if

breaking the unique identifier/code means that one can link the information back to the individual from whom it was obtained.

- Linked implies that the data and the patient's identity are actually or potentially united.

- Unlinked means that the information is forever separated and can never be linked back to the individual from whom the information was obtained.

Accordingly, the consent form needs to accurately reflect what is happening. For example, if linked: "The information collected about you will be stored [under your name or other unique identifier]. Your name or other public identifiers will not be included with any information shared with other investigators." If anonymous, or unlinked: "Once collected, this information will be forever separated from your identity and can never be reconnected."

The confidentiality of medical information is at the bioethical heart of the doctor/patient relationship. If you are accessing medical information for research purposes, and you are not the patient's physician, you are doing so as a surrogate for the patient's physician. Just as it is between physicians and patients, this means that none of the information that you acquire through interaction with subjects or through access to patient records should ever be revealed outside of the narrow context of the approved research. It is a unique privilege for you to have

Related OHRS Guidance and Policy Documents (available on the OHRS website)**:**

- Policy – DFCI IRB Requirements Relating to the Use of an Honest Broker and a Usage Agreement in Banking Research
- Policy – Sharing and Transfer of Data or Specimens
- Guidance – Research Limited to the Use of Data or Specimens
- IRB Resource – Review of Data and/or Specimen Collection Protocols