

## **Section 12: Tissue/Data Collection and Record Reviews**

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The section discusses research methods such as tissue banking and medical chart review.

### **Tissue and Data Collection**

#### **12.1 Banking Specimens and/or Data for Future Research**

Human tissue samples have long been stored and proven to be valuable sources of information for research purposes. Whether collected ahead of time or prospectively, all research involving specimen and or data banking at DF/HCC requires review by an IRB representative. The regulations do not specifically discuss banking tissues, specimens, or collecting data for future use.

The following should be submitted to the IRB as a request for approval of research involving the collection of tissue, specimens, and data.

A new project application and protocol should be submitted describing the bank to be created. The following information should be included:

1. The types of specimens and/or data to be collected;
2. The types of research planned for the specimens;
3. A description of the process for identifying potential participants (specimen donors);
4. A description of the process for obtaining consent (or an explanation, based on the regulations, that a waiver of consent will be requested);
5. A description of where the specimens and/or data will be housed and who will be responsible for overseeing the bank;
6. A discussion as to how long the specimens and/or data will be kept and if applicable, plans for destroying the material upon completion of the trial;
7. If there are any plans to share the specimens or data with other researchers, this must be defined in the protocol and consent document. This should include a description of how this access will be tracked. The protocol must include a Usage Agreement to be signed by the collector PI and the recipient investigator that sets out the conditions for use of the data or specimens; and
8. The repository's policy concerning the return of individual research results to participants.

With regard to the consent document, the above information should be clearly and simply explained. In all cases, contact information should be included, as well as contact information for the IRB and a brief discussion of any risks to privacy and confidentiality and any physical risks that may be at issue. Participants must also be informed that current and future care as well as current and future participation in clinical trials will not be affected in any way based on their decision whether or not to participate in research involving the collection of tissue, specimens or data.

**The following information should be included:**

- An explanation of how confidentiality will be maintained
- The rights and limitations of participants to require destruction of their samples and/or associated data at a future date
- The rights and limitations of participants to require that their samples and/or associated data be stripped of any identifying information
- Identifying information available to other researchers if their samples and/or associated data are part of a registry or database

Investigators are encouraged to review the OHRs Information Sheets “Instructions on the Collection and Sharing of Data and Tissue Specimens” and “Linked and Anonymous Specimens” found on the OHRs section of the DF/HCC website.

## **12.2 Access to Banked Tissue/Data by Other Investigators**

Access to banked tissue and/or data by investigators depends upon many factors including whether identifiable information is being sought and what the approved banking protocol permits in terms of release of tissue and/or data. The IRB encourages usage agreements in approved banking protocols that permit release of coded or anonymous tissue or data. The sharing of identifiable tissue or data would require IRB review and approval of a new protocol.

Investigators should be aware that IRB approval does not guarantee access to any tissue or data bank. Permission from the investigator(s) or the committee that has oversight of the specimen bank is also required and should be obtained prior to submission to the IRB. For more information, see the section on Privacy and Confidentiality.

## **12.3 Research Involving Previously Banked Tissue**

Research that involves existing pathological or diagnostic specimens may be exempt from IRB review. As stated in [45 CFR 46.101\(b\)](#), a trial involving the collection or trial of existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt from IRB review if the sources are publicly available or the information will be recorded in such a manner that participants cannot be identified (directly or through identifiers linked to the subjects). Researchers themselves cannot make such a determination. All research activities must be reviewed by OHRs. See the OHRs sheet “Request for Exemption or Determination that Activity is Not Human Research” for more information on making such a request.

Investigators are encouraged to review the “Instructions on the Collection and Sharing of Data and Tissue Specimens” Information Sheet found on the OHRs section of the DF/HCC website.

## **Record Reviews**

### **12.4 Research Involving Record Reviews**

Another source of information in research that may not involve direct interaction with research participants is the review of previously collected medical information (i.e., medical charts, X-rays, billing records, disease registries, participant databases). Trials involving review of such information do require IRB review and approval. The IRB may authorize a waiver of informed consent. For the criteria necessary for a waiver of the informed consent requirement, see [IRB Waiver of Informed Consent and Waiver of Informed Consent and Authorization for Research](#).

A new project application and protocol should be submitted describing the data to be collected. The following information should be included in the protocol:

- Purpose or hypothesis being studied
- Types of analyses to be conducted
- Source(s) of the medical information
- Statement that the chart information to be used in the trial already exists, if applicable
- Statement that some or all of the chart information that will be used will be from data sources created in the future (e.g., after the date of IRB approval), if applicable
- Inclusive dates of medical record information that will be used in the trial
- Description of those who will have access to the collected information
- Description of how long the information will be kept and plans for destroying the information upon completion of the trial
- List of specific variables that will be used from the medical record chart
- Plans for maintaining the privacy and confidentiality of the information
- Plans for coding, or de-identifying, the information

Upon review of the proposed research, an IRB member may determine the trial is exempt from IRB review (i.e., if the data set contains no identifiers or the data are publicly available). See [Request for Exemption or Determination That Activity is Not Human Subject Research](#) for further information. Otherwise, the study may be eligible for expedited IRB review.