

Policies and Procedures

SECTION: Research and Compliance	NUMBER:			
CHAPTER: Individual Departments or responsible areas/parties for research records	ISSUED: 04/08/09	REV. A:	REV. B:	REV. C:
POLICY: Retention of University Research and Compliance Records	REV. D:	REV. E:	PAGE 1 OF 3	

Purpose

The purpose of this policy is to establish a University-wide procedure and process for the retention and disposal of University Records related to research.

Scope

This policy is applicable to all University employees who create, maintain, and/or dispose of University records related to research.

Policy Statement

1. The Creighton University Research and Compliance Office is committed to the retention of its records relating to research in order to meet legal requirements, optimize use of space, minimize cost, and destroy outdated and unnecessary records. This Policy identifies certain records that must be retained for specific periods of time and designates official repositories for their maintenance as shown in the Research and Compliance Records Retention Worksheet.
2. All University Records relating to research are the property of Creighton University, regardless of their physical location, even when they are in the possession of individuals, and as such, may not be permanently removed from the University nor destroyed except in accordance with this Policy.
3. University Records relating to research means any recording of information, regardless of the means of recording, that relates to the conduct of University research that is prepared, owned, used, or retained by an operating unit or employee of the University, including all documentary materials recorded by any medium, transmitted by electronic mail or fax, and every other means or form of communication or representation.
4. Ordinarily, University Records relating to research shall be maintained in a medium owned or controlled by the University. University business relating to research and compliance shall not be conducted on private, web-based electronic mail accounts, except where conducting such business on a University owned electronic mail account is impractical.

Roles and Responsibilities

1. The Associate Vice President for Research and Compliance, or his/her designee, is responsible for overseeing research record retention and destruction that is consistent with this Policy.

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2. Individual Departments or responsible areas/parties as outlined in the Research and Compliance Records Retention Worksheet are responsible for the development, coordination, implementation, and management of records at Creighton University. Implementation includes using the Research and Compliance Records Retention Worksheet as appropriate. Questions regarding this program shall be directed to the Associate Vice President for Research and Compliance.

Retention of University Records

1. University Records relating to research must be categorized and grouped according to the functional purpose they serve (see Research and Compliance Records Retention Worksheet for document types).
2. Departments and investigators must review all categories of University Records related to research under their control as necessary and must assign a retention period in accordance with the Research and Compliance Records Retention Worksheet.
3. The department or investigator must be aware of applicable state or federal requirements that require that University Records relating to research must be retained for a longer period than set forth in the Research and Compliance Records Retention Worksheet;
 - a. The University Record relating to research has been requested in any legal proceeding or is deemed likely to be requested in any legal proceeding as determined by legal counsel;
 - b. The University Record relating to research is needed to perform current or future activities in support of the administrative functions for which an operational unit is responsible;
 - c. The University Record relating to research contains evidence of legally enforceable rights or obligations of the University, or the University Record related to research is needed to fulfill statutory and regulatory requirements, or a business purpose of the unit.
4. The retention period is satisfied by retaining an electronic record of the information that accurately reflects the information set forth in the record and remains accessible for later reference.

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Disposal Procedures

1. When the prescribed retention period for the University Record relating to research has passed, the University Record must be properly disposed unless there is an exception that requires you to keep the records longer.
2. Confidential or personal records, e.g., records containing personally identifiable information, trade secrets, personal or sensitive financial information, research results, or records subject to any privilege, must be rendered irretrievable and illegible by shredding or other means.
3. All electronic mail messages, whether contained in an inbox, sent folder, deleted folder, or otherwise, should be reviewed regularly by the account owner. Messages with independent and ongoing value to the University and organizational unit, or which are required to be retained under this Policy, should be segregated and saved in an appropriate file.
 - a. **Caution:** In general, electronic files and records are not entirely deleted unless they are written over; specialized software tools can be obtained for this task.
4. Special measures must be taken when computers are discarded to ensure the information related to research on hard drives is not recoverable. Machines may be redeployed or even resold outside the University after they leave your work unit.

Resources

Research and Compliance Records Retention Worksheet

Contacts

The Associate Vice President for Research and Compliance will respond to questions and provide guidance regarding interpretation of this policy.

