

| NUMBER | DATE | AUTHOR | APPROVED BY | AUDIENCE | USE | PAGE |
|---------|-----------|---------------------|------------------------|----------------------------|---------------------------------|-------------|
| HRP-086 | 10/1/2017 | Center For Research | Institutional Official | Investigators or Designees | Required: X Elective: | Page 1 of 3 |

1 PURPOSE

- 1.1 The guidance establishes process for the banking of specimens (human biological materials)/data at Sharp HealthCare (SHC). The banking of specimens/data refers to the creation of banks and/or databases (“repositories”) to collect, store, and distribute human biological materials (specimens) and data for future research purposes. Repository activities involve three components: Collection of specimens/data; storage and management of the specimens/data; and distribution of specimens/data to “recipient” investigators for use in a future research project.
- 1.2 The guidance begins when the SHC Institutional Review Board (IRB) has determined that the banking of specimens/data is intended by an investigator, and/or research site designee.
- 1.3 The guidance ends when the IRB, principal investor, and/or research site designee determines that the guidance should no longer be observed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 If applicable, previous versions available in Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

- 3.1 Non-Research Repositories:
 - 3.1.1 If specimens or data were originally collected for non-research purposes AND were added to the repository/database without any links (if links included, this policy does not apply) to identifiable private data or information, it is a “non-research” repository/database. Studies using specimens/data from non-research repositories or databases are considered Not Human Subjects Research (NHSR) and do not need IRB review and approval.
- 3.2 Research Repositories:
 - 3.2.1 If specimens or data were collected for research purposes, it is a research repository. Collection of specimens/data, repository storage or data management and use of specimens or disclosure of data are all considered “research activities” and require IRB review and approval.
 - 3.2.2 Specimen/data repositories may include two kinds of specimens/data: a) those collected with the expressed purpose of distribution to other investigators, and b) those collected by individual investigators, and not originally intended to be shared with others, but which are subsequently shared as part of a repository.
 - 3.2.3 Any collection which contains specimens/data that are potentially identifiable (i.e. directly or indirectly with a code) and are distributed to someone other than the named investigator(s) making the collection, regardless of the original intent, may be considered to be a repository requiring SHC IRB oversight.
- 3.3 Collection of a Specimen/data for a Repository:
 - 3.3.1 Investigators who collect directly or indirectly identifiable specimen/data require IRB review at the site of collection (even if different from the site of the repository). Under most circumstances, written informed consent from the subject is required and should include information about the repository and the conditions under which the specimens/data will be shared with others.
- 3.4 Confidentiality risks of research participation may extend beyond the duration of the subject's direct participation in research. This is common when records or samples with identifiers are retained by the investigator. These confidentiality risks and/or new disclosure concerns are important to consider.
- 3.5 The ability to re-test samples containing extractable DNA has made it possible that retained samples may contain information that cannot be foreseen at the time of initial collection, but that may eventually be of great importance or sensitivity. Investigators should destroy identifiers to their samples/data as is possible.

| NUMBER | DATE | AUTHOR | APPROVED BY | AUDIENCE | USE | PAGE |
|---------|-----------|---------------------|------------------------|----------------------------|---------------------------------|-------------|
| HRP-086 | 10/1/2017 | Center For Research | Institutional Official | Investigators or Designees | Required: X Elective: | Page 2 of 3 |

- 3.6 In regards to storing data/ specimens outside of SHC, if the repository is located at an external institution or organization, the investigator must submit (to the SHC IRB) a copy of the external site's IRB approval letter for operation of the repository at that institution or organization.
- 3.7 The IRB at the institution where the repository is located must approve and maintain oversight of a protocol that: (a) specifies the conditions under which data and specimens may be accepted and shared with other investigators or designees and (b) ensures adequate privacy protections for subjects contributing to the repository.
- 3.8 Any "research" specimen/data repository that distributes materials/data requires IRB approval prior to the distribution. The investigator must follow the conditions under which the specimens/data will be shared as described in the IRB initial review application.
- 3.9 These conditions must consider the privacy of the individuals from whom the tissue came, what the informed consent permitted, and the intent of the person to whom the tissue is sent. The recipient of the tissue samples must abide by the conditions specified.
- 3.10 A committee, established under the IRB guidelines and pursuant to the IRB approval for the repository, should evaluate each request for samples to see if the request is consistent with the IRB's conditions for sharing samples and with the original informed consent.
- 3.11 The transfer of materials among collaborators requires the use of Material Transfer Agreements (MTAs). MTAs ensure SHC's rights are protected when specimens or reagents are shared with colleagues or private entities. An MTA protects the intellectual and other property rights of the provider and generally addresses:
 - 3.11.1 Limits on the use of the research materials, inventions, and results
 - 3.11.2 Prohibitions on the redistribution of the material
 - 3.11.3 Conditions of use, including prohibitions of use in animals or humans
 - 3.11.4 Conditions for publication, usually with provisions that the manuscript must be seen by the donor before submission for publication
 - 3.11.5 A hold-harmless cause, meaning that the donor has no liability resulting from the use of the material
 - 3.11.6 The return of unused materials.
- 3.12 MTAs need to be reviewed to ensure compliance with Sharp HealthCare policies, principles and guidelines, and all MTAs need to be signed by an authorized representative of Sharp HealthCare. Review and approval of MTAs is conducted by the clinical trials contracts and budgets specialist or the Legal Affairs Department of Sharp HealthCare.

