

Guideline Number:	01	Version Number:	1.0
Approval Date:	November 10, 2017		
Title:	Records Retention Guideline		

Purpose

This guideline describes the record life cycle for records created and managed by the Institutional Animal Care and Use Committee (IACUC), the Institutional Research Board (IRB), the Institutional Biosafety Committee (IBC), and the Conflict of Interest (COI) group. Included in this guideline are role delineations to identify the Office of Record and processes that define how a record moves from being active to being closed, and to being permanently archived or destroyed.

Regulatory Background

Institutional Review Board (IRB)

From 45 CFR § 46.115: *The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.*

For the purposes of this guideline, the “completion of the research” is defined as the time point when the definition of human subjects research is no longer met. Specifically, the following 4 criteria must be met in order for the research to be considered closed. The date the record is closed is considered equivalent to the date the research is completed.

- The protocol is permanently closed to enrollment
- And all subjects have completed all protocol-related interventions and interactions
- And no additional identifiable private information about the subjects is being obtained
- And analysis of private identifiable information is completed

Records related to research that require HIPAA authorization and/or involve protected health information (PHI) must be retained for at least 6 years after completion of the research. 45 C.F.R. § 164.105(c)(2).

Per IRB Policy 202: Initial Review of Research Involving Human Participants, 60 days prior to protocol expiration, the Principal Investigator (PI) is notified that a continuing review is required in order for the protocol to remain active. Reminders are sent at 60 and 30 days prior to expiration. If the continuing review is not completed and approved by the study’s expiration date, the IRB will administratively close the submission. IRB records may also be closed if the PI submits a closure request to the IRB and the study meets all of the criteria defined above.

Institutional Animal Care and Use Committee (IACUC):

From Animal Welfare Act, 9 CFR 2.35 (f): *All records and reports shall be maintained for at least three years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be available for inspections and copying by authorized APHIS or funding Federal agency representatives at reasonable times.*

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) (IV,E,12) requires that awardee institutions maintain records for 3 years after completion of the animal activity, including: a copy of the approved Assurance, minutes of IACUC meetings, records of applications, proposals and proposed significant changes, records of semiannual report and recommendations to the IO, and records of accrediting body determinations. These records must be made available to APHIS/AC or NIH/OLAW when requested.

Office of Laboratory Animal Welfare (OLAW): All records are to be kept for a minimum of 3 years, with the exception of records that relate directly to protocols which must be kept for the duration of the activity and for an additional 3 years after completion of the activity.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform to the recommendations of the *Guide for the Care and Use of Laboratory Animals* (Guide) (<https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-use-oflaboratory-animals.pdf>) and to commonly acceptable professional standards. Note that the Guide does not make recommendations concerning records retention.

For the purposes of this guideline “completion of the activity” is defined as 3 years after the date noted on the IACUC approval notification. For 3rd year re-writes in which a *de novo* review is required, the PI is notified 150 days prior to protocol expiration that a third year re-write is required in order for the research to continue. Reminders are sent at 90 and 60 days prior to expiration. For annual reviews, reminders are sent 90, 60, and 30 days prior to the annual renewal review due date. If the IACUC does not receive the PI’s response within the allotted time frame the IACUC will administratively terminate the protocol.

Institutional Biosafety Committee (IBC)

There are no regulatory requirements that discuss records retention for the IBC. Therefore, and to remain consistent with the IACUC and IRB, Princeton University will adopt practices consistent with regulations affecting the IACUC and IRB. Princeton University will retain IBC registration, meeting minutes, and rosters of IBC members for a period of three years. For registration, the 3 years begins after the expiration noted on the IBC approval notification or termination.

For 3rd year re-writes, the PI is notified approximately 60 days prior to registration expiration that a third year re-write is required in order for the research to continue. Reminders are sent at 45 and 30

days prior to expiration. For annual reviews, reminders are sent at approximately 60, 45, and 30 days prior to the annual renewal review due date. If the IBC does not receive the PI's response within the allotted time frame, the IBC will administratively terminate the registration.

Conflict of Interest (COI)

Consistent with federal regulations and guidance from the National Science Foundation (NSF) Proposal & Award Policies & Procedures Guide 17-1 (2017), Ch. IX(A)(7), the PHS/NIH grants (42 CFR 50.604 (i)), and HHS research contracts (45 CFR § 94.4(i) and 48 CFR part 4, subpart 4.7), the institution will retain COI-related documents, including meeting materials (including minutes), conflict management plans, and disclosure forms, for at least three years beyond the date of submission of the final expenditures report of the grant or research contract to which they relate, or until the resolution of any funding agency action (e.g., audit, litigation, or claim) involving those records, whichever is longer. Such records will be retained regardless of whether or not a disclosure resulted in a determination of a financial conflict of interest.

Additional retention might be required under 45 C.F.R. 75.361 for special situations, including if the University "is notified in writing by the awarding agency, cognizant agency for audit, oversight agency for audit, cognizant agency for indirect costs, or pass-through entity to extend the retention period," or if the records are subject to a legal hold (discussed in more detail below).

