

OHRS Information Sheet Linked and Anonymous Specimens

This OHRS Information Sheet provides clarification regarding **important definitions** relevant to research involving tissue 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 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.
- Anonymous means "without a name." Anonymous means truly without 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.") **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 access to this information and a serious responsibility for you to protect it.

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 – Instructions on the Collection and Sharing of Data and Tissue Specimens
- Policy – Linked and Anonymous Specimens
- Guidance – Research Limited to the Use of Data or Specimens
- Worksheet – Human Research Determination
- IRB Resource – Review of Data and/or Specimen Collection Protocols