4 RESPONSIBILITIES

- 4.1 The person designated to conduct the research should ensure these procedures are carried out to ensure safe and proper usage of repositories and banking of specimens/data.

5 PROCEDURE

- 5.1 The following procedure should be followed when establishing a repository at SHC.
 - 5.1.1 The investigator is to develop written guidance on operating and managing the repository. This guidance is to be provided to the IRB.
 - 5.1.2 The following documents must be included with *FORM: Initial IRB Review Application (HRP-211)*:
 - 5.1.2.1 Purpose of the repository
 - 5.1.2.2 Specimen and data collection procedures
 - 5.1.2.3 Specimen and data storage/retention
 - 5.1.2.4 Specimen derivation and processing
 - 5.1.2.5 Specimen and data distribution
 - 5.1.2.6 Obtaining informed consent

GUIDANCE: Repositories: Banking of Specimens/Data

| NUMBER | DATE | AUTHOR | APPROVED BY | AUDIENCE | USE | PAGE |
|---------|-----------|---------------------|------------------------|----------------------------|---------------------------------|---------------------------|
| HRP-086 | 10/1/2017 | Center For Research | Institutional Official | Investigators or Designees | Required: X Elective: | Page 3 of 3 |

- 5.1.2.7 Procedures for protecting privacy and confidentiality (for example, anonymization of specimens/data, coding of specimens/data, encryption, limited access/secure storage)
- 5.1.2.8 Employee confidentiality measures and confidentiality agreement
- 5.1.2.9 Procedures for return of research results (if and under what conditions)
- 5.1.2.10 Repository oversight
- 5.1.2.11 Sample informed consents for subjects contributing to the repository
- 5.1.2.12 Sample agreements for investigators collecting tissues for the repository and for investigators receiving tissues from the repository. These agreements should address use of specimens/data, human subject protections, sharing of specimens with third parties, commercial use of specimens, biohazards, and indemnification.
- 5.1.2.13 A plan for the disclosure of clinically relevant results/incidental findings including the mechanism for evaluating whether the results of research testing are clinically relevant and might warrant disclosure to the research participants. A mechanism for disclosure to participants of clinically relevant results/incidental findings to be included.
- 5.1.2.14 A Certificate of Confidentiality, if needed. Certificates of Confidentiality are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Additional information is available at the NIH Certificate of Confidentiality Kiosk web site.
- 5.1.3 If the experimental design allows it, all identifiers should be stripped from the stored samples or data, such that they can never be traced to the individual
- 5.1.4 If the experimental design requires that the specimens/data be referable back to an individual subject, retention creates a durable confidentiality risk that must be both controlled and disclosed.
- 5.1.5 If the need to link data to the individual is time limited, the data should be stripped of identifiers (rendering the samples truly anonymous) as soon as the time window has closed.
- 5.1.6 Storage with easily traceable identifiers such as patient names, initials, social security numbers, or medical record numbers is almost never appropriate. An additional safeguard for maintaining confidentiality while retaining a link is to use a code in place of identifiers.

6 MATERIALS

- 6.1 FORM: Initial IRB Review Application (HRP-211)

7 REFERENCES:

- 7.1 NIH Certificate of Confidentiality Kiosk web site

This document is available on [www.sharp.com/research, IRBANA](http://www.sharp.com/research_IRBANA) or by contacting research@sharp.com.