Princeton University adopted a University-wide Records Management Principles, which was approved by the University Executive Compliance Committee on February 15, 2017.

Responsibilities

RIA

- Maintains all record types defined above according to the table below

Researcher/PI

- Creates, modifies (amends), and renews protocol/application
- Maintains research-related records including original notebooks, analysis, interpretation, research staff and student training records, and research-specific hard/software
- Submits annual COI Form, travel disclosures and ongoing COI disclosures as required under PHS regulation and University policy

University Archivist determines whether a record has long term administrative or historical value to the University and therefore warrants permanent retention in the University Archives. A record that is not determined to be archival may be temporarily stored during an inactive period before destruction.

Office of the General Counsel (OGC)

- Provides guidance on legal retention requirements for records in the general course of business
- Coordinates document holds when a legal proceeding (a lawsuit, administrative proceeding, government investigations, or government audit, for example) is threatened, likely, pending, or ongoing.

Definitions

Record: Per the Princeton University Records Management Principles, records are generally defined as information created, received, and maintained as evidence and information by an organization or person, in pursuance of legal obligations or in the transaction of business. In the University context, records consist of recorded information that is created or received by University employees in the course of performing official functions on behalf of the University. Records are defined by content rather than by format and thus include those that are paper, analog, electronic, or any other format from which information can be retrieved. Records include, but are not limited to, official University publications (including web pages), fiscal data, correspondence (including email), meeting minutes, reports, academic records, and employee files. Records may further be classified as

Active: those that are frequently referred to or that are needed to support the current business activity of a unit.

Inactive: those that have not been needed for at least one year or for which the active period has passed. Inactive records should be securely stored until the end of the designated retention period. Unless records have been defined as permanent records they should be destroyed after the designated retention period has elapsed.

Permanent (or archival records): those which have enduring historical, administrative, or research value to the University and which the University Archives retains, preserves, and provides access to in perpetuity.

The following types of record categories have been developed by RIA for the purposes of this guideline and for which retention periods are defined.

1. Committee meeting records: agendas, attendance, minutes, voting for IACUC, IRB, IBC and COIR Panel.
2. Registration Documents – USDA, OHRP, NIH IBC Registration, PHS Assurance Statement, AAALACi accreditation, NJ Department of Environmental Protection Exotic and Wildlife Permit, etc.
3. Committee Rosters: memberships, appointment letters, affiliations, capacity (e.g. scientist, nonaffiliated member, non-scientist, AV, Chair, etc.).
4. Protocols – including applications, registrations, amendments, modifications, annual/continuing reviews, 3rd-year re-writes for IACUC and IBC. Common vernacular within regulatory

compliance parlance typically refers to IACUC protocols, IRB applications, and IBC registrations. For the purposes of this guideline, the terms protocol, application, and registration are considered identical.

5. Internal/external inspection/registration documents – Post-approval monitoring (PAM) reports, semiannual facility inspections and program reviews, reports to IO, annual reports to external agencies (Federal Wide Assurance, annual reports to USDA, OLAW and AAALACi), site visits/audits from outside agencies (e.g. AAHRP, AAALACi, PwC, OLAW, OSP), inspections from USDA or OHRP.
6. AAALAC International Program Description.
7. Incident reports - anonymous reports, reportable new information, adverse events, and investigations for IACUC, IRB and IBC.
8. Research records – those relating to actual research activity including, but not limited to, consent forms, research data, technical reports, etc. In general, the PI is the office of record for research-related records.
9. Training – includes records of online training, attestations, orientations, and webinars or hands-on training in which attendance was taken.
10. Study-related SOPs.
11. Committee Charters, policies, guidelines and SOPs.
12. Inter-institutional agreements.
13. COI disclosure Forms.
14. COI Management Plans - including discussions related to financial conflict of interest determinations.

Office of Record: The department or unit that is the primary custodian or steward of the record and is responsible for decisions related to the maintenance, access, and retention of the records, in collaboration with University Records Management and the Office of the General Counsel (OGC). The department or unit that generates a record is the Office of Record for that record unless and until that record is transmitted to, and accepted by, a Central Administrative Office, in accordance with the Central Administrative Office's guidelines.

Retention Period: The length of time records must be kept before they are eligible for destruction or archival preservation. The retention period begins at a cut-off date (e.g., the end of the fiscal, calendar, or academic year) or is triggered by a cut-off event, such as a termination of employment, contract closure, etc. For RIA this cut-off might include the date of the committee meeting in the case of minutes, or the date that the protocol was approved or closed or terminated.

Record Destruction or Deletion or Disposal: destruction includes shredding/recycling paper records or deleting/purging electronic records.

Record life cycle: refers to record creation, use, maintenance, and disposition (transfer to Archives or destruction).

Guideline

A record is created when it is submitted to the IACUC, IRB, or IBC Inbox or via the COI Reporting Tool or through an electronic management system. At creation, IBC, IRB or IACUC records are given a unique identifying number and enter the compliance review process.

Active hardcopy records will be maintained on site (87 Prospect) and digital records will be maintained within an electronic management system.

