

OHRs Information Sheet

Instructions on the Collection and Sharing of Data and Tissue Specimens

The collection, storage, and distribution of data and/or human tissue specimens (hereinafter referred to as “specimens”) *for research purposes* are governed by the Federal regulations for the Protection of Human Subjects in research found at 45 CFR Part 46. An Institutional Review Board (IRB) oversees all elements of these activities, including the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/ or specimens with Recipient Investigators. The IRB determines whether informed consent or a waiver of informed consent is appropriate for either the initial collection of data and/or specimens or the release of data and/or specimens.

This Info Sheet is designed to answer three of the most frequently asked questions relating to the collection and sharing of data and/or specimens for research purposes:

1. How do Principal Investigators who will collect data and/or specimens (“collectors”) establish a repository?
2. How may data and/or specimens be released from the repository?
3. When do investigators need to obtain IRB approval to use specimens from an IRB-approved repository?

I. How is a repository established?

To establish a repository, the Principal Investigator (“Collector PI”) who will collect data and/or specimens obtains IRB approval for establishing and maintaining the repository. The Collector PI determines the conditions under which s/he will share data or specimens from the repository with Recipient Investigators. Recipient investigators are investigators who are not named investigators on the protocol. The conditions for use of data or tissue specimens from the repository should be incorporated into a “Usage Agreement” to be signed by both the Collector PI and Recipient Investigator. The Collector PI is responsible for maintaining a copy of the signed Usage Agreements.

To apply for IRB approval, the Collector PI should submit the following for IRB review and approval in addition to the application form and front sheet: (a) protocol with repository operating procedures; (b) informed consent document or request for waiver of consent; (c) if applicable, sample collection protocol for use by external collector-investigators; and (d) a submittal agreement for collector-investigators.

As the above items are developed the following items should be considered:

(A) Repository Operating Procedures. The Repository operating procedures (SOPS) should specify the conditions under which data and/or specimens may be accepted and shared. The protocol should contain adequate provisions to protect the privacy of subjects and maintain confidentiality of data.

The following are key components that should be included in the SOPs or protocol:

(1) Identify the Administrator

- Who will be the Administrator of the repository and be responsible for the research, including the execution of the usage agreements signed by the recipient investigators?

(2) Specimen and Data Collection Procedures:

- How will subjects be identified?
- What specimens will be collected?
- What subject data (e.g., demographic, medical history, current diagnosis, etc.) will be collected with the specimen?
- How will those data be collected?
- Who will collect it?
- Which sites are collecting the specimens and associated data?
- For specimens collected in the course of routine medical care, what procedures are in place to ensure that adequate material is available for clinical purposes and that patient care will not be compromised as a result of specimen collection for research purposes?

(3) Specimen and Data Storage

- Who will have access to subject identities? (by position and/or names)
- Are specimens and associated data linked in any way to subject identity? (e.g., can anyone trace the identity of the subject, including repository personnel?)
- If specimens are de-linked from subject identities, explain the procedure by which this is done. (e.g., when is the de-linking performed, what entity performs the de-linking, what identifying information is removed, and how?)
- How will specimens stored by the repository be labeled? (For example, a unique identifier assigned by the specimen repository. Give specific examples of the labeling or tracking system to be used.)
- State the physical location of the repository (room/building).
- How will specimens and associated data be stored? Describe the procedures for secure storage of specimens and associated data.
- How long will specimens and data be stored?

(4) Sample Collection Protocol.

- This should be included as an appendix to the SOPs or protocol if data or specimens will be contributed to the repository by investigators outside of the DF/HCC consortium. The sample collection protocol will be submitted by the non-DF/HCC investigators to their local IRB for review and approval.

(5) Submittal agreement for collector-investigators.

- This should be included as an appendix to the SOPs or protocol. A "Submittal Agreement" is a document that attests that specimens collected were obtained with written informed consent of the donor-subjects utilizing an informed consent document approved by the local IRB. It should also contain an acknowledgment that collector-investigators

are prohibited from providing recipient-investigators with access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained. [See *Sample Submittal Agreement for Collector-Investigators* provided at end of this document]

(B) Informed Consent. The submission to the IRB must include an informed consent document. Written informed consent should be obtained from each donor-subject in accordance with 45 CFR 46.116. The informed consent document should be clear and address the following topics:

- Simple, generic description of a research repository
- Purpose of the specific repository for which consent is being obtained
- How and when specimens will be collected
- Whether specimen collection will involve any additional procedures other than those in which the subject will be engaging for clinical purposes
- How and where specimens will be stored
- Name and contact information of repository principal investigator
- Name and contact information of repository administrator (if not the same as the PI)
- Types of research for which specimens may be used
 - May include options checklist
- Privacy and confidentiality protections, including coding procedures
- Use of data and tissue by named investigators
- Criteria for release of specimens that cannot be identified by recipient investigator
- Criteria for release of specimens that can be identified by recipient investigator
- Conditions under which additional IRB review would be needed
- Conditions under which subject may be re-contacted

OR

Request for Waiver of Consent. An investigator may request a waiver of informed consent for the collection, storage and/or sharing of data and/or specimens. A waiver may be granted only where the investigator can substantiate the following requirements (45 CFR Part 46.116(d)):

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and,
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If an investigator is obtaining data or a specimen directly from an individual, it will be extremely difficult to justify that individual informed consent could not practicably be obtained.

II. How may data and specimens be released from the repository?

As noted above, the Collector PI determines the conditions under which s/he will share data or specimens from the repository. If data or specimens will be shared with investigators not named on the collection protocol, then the Collector PI and the Recipient Investigator must

sign a usage agreement. The usage agreement will set forth the conditions under which the data or specimens are released.

