Human Biospecimen and Information Research Repositories Policy

Scope

Applies to Mayo Clinic Human Research Protection Program personnel when initiating and overseeing human biospecimens and storing, using, and distributing them for research repository activities and human subject research for which Mayo Clinic Institutional Review Board (IRB) is the IRB of Record.

Purpose

To outline the requirements to initiate and oversee human biospecimens and information research repository activities for the collection, storage, use, and distribution of human biospecimens and information for research purposes.

Policy

The Mayo Clinic IRB and investigators will ensure that the collection, storage, use, and distribution of human biospecimens and information for research purposes adhere to local, federal, and international protection of human subjects.

IRB Responsibilities

- Review and approve human biospecimen and/or information research repositories that involve interaction or intervention with human subjects to obtain biospecimens, or that record and maintain identifying private information, which may or may not be associated with biospecimens.
- Evaluate the possible risks, and scientific and/or clinical benefits of the proposed repository.
- Have knowledge of any additional legal or ethical considerations applicable to research using human biospecimens and/or information received from or shared with international or other external collaborators.

Investigator Responsibilities

- Ensure that the collection, storage, use, and distribution of human biospecimens and/or information for research purposes adhere to local and federal protections of human subjects, including the Department of Health and Human Services (DHHS) 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 (PHI).
- Obtain IRB approval before initiating human biospecimen and information research repository activities. Use of the Mayo Clinic Human Biospecimen and Information Research Repository Protocol Template is preferred.
- Develop informed consent materials conforming to institutional templates and other requirements.
- Obtain Mayo Clinic Biospecimens Subcommittee approval, if applicable. Investigators at other institutions for which the Mayo Clinic IRB is the IRB of record will obtain applicable institutional approvals.
- Describe the consent process in the IRB application, or justify a waiver of consent/ Health Insurance Portability and Accountability Act (HIPAA).

- Obtain written informed consent from subjects, as applicable, prior to any research handling of subjects' identifiable specimens and/or information.
- Obtain a Certificate of Confidentiality from National Institutes of Health (NIH), if applicable, to protect the confidentiality of repository biospecimens and information. Additional information regarding Certificates of Confidentiality can be accessed at Certificates of Confidentiality (CoC) - Human Subjects.
- Ensure that all research studies that use identifiable repository biospecimens and/or information 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 (MTA), 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 biospecimens and/or information received from or shared with international or other external collaborators.
- Include within the written repository plan/protocol, and among the basic elements of informed consent, 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.
    - Permission to access the biospecimens and/or information, including by researchers, federal health agencies, the IRB, etc.
    - Link to subject identity, if any
    - Where and how long biospecimens and/or information will be stored.
    - Conditions under which biospecimens and/or information will be shared both within and outside of the institution.
    - 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.
    - 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 for future use of biospecimens and/or information, and disposition of any remaining biospecimens.
- Disposition of biospecimens following the death of the subject, i.e. whether the subject wishes that their biospecimen(s) become the property of Mayo Clinic or the property of the subject's family.
- Any costs or payments to subjects.
- Plans for obtaining consent when child subjects reach the legal age of consent
- Justification for any consent or HIPAA waivers requested

Note: Use within the institution, or disclosure outside of the institution of identifying private information for research purposes is allowable with subject authorization through the consent process/HIPAA authorization. Possible exceptions to the consent and HIPAA authorization process include use of a limited data set.

Policy Notes

N/A

Related Procedures

N/A

Related Documents

The Human Specimen Repository Protocol Template is located in the IRB forms library: Forms and Templates

Instructions and language specific to biorepositories have been added to the Mayo Clinic Consent Form Template: Consent Form Template and Tools

Definitions

Data Use Agreement: Refers to an agreement between the institution and the investigator and 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 Biospecimen and/or Information Research Repository: A collection of human biospecimens and/or information for research purposes, the physical structure where the collection is stored, and all relevant processes and procedures.

Private Information: Private information is information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

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 (PHI): Individually identifiable health information transmitted by electronic media, maintained in electronic media, or maintained in any other form.

References

Office for Human Research Protections (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)

Office for Civil Rights (OCR)

Summary of the HIPAA Privacy Rule (May 2003)

National Institutes of Health (NIH)

Research Repositories, Databases, and the HIPAA Privacy Rule (January 12, 2004)

National Cancer Institute (NCI)

NCI Best Practices for Biospecimen Resources (March, 2016)

Report of the Public Responsibility in Medicine and Research (PRIMR) Human Tissue/Specimen Banking Working Group: Tools for Investigators, IRBs and Repository Managers (March, 2007)

45 CFR 46 Protection of Human Subjects

The HIPAA Privacy Rule

Owner

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Contact

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Revision History

Date	Synopsis of Change
06/20/2022	Scheduled review. Transferred to standardized template and made minor edits. Updated owner and contact.
08/29/2019	Updated to reflect biospecimen and/or information research repositories. Clarified that the Human Biospecimen and/or Information Research Repository Protocol Template is preferred. Added link to subject identity plans for consenting child subjects who reach legal age of consent, and justification of any waivers to the list of items to be addressed. Updated hyperlinks and made editorial revisions for clarity. Updates to Scope and Purpose by the

	Policy office.
08/29/2017	Minor revision. Updated the following definitions per Glossary review: Data Use Agreement, and Human Biospecimen.
02/07/2017	Clarification that written informed consent must be obtained prior to any research handling of identifiable specimens; administrative edits.
03/02/2016	Scheduled review; added "Revision History" to end of document.
05/18/2012	Approval for need to establish document: IRB