Records will be maintained according the schedule below. A record either has a retention period or is archived, but not both.

If an audit, inspection, or other visit, especially by a regulatory agency, has been scheduled in advance, do not destroy any records even though a scheduled review is pre-planned.

Records associated with ongoing research will be maintained indefinitely until the study is closed or terminated. Once the study is closed or terminated, records will be maintained for an additional 3-year period, or longer as provided in the schedule below.

Inactive records may be temporarily stored during the retention period and before being destroyed. Inactive records should be labeled with an inventory of the contents and the date upon which the records may be destroyed.

Records for archival purposes may be transferred to the University Archives according to the transfer procedures posted on the Mudd Library website at any time after the records are no longer actively used.

- Once each year, typically during a less busy time period, RIA will review all records and make the following determination:
- If the record is active, should it remain active or be moved to inactive status? Inactive records may remain on site at 87 Prospect or transferred to a storage facility
- If the record is inactive, should it be destroyed or transferred to the Archives?
- If the determination is made to destroy the record, all hardcopies should be physically destroyed and all electronic copies should be wiped clean from the hard drive and from all other computers known that may store the record.
- Before destroying the records, RIA will check to ensure that they are not subject to a legal hold as described below.

The destruction of records should be documented including the records that were destroyed and the date of destruction. RIA will send a notification to the University Records Manager once records have been destroyed notifying him/her of the action.

RIA will monitor grant closure dates for PI's, who have COI Management Plans, in Peoplesoft using the Grants module. COI Forms and Management Plans must be retained for 4 years after the end date listed in the PeopleSoft Grants module.

All records transferred to the Princeton University Archives for permanent retention will undergo the archival appraisal process and will be processed and described according to current archival standards <http://rbsc.princeton.edu/divisions/princeton-university-archives>. All University records will be open to researchers on a non-discriminatory basis following the expiration of any restrictions. University records may be restricted after consultation with the University Archivist or in accordance with legal restrictions for a specific and reasonable period of time.

Record Type	Office of Record	Retention Period	Archive*
Committee Meeting Records	RIA	7 years from date of meeting	No
Registration Documents	RIA	not applicable	Yes
Committee Rosters	RIA	7 years	No
Protocols	RIA	7 years**	No
Protocols: Senior Thesis	RIA	4 years from date of approval	No
Protocols: Junior Project	RIA	5 years from date of approval	No
Internal/External Inspection/Registration Documents	RIA	7 years	No
Incident Reports	RIA	7 years	No
Research Records and Research Data	PI	***	
AAALACi Program Description	RIA	not applicable	Yes
Training Records	RIA	7 years	No
Research-related SOPs	PI	***	
Committee policies, guidelines, SOPs	RIA	7 years	No
Interinstitutional Agreements	RIA	7 years	No
COI disclosure Forms ****	RIA	4 years	No
COI Management Plans****	RIA	4 years	No

*Archival recommendations made by University Archivist Daniel Linke in an email to RIA dated 9/1/16.

Protocols associated with ongoing research will remain active as long as the research continues *PIs are responsible for maintaining research records, research data and research-related SOPs according to university, department, or funding agency guidance.

****4-years after the end date listed in the PeopleSoft Grants module.

Legal Hold. OGC will determine whether a given set of circumstances legally obligates the University to retain certain records – for example, in connection with a threatened, likely, pending, or ongoing legal proceeding – and will notify affected individuals accordingly. Records subject to a legal hold must be retained by the Office of Record, even if those records would normally be destroyed under the Office of Record’s record retention practices. All disposal of records subject to a legal hold must cease when the hold is in place. OGC will notify the Office(s) of Record once it is permissible to resume usual recordkeeping practices.

To help the University meet its legal record retention obligations, any individual who has reason to believe that the University has become, or is likely to become, a party to a legal proceeding (a lawsuit, administrative proceeding, government investigation, or government audit, for example) will promptly inform OGC.

References

IRB

US Department of Health and Human Services regulations at 45 CFR 46
<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/>

IRB Policy 202: Initial Review of Research Involving Human Participants

IACUC

Animal Welfare Act and Regulations <https://www.nal.usda.gov/awic/animal-welfare-act>

PHS Policy on the Humane Care and Use of Laboratory Animals
<http://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf>

IBC

Office of Biotechnology Activities Website <http://osp.od.nih.gov/office-biotechnology-activities>

COI

National Science Foundation (NSF) Proposal & Award Policies & Procedures Guide 17-1 (2017), Ch. IX(A)(7) available at https://www.nsf.gov/pubs/policydocs/pappg17_1/pappg_9.jsp; 42 C.F.R. § 50.604(i)

PHS/NIH grants (42 CFR 50.604(i))

HHS research contracts (45 CFR § 94.4(i) and 48 CFR part 4, subpart 4.7)

Princeton University Records Management website: <http://records.princeton.edu/>

University-wide Records Management Principles as approved by the University Executive Compliance Committee and endorsed February 15, 2017.

Version History

Version Number	Revision Date	Revision Description
1.0	11/10/2017	Initiation