

Policy #101

DATA RETENTION

Subject and Scope

This policy applies to all human subjects research conducted under the auspices of Brandeis University and sets forth the policy regarding the minimum amount of time human subjects research data must be retained by the Brandeis Principal Investigator and the University.

Policy

All human subjects research data obtained through research conducted under the auspices of Brandeis University must be retained for a minimum of three years after the study has been closed by the IRB and the final report has been submitted to the funder, if applicable.

In circumstances where data is regulated by multiple retention standards (see below for common standards), the longest period of retention applies.

The principal investigator is responsible for the stewardship of all research data. The Brandeis University Human Research Protection Program is responsible for the additional stewardship of all administrative records.

Definitions

Research Data: Human subjects' data, documentation of subject eligibility, original signed and dated consent forms (or record of consent if verbal), master keys, and findings review logs, as well as ancillary materials such as administrative and financial records.

Administrative Records: All related correspondence, initial and revised applications, principal investigator or student and faculty assurance, sample consent/information documents (including scripts), sample recruitment materials, study instruments, translation certifications, permissions/agreements (letters, DUAs, MOUs, MTAs, IAAs, IAs, confidentiality agreements, etc.), international research addendums, statement of HIPAA protected health information use, application for waiver or modification of authorization for use or disclosure of PHI, modification and continuation requests, progress reports, statements of significant new findings provided to subjects, reports of unanticipated problems, post approval monitoring findings, and current training (CITI, biosafety, etc.) certifications.

Applicable Policies, Guidelines, Rules, and Regulations

There are a number of policies, guidelines, rules, and regulations regarding the retention of research data – many are outlined below.

45 CFR 46, the federal regulations for human subjects research: All research data must be retained for a minimum of three years after the completion of the research.

HIPAA: All research data must be retained for a minimum of six years after the disclosure of the health information.

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NIH: All research data must be retained for a minimum of three years after the final financial report has been submitted to NIH.

NSF: All research data must be retained for a minimum of three years after the final report has been submitted to NSF.

VA: All research must be retained indefinitely.

APA: All research data should be retained for a minimum of five years after the completion of the research.

FDA: All research data must be retained for a minimum of two years after the date a marketing application is approved for the drug for the indication for which it is being investigated.

42 CFR 93, the federal regulations on research misconduct: All research data related to research under investigation for research misconduct must be retained for a minimum of six years after the final resolution of the misconduct case.

Child Subjects: All research data involving children as subjects must be retained for at least seven years after the subjects have reached the age of majority.

Subjects with Diminished Capacity: All research data involving subjects with diminished capacity must be retained for at least seven years after the mental incapacity has been removed.

Student Researchers: For Brandeis University student-initiated research, all research data must be retained until the degree has been conferred or the student has otherwise left Brandeis University.

Intellectual Property: All research data associated with intellectual property resulting from the research, which has been or may be commercialized by Brandeis University, must be retained for as long as is necessary to protect the intellectual property.

Other Funders: Many funders have their own policies regarding the retention of research data – it is important to check with the funder for their policy.

Journals: Many journals have policies regarding the retention of research data related to articles they are publishing – it is important to check with the journal for their policy.