

Human Specimen Research Repositories - Policy

Scope

Mayo Clinic Human Research Protection Program

Research for which Mayo Clinic IRB is IRB of Record

Purpose

This procedure provides guidance to the Office for Human Research Protection Institutional Review Board (IRB), and to investigators who initiate and oversee human specimen repository activities for the collection, storage, use, and/or distribution of human specimens and associated data for research purposes.

Background

The Mayo Clinic IRB and investigators will ensure that the collection, storage, use, and distribution of human specimens and associated data for research purposes adhere to local, federal, and international protections of human subjects.

IRB Responsibilities

The IRB is responsible to:

- Review and approve human specimen research repositories that involve interaction or intervention with human subjects to obtain specimens, or that record and maintain identifying private information associated with the specimens.
- Evaluate the possible risks, and scientific and/or clinical benefits.
- Have knowledge of any additional legal or ethical considerations applicable to research utilizing human specimens and/or data received from or shared with international sites or collaborators.

Investigator Responsibilities

The investigator is responsible to:

- Ensure that the collection, storage, use, and distribution of human specimens and associated data for research purposes adhere to local and federal protections of human subjects, including the Department of Health and Human Services regulations titled Standards of Privacy for Individually Identified Health Information, also known as the Privacy Rule, and its requirements for use or disclosure of protected health information.
- Obtain IRB approval prior to initiation of repository research activities. Mayo Clinic investigators will also obtain Biospecimens Subcommittee approval, if applicable. Investigators at an institution for which the Mayo Clinic IRB is the IRB of record will obtain applicable institutional approvals.
- Submit the Human Specimen Repository Protocol template to the IRB for review and approval.
- Detail the consent process within the protocol, or justify a waiver of consent/HIPAA.

- Obtain written informed consent from subjects prior to any research handling of subjects' identifiable specimens.
- Obtain a Certificate of Confidentiality from NIH, if applicable, to protect the confidentiality of repository specimens and data. Information can be accessed at <http://grants.nih.gov/grants/policy/coc/>
- Ensure that all research studies that utilize identifiable repository specimens and data have obtained separate IRB approval for their proposed use of the repository.
- Ensure that processes are in place, if applicable, for the return of genetic or other results to repository subjects, including provisions for counseling and formal evaluation of risks and benefits to the subjects and, potentially, to members of the subject's family.
- Ensure that processes are in place for the oversight of repository activities, including access committees, advisory boards, etc.
- Ensure that a Data Use Agreement, as applicable, has been executed for disclosure of a limited data set.
- Ensure that a Material Transfer Agreement, as applicable, has been executed for the transfer of research materials between the institution and a recipient organization.

Have knowledge of any additional legal or ethical considerations applicable to research utilizing human specimens and/or data received from or shared with international sites or collaborators.

Policy

The Human Specimen Repository Protocol Template is used to document the protocol. The template is located in the IRB forms library.

<http://intranet.mayo.edu/charlie/irb/child-of-page-1/forms-library/>

Mayo Clinic investigators will utilize the Mayo Clinic Consent Form Template to document the consent. Instructions and language specific to biorepositories have been added: <http://intranet.mayo.edu/charlie/irb/child-of-page-1/forms-library/informed-consent-template-instructions-and/>

- Included within the protocol, and among the basic elements of informed consent, will be a clear description of:
 - The definition, purpose, specific aims, and operation of the repository, including oversight boards, committees, etc.
 - Subject eligibility, involvement and procedures.
 - Examples of the types of research to be conducted.
 - Genetic analysis of specimens.
 - Permissions to access the specimens and data, including researchers, federal health agencies, the IRB, etc.
 - Where and how long specimens and data will be stored.
 - Conditions under which data and specimens will be shared both within and outside of Mayo Clinic.

- Possible risks and management of risks, including risks to privacy and confidentiality, and procedures for protecting the privacy of subjects and maintaining the confidentiality of data. Codes and numbers assigned to specimens or data may not be derived from or related to information about the subject. Use within Mayo Clinic, or disclosure outside of Mayo Clinic, of identifying private information for research purposes is allowable with subject authorization through the consent process/HIPAA authorization. Possible exceptions to the consent/HIPAA authorization process include use of a limited data set.
- Possible benefits.
- The repository's policy (and process) regarding return of individual research results to subjects, including provisions for counseling.
- Procedure for withdrawal of consent and disposition of any remaining specimens.
- Disposition of specimens following the death of the subject, i.e. whether the subject wishes that their specimen(s) become the property of Mayo Clinic or the property of the subject's family.
- Any costs or payments to subjects.

Related Procedures

N/A

Related Documents

N/A

Definitions

Data Use Agreement: An agreement into which Mayo Clinic and the investigator enter with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

Human Biospecimen: A quantity of tissue, blood, urine or other human-derived material. A single biopsy may generate several biospecimens, including multiple paraffin blocks or frozen biospecimens. The molecular makeup of such specimens reflects the physiologic or pathologic condition of the person from whom they derive; therefore, they provide sensitive and specific insight into the biologic state of the donor. A biospecimen can include subcellular structures (such as DNA), cells, tissue (such as bone, muscle, connective tissue and skin), organs (such as liver, bladder, heart and kidney), blood, gametes, embryos, fetal tissue, and waste (such as urine and stool). Portions or aliquots of a biospecimen are referred to as samples. (Derived from National Cancer Institute Best Practices for Biospecimen Research.)

Human Specimen Research Repository: A collection of human specimens and associated data for research purposes, the physical structure where the collection is stored, and all relevant processes and procedures.

Limited Data Set: A limited data set allows retention of specific elements of identifying private information: geographic subdivisions, town, city, state, zip code, dates, age. Limited data sets are not considered to be de-identified information.

Material Transfer Agreement (MTA): A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use the materials for his or her own research purposes.

Protected Health Information: Individually identifiable health information transmitted by electronic media, maintained in electronic media, or maintained in any other form.

References

Office for Human Research Protection (OHRP)

[Issues to Consider in the Research Use of Stored Data or Tissues](#) (November 7, 1997)
[Guidance on Research Involving Coded Private Information or Biological Specimens](#) (October 16, 2008)

National Institutes of Health (NIH)

[NIH Publication Number 04-5489: Research Repositories, Databases, and the HIPAA Privacy Rule](#) (January 12, 2004)

National Cancer Institute (NCI)

[NCI Best Practices for Biospecimen Resources](#) (June, 2007)
[What Human Specimen Repositories Need to Tell Their IRBs](#) (June, 2007)

Public Responsibility in Medicine and Research (PRIM&R)

[Report of the PRIM&R Human Tissue/Specimen Banking Working Group: Tools for Investigators, IRBs and Repository Managers](#) (March, 2007)

45 CFR [46](#) (Protection of Human Subjects)

45 CFR [160](#) & [164](#) (Health and Human Services Privacy Rule)

Approved by

Pamela Kwon on behalf of the Office for Human Research Protections

Owner

Pamela Kwon on behalf of the Office for Human Research Protections

Contact

Angela Patterson La Baw, Michelle Daiss

Revision History

| Date | Synopsis of Change |
|---------|---|
| 8/29/17 | Minor revision. Updated the following definitions per Glossary review: Data Use Agreement, and Human Biospecimen. |

| | |
|----------|--|
| 2/7/2017 | Clarification that written informed consent must be obtained prior to any research handling of identifiable specimens; administrative edits. |
| 3/2/2016 | Scheduled review - Added "Revision History" to end of document. |