As the repository SOPs and protocol are developed, the following information should also be incorporated as appropriate:

(1) Usage agreement for recipient-investigators. This should be included as an appendix to the protocol. The usage agreement should describe the conditions for release of the specimens to the Recipient Investigator. Typically, the agreement will stipulate the following conditions:

- The repository shall not release any identifies to the investigator
- The recipient investigator shall not attempt to recreate identifiers, identify subjects, or contact subjects
- The recipient investigator shall use the specimens and associated data only for the purposes and research specified by the repository.
- The recipient investigator agrees that he/she will seek IRB approval for a new research protocol in the event that the recipient investigator wishes to link the data or specimens to the human subjects from whom they were obtained.

If the Recipient Investigator agrees to those conditions, the Collector PI and Recipient Investigator both sign the Usage Agreement. The Collector PI may then provide the specimens or data based on the signed Usage Agreement alone. **No further IRB review and approval is required.** [See *Sample Usage Agreement* provided at end of this document]

(2) Specimen and Data Distribution

- Is there a usage agreement that is included with the protocol and approved by the IRB?
- Does the usage agreement describe what types of associated data will be provided with the specimen?
 - Does the usage agreement state any limits on secondary distribution of specimens? (For example, is there a policy that forbids investigators from transferring specimens to third parties?)
 - Does the usage agreement state that investigators agree they will not attempt to try to identify the human subject from whom the specimen was obtained without a new IRB-approved protocol?
- Will specimens be made available to commercial organizations? If so, what are the conditions for access by the commercial organizations? What, if any, restrictions will be placed on use by commercial organizations? Will specimens be made available to develop commercial products? What, if any, agreements will the organizations be required to sign?

(3) Protection of Subject Autonomy, Privacy, and Confidentiality

- What policies and procedures are in place to protect confidentiality?
- Does the repository require documentation of IRB approval of specific research projects before distributing specimens to researchers?

(4) Anticipated Research Using the Specimens and Return of Research Results

- What are the types of studies for which specimens may be used? The protocol and consent or the request for waiver of consent must be consistent and disclose clearly the proposed research uses. IRB will need to consider whether the consent obtained is appropriate based on the anticipated types of research to be performed using repository specimens and associated data.
- What is the repository's policy concerning the return of individual research results to subjects? (Be explicit about the processes proposed to evaluate the risks and benefits associated with the return of the individual research results to subjects.)

III. When do Recipient Investigators need to obtain IRB approval to use specimens from an IRB approved repository?

The Recipient Investigator must obtain IRB approval under the following circumstances:

- If the Recipient Investigator wants to use the data and/or specimens in a manner that goes beyond what is described in the usage agreement (e.g., get subject identifiers so that additional data items can be obtained from medical records), the Recipient Investigator must submit an IRB application for review and approval. The IRB application should specifically describe why the Recipient Investigator is not able to do his/her study without going beyond the terms of use in the usage agreement.
- If the Recipient Investigator is being funded by a funding source (e.g., NIH, DoD) that requires evidence of IRB approval, the Recipient Investigator should submit an IRB application for review and approval. The Recipient Investigator should include with his/her IRB application a copy of the funding agency grant, and a copy of the signed usage agreement so that the IRB knows that the terms of the usage agreement will be followed. IRB approval of the Recipient's use of the specimens or data may be determined to be exempt from the federal regulations.

**[SAMPLE SUBMITTAL AND CONFIDENTIALITY AGREEMENT
FOR COLLECTION OF DATA AND/OR SPECIMENS]**

NAME OF REPOSITORY
CONFIDENTIALITY AGREEMENT
FOR COLLECTION and SUBMISSION OF
DATA and/or SPECIMENS

I, the collector-investigator, affirm that I will not provide the recipient-investigator access to the identities of the donor-subjects or to information through which the identities of the donor-subjects could readily be ascertained.

A copy of my IRB-approved Informed Consent Document for the collection of these specimens is attached.

Recipient-Investigator's Name: _____

Collector-Investigator's Name: _____

Collector-Investigator's Institution: _____

Institution's Federal wide Assurance Number: _____

Collector-Investigator Signature

Date

[SAMPLE USAGE AGREEMENT]NAME OF REPOSITORY
USAGE AGREEMENT

The recipient acknowledges that the conditions for use of this research material are governed by the Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) on behalf of the Dana-Farber/Harvard Cancer Center (DF/HCC) in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. The recipient agrees to comply fully with all such conditions and to report promptly to the Repository Administrator (Principal Investigator) any proposed changes in the recipient's research project and any unanticipated problems involving risks to subjects or others. The recipient remains subject to applicable State or local laws or regulations and DF/HCC policies that provide additional protections for human subjects.

The research material provided to the recipient may be utilized only in accordance with the conditions stipulated in this Usage Agreement, as approved by the DFCI IRB, as follows:

- The recipient will receive no information that could identify the subject.
- If the recipient requests identifying information, the personnel of the Repository will not provide it.
- The recipient may not contact individuals who are collecting the material to obtain any identifying information.
- All material is identified by a code number that is assigned by the Repository for tracking purposes.
- Subject information will be kept confidential
- In addition to the research material itself, the following is specific information that may be provided by the Repository to the recipient in accordance with the IRB approved repository operating procedures and/or protocol:

Any use of this material beyond the terms of this agreement requires prior review and approval by the DFCI IRB and, where appropriate, by an IRB at the recipient site, which must be convened under an Office for Human Research Protections approved Federal wide Assurance.

If the recipient's use of this material is within the above guidelines and conditions, DFCI IRB review of the recipient's research project is not required.

Principal Investigator
Name of Repository

Date

Recipient Investigator
Recipient Investigator's Project Title:

Date