Research and Compliance Records Retention Worksheet

Document Type Electronic/Paper	Repository (Responsible area/party for housing document)	Retention Period	Related Regulatory Authority
GRANTS ADMINISTRATION			
Awards: Awarded Grant Proposal, Award Documents/Records, Cooperative Agreements, Contracts, Purchase Orders, Sub-agreements	Grants Administration	7 years after the Final Financial Status Report unless contract provisions are more stringent	Statute of Limitations; OIG Guidelines for Evaluating State False Claims Act
Awards: State of Nebraska (LB595, LB692), Health Future Foundation	Grants Administration	7 years after the final progress report	Grants Administration Policy
Unfunded Proposals submitted to External Agencies	Grants Administration	3 years after submission	OMB A-110, NIH Grants Policy Statement, NSF Grants Policy Manual
Grant/Contract Research Data	Principal Investigator or Department	7 years after the Final financial Status Report	Statute of Limitations; OIG Guidelines for Evaluating State False Claims Act
CLINICAL RESEARCH			
Essential Documents* <ul style="list-style-type: none"> • Regulatory documents • Case histories • Binder documents • Source documents • Original source documents • Paper Medical Records • Other study material 	Principal Investigator	7 years following the date of completion of the research study unless contract provisions are more stringent	21 CFR 312.62
* http://www.fda.gov/cder/guidance/iche6.htm			
Investigation Drug Records	Principal Investigator	2 years following the date a marketing application is approved; or, if no application is to be filed; or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified	21 CFR 312.62

Investigation Device Records	Principal Investigator	6 years after one of the following two dates, whichever is later: the date on which the investigation is terminated or completed; or the date that the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a product development protocol	21 CFR 812.140
Industry Sponsored Clinical Research Data	Principal Investigator or Department	6 years post marketing approval or IND and IDE withdrawal or unless contract provisions are more stringent	FDA or per contract terms
HUMAN RESEARCH PROTECTION PROGRAM OFFICE			
Human Subjects Records <ul style="list-style-type: none"> • Approval Applications/Forms • Consent Forms • Related Documents (Protocol, study related correspondence and sponsor related documents) 	Human Research Protection Program Office	6 years after completion of the activity	21 CFR 56.115
HIPPA Research Records (Correspondence, source documents)	Human Research Protection Program Office	6 years after the later of the date of their creation or last effective date	45 CFR §164.530(j)
Research data related to human subject protocols	Principal Investigator	At least 3 Years after completion of activity or per terms of grant/contract	CU Policies and Procedures
ANIMAL RESEARCH			
<ul style="list-style-type: none"> • Approved Application/Forms Protocols • Significant Modifications to Protocols • IACUC minutes (attendance, activities, deliberations) • Semi-annual Reports 	IACUC Office IACUC Office IACUC Office IACUC Office	3 years after completion of the activity 3 years after completion of the activity 3 years after completion of the activity 3 years	9 CFR. 2.35(f), PHS Policy, IV.E 9 CFR. 2.35(f), PHS Policy, IV.E 9 CFR. 2.35(f), PHS Policy, IV.E 9 CFR. 2.35(f), PHS Policy,

<ul style="list-style-type: none"> Assurance USDA Registration AAALAC records APHIS Form 7001/VS Form 18-1 APHIS Form 7005/VS Form 18-5 APHIS Form 7006/VS Form 18-6 Occupational Health & Safety Questionnaire Tetanus Vaccine Record Animal Health/Medical Records and Husbandry documents and other related records Research data related to animal protocols 	<p>IACUC Office</p> <p>IACUC Office</p> <p>IACUC Office Animal Resource Facility/ARF</p> <p>ARF</p> <p>ARF</p> <p>Research Compliance Monitor/ Auditor Office</p> <p>Research Compliance Monitor/ Auditor Office</p> <p>ARF</p> <p>Principal Investigator</p>	<p>3 years (ambiguous since Assurance is valid for 5 years) 3 years</p> <p>3 Years At least 3 years after completion of activity</p> <p>At least 3 years after completion of activity</p> <p>At least 3 years after completion of activity</p> <p>Duration of employment plus 30 years</p> <p>Duration of employment plus 30 years</p> <p>At least 3 Years after completion of activity</p> <p>At least 3 Years after completion of activity or per terms of grant/contract</p>	<p>IV.E PHS Policy, IV.E</p> <p>Creighton University IACUC Policies and Procedures PHS Policy, IV.E 9 CFR 2.35(f)</p> <p>9 CFR 2.35(f)</p> <p>9 CFR 2.35(f)</p> <p>29 USC.§657; CFR §1904.5 (Occupational Safety & Health Act)</p> <p>29 USC.§657; CFR §1904.5 (Occupational Safety & Health Act)</p> <p>9 CFR 2.35(f)</p> <p>CU Policies and Procedures</p>
INSTITUTIONAL BIOSAFETY			
Meeting Minutes, Faculty Registration & Attachments, Membership List, Procedures	IBC Office	3 years	
NIH/OBA Registration, annual reports and notices of new memberships	IBC Office	Indefinite	NIH
Select Agent and Toxin Registrations	IBC Office		42 CFR 73.3 42 CFR 73.4 9 CFR 121.3
DEA Controlled Substance records	Principal Investigator		Homeland Security
ENVIRONMENTAL HEALTH AND SAFETY			
Hazardous Waste Documents	Environmental Health & Safety (EH&S)	Life of Institution	EPA

