Yale University Human Research Protection Program

HRPP Policy 730 Human Research Record and Biological Specimen Retention and Transfer

Responsible Office	Office of Research Administration	Effective Date	10/14/2009
Responsible Official	HRPP Director	Last Revision	01/08/2018

Scope

This policy describes the minimal requirements for data retention and the Institutional Review Board (IRB)-related considerations for the transfer of University human research records including biological specimens. This policy applies to records and specimens of research participants collected, created or maintained in the course of human research and is applicable to all University investigators conducting human research.

Policy Statement

All University human research records related to the conduct of human research will be retained for no less than three (3) years from the conclusion of the research. Records will be retained in accordance with applicable legal, regulatory and/or contractual requirements including but not limited to Food and Drug Administration (FDA), funding agency, patenting, and Health Insurance Portability & accountability Act (HIPAA) requirements. When University human research records are no longer deemed useful following the proscribed record retention period, the records will be de-identified or destroyed in accordance with University media control and/or biological specimen policies.

Principal Investigators who wish to transfer University human research records or biological specimens to another institution during the course of the retention period may request approval to transfer the records. Other investigators may request that copies of data records or partial biological samples be transferred. Transfer requests will generally be approved unless one of the exceptions described herein applies. Transfers may be subject to further contractual agreements with the proposed accepting institution, funding agency agreements and/or Yale so that the University may comply with any lingering legal, regulatory or contractual obligations associated with Yale having created, collected or stored such records during the conduct of the research.

Reason for the Policy

Human research records are subject to a complex array of obligations such as funding agency agreements, patent and licensing requirements, human subject and HIPAA regulatory requirements, and state medical record retention requirements to name a few. This policy is meant to ensure that human research records are maintained, transferred and eventually destroyed in accordance with the legal, regulatory, contractual or policy obligations applicable to a given set of records or biological specimens.

This policy also intends to clarify when an investigator may transfer original research records or copies of research records to a new institution. Yale, as owner of all University records, is responsible for ensuring that records and biological specimens are available to appropriate Yale personnel for further research, treatment, and administrative purposes. Hence, Yale acting through the IRB will consider the current or anticipated needs of other Yale faculty and staff in determining whether human research records and biological specimens, should be transferred to a new institution.

Definitions

Human Subject or Human Participant
45 CFR §46 (Common Rule definition)

"A living individual about whom an investigator (whether professional or student) conducting research obtains either (1) Data through intervention or interaction with the individual; or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Record

A record is any information preserved in a fixed medium, whether on paper, electronically, or otherwise.

Research

45 CFR §46.102(d) (Common Rule – Subpart A) –

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes.

University Human Research Records

University Records which are created or received in the course of conducting human research and include any biological specimens and associated data.

University Records

University Records ("Records") are (i) records created or received by a Yale faculty member, staff member, student, or trainee in his or her role as a Yale employee, or (ii) records created or received by a Yale student or trainee in the course of providing a service to Yale or to others as part of his or her education or training, except the following:

- Intellectual property which by University policy is owned, licensed, or otherwise legally controlled by a Record User; and
- Records created or received by faculty members while participating in the peer review of (i) a manuscript, (ii) a sponsored research application, or (iii) the qualifications of a person seeking employment at another institution.

Policy Sections

730.1 Minimum Record Retention Requirements

Principal Investigators are responsible for maintaining University human research records for a minimum of three (3) years from the completion of the research. University human research records, which must be maintained, include the following:

- Primary source data collected or created in the course of the research project
- Consent forms signed by the participant
- Biological samples and associated data
- Tabulations or other manipulations of the data created for the purpose of data analysis

Secondary copies of the data and interim data manipulations are not required to be maintained but are nonetheless subject to University policies related to record retention and protection. Data, which has been de-identified in accordance with HIPAA Policy 5039, are no longer deemed to involve human subjects and are no longer subject to IRB policies and procedures but are required to adhere to other applicable University research policies related to data retention, protection, and destruction.

Principal Investigators are responsible for consulting University policies as well as federal and state laws and regulations related to data retention including but not limited to HIPAA, FDA, medical records, and funding agency requirements as applicable. Records must be maintained for at least as long as the longest record retention period applicable to a given set of research records.

730.2 Requests to Transfer University Human Research Records

Principal Investigators who are leaving the University and wish to transfer University human research records to a new institution may request approval to transfer the identifiable records or biological samples using IRB Form 720FR1. Such requests require that ethical, regulatory, and professional obligations are respected, including:

- Obtaining IRB approval from the new institution for use and/or storage of the data or biological samples.
- Recording disclosure of any PHI in accordance with HIPAA policy 5003 Accounting for Disclosures
- Upholding any intellectual property rights of the University and research team members as co-owners of the data
- Consideration of expectations of research participants as delineated in the informed consent document(s)
- Access and audit rights of the sponsor are exercised and maintained in a manner consistent with established agreements and legal or regulatory requirements.
- Ensuring adequate continuation of patient care in clinical trials.

To initiate a data or bio specimen transfer, the Investigator must submit a written request to the Department Chair, or designee and the IRB which includes a description of the data which is to be transferred; such as lab note books, primary data scoring records, primary diagnostic information, computer files, consent documents, tissue samples etc. The request for transfer must be approved by the Department Chair and the IRB. Requests to transfer the data or copies of the data or portions of biological specimens will be approved when the following criteria are satisfied:

- When the requestor is not the PI, then the PI approves that copies of the data, or portions of biological specimens may be transferred.
- If the requestor is the PI and the original data and/or specimens is requested for transfer, then provisions must be in place to permit Yale, federal and/or sponsor auditors access to the data and related research information at the new institution as needed to conduct audits related to research compliance and adherence to federal and state law and to any governing research contract(s) with the research sponsor.
- Other University research or clinical requirements are satisfied.
- If the records include biological specimens, a material transfer agreement may be required. Investigators should consult Grant and Contract Administration to determine if an agreement is necessary.
- If the data includes PHI as defined by HIPAA, and the data will not be stripped of identifiers to qualify as a de-identified or as a limited data set or if the transfer will occur without prior patient/subject authorization then the investigator must provide documentation of the disclosure in the accounting for disclosure log maintained at Yale.
- If the data/tissue will be maintained as a repository at an institution external to Yale, then IRB approval and oversight must be transferred to the new institution.

Related Information

Yale Policy 1609: Media Control

HIPAA Policy 5039: De-Identification and Limited Data Sets

HIPAA Policy 5003: Accounting for Disclosures of Protected Health Information

HIPAA Policy 5031: Authorization Requirements for Use and Disclosure of Protected Health Information.

Material Transfer Agreements: https://ocr.yale.edu/facultymaterial-transfer-agreements

Exiting Faculty Checklist: https://your.yale.edu/.../other/exiting-faculty-checklist

Contacts

Subject	Contact	Phone
IRB Review of Biomedical Research	Human Investigation Committees	hrpp@yale.edu 203-785-4688
IRB Review of Social Science, Behavioral, Education and Humanities Research	Human Subjects Committee	Human.subjects@yale.edu 203-436-3650
Material Transfer Agreements	Grant and Contract Administration	785-4689

Roles and Responsibilities

Human Investigation Committee**:**

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human subjects research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

Grant and Contract Administration (GCA) (Sponsored Research)

The Office of Grant and Contract Administration (GCA) provides assistance to faculty and staff in obtaining and managing sponsored awards that support scholarly activities while assuring proper stewardship of those funds. The office is charged with review and approval of proposals sent to and received from all sponsors

Revision History

10/14/2009; 12/01/2009; 10/01/2012; 04/04/2013; 01/08/2018