Shipping Dangerous Goods Including RMW	EH&S Principal Investigator	2 year cycle	DOT (FAA)
OSHA Training Records	EH&S	Minimum 30 years for many	Dept. of Labor
Asbestos Records	EH&S	Life of Institution	EPA and State of Nebraska
UST Records	EH&S & Fleet	Life of Tanks	EPA
SPCC Documents	EH&S	Life of Tanks	EPA
Safety Committee Minutes	Risk Management		University Policy
RADIATION SAFETY			
<ul style="list-style-type: none"> • Results of surveys and calibrations • Results of surveys to determine dose from external sources • Results of measurements and calculations used to determine individual intakes • Results of air samplings, surveys, and bioassays • Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment • Determination of prior occupational dose • Planned special exposure • Individual monitoring results • Dose to individual members of the public • Waste disposal • Records of receipt of byproduct material • Records of transfer of byproduct material • Records of disposal of byproduct material • Authority and responsibilities of Ration Protection Program • Radiation Protection Program changes • Written directives • Procedures for administrations requiring a written directive • Calibrations of instruments used to measure activity of unsealed byproduct material • Radiation survey instrument calibrations • Dosages of unsealed byproduct material for medical use • Leak tests and inventory of sealed sources and 	Radiation Safety Office	3 years Duration of License Duration of License Duration of License Duration of License Duration of License Duration of License Duration of License Duration of License Duration of Possession and 3 years after transfer 3 years after transfer Duration of License 5 years 5 years 3 years Duration of License 3 years 3 years 3 years	NRC 20.2103(a) NRC 20.2103(b)(1) NRC 20.2103(b)(2) NRC 20.2103(b)(3) NRC 20.2103(b)(4) NRC 20.2104 NRC 20.2105 NRC 20.2106 NRC 20.2107 NRC 20.2108 NRC 30.51(a)(1) NRC 30.51(a)(2) NRC 30.51(a)(3) NRC 35.2024 NRC 35.2026 NRC 35.2040 NRC 35.2041 NRC 35.2060 NRC 35.2061 NRC 35.2063

<ul style="list-style-type: none"> brachytherapy sources • Surveys for ambient radiation exposure rate • Release of individuals containing unsealed byproduct material or implants containing byproduct material • Mobile medical services • Decay-in-storage • Molybdenum-99 or strontium-82 or strontium-85 concentrations • Safety instruction • Surveys after source implant and removal • Brachytherapy source accountability • Calibration measurements of brachytherapy sources • Decay of strontium-90 sources for ophthalmic treatments • Installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units 		3 years	NRC 35.2067
		3years	NRC 35.2070
		3 years	NRC 35.2075
		3 years	NRC 35.2080
		3 years	NRC 35.2092
		3 years	NRC 35.2204
		3 years	NRC 35.2310
		3 years	NRC 35.2404
		3 years	NRC 35.2406
		3 years	NRC 35.2432
	Life of Source	NRC 35.2433	
	3 years	NRC 35.2605	
Radiation Survey Usage	Principal Investigator	7 years	
CONTROLLER'S OFFICE			
Grant/Contracts Financial Status Reports (SF269 or 269A), Federal Cash Transaction Reports (SF272)	Controller's Office	7 years from date of submission of final financial reports	NIH Grants Policy Statement; OMB Circular A-133
Property Inventory	Controller's Office – Property Office	5 years after final disposition of property	NIH Grants Policy Statement; OMB Circular A-133
Personnel Activity Report Forms	Controller's Office	7 years after the end of the fiscal year in which the pay period took place	NIH Grants Policy Statement; OMB Circular A-133
Grant Files and Related Emails	Controller's Office	7 years after the end of the fiscal year in which the Final Financial Status Report	NIH Grants Policy Statement; OMB Circular A-133
Vendor Invoices	Controller's Office	7 years after the end of the fiscal year in which the invoice was paid	Internal Revenue Service; NIH Grants Policy Statement; OMB Circular A-133
Journal Entries	Controller's Office	7 years after the end of the fiscal year in which the journal entry was processed	Internal Revenue Service; NIH Grants Policy Statement; OMB Circular A-133

Deposit Slips	Controller's Office	7 years after the end of the fiscal year in which the deposit was made	Internal Revenue Service; NIH Grants Policy Statement; OMB Circular A-133
Timesheets	Controller's Office	3 years	Fair Labor Standards Act
Employee Action Forms	Controller's Office	4 years	
HUMAN RESOURCES			
Employee I-9 Documents	Human Resources	3 years after hire or 1 year after termination, whichever is later	Immigration Reform & Control Act (IRCA)
Student Employment Records, including I-9 documents	Student Financial Aid Office	3 years after hire or 1 year after termination, whichever is later	Immigration Reform & Control Act (IRCA)
All Terminated Employee Files	Human Resources	2 years after termination on CU property; 7 years after separation	Immigration Reform & Control Act (IRCA)