Policies and Procedures

SECTION: Research and Compliance	NUMBER:			
CHAPTER: Individual Departments or Responsible Areas/Parties for Research Records	ISSUED: 04/08/09	REV. A: 12/10/2018	REV. B:	REV. C:
POLICY: Retention of University Research and Compliance Records	REV. D:	REV. E:	PAGE 1 OF 4	

1. PURPOSE

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

2. SCOPE

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

3. POLICY STATEMENT

3.1. 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its records relating to research in order to meet legal requirements, optimize use of space, minimize cost, and destroy outdated and unnecessary records.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.

3.2. All Creighton 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 Creighton University or destroyed, except in accordance with this policy.

3.3. Creighton University records relating to research refers to any recording of information, regardless of the means of recording, that relates to the conduct of Creighton University research that is prepared, owned, used, or retained by an operating unit or employee of Creighton 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.

3.4. 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.

4. ROLES AND RESPONSIBILITIES

4.1. The Director of Research Compliance, or his/her designee, is responsible for overseeing research record retention and destruction that is consistent with this Policy.

4.2. 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 Director of Research Compliance.

5. RETENTION OF CREIGHTON UNIVERSITY RECORDS

5.1. Creighton 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).

5.2. Departments and investigators must review all categories of Creighton 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.

5.3. The Department or investigator must be aware of applicable state or federal requirements that require that Creighton University records relating to research must be retained for a longer period than set forth in the Research and Compliance Records Retention Worksheet:

5.3.1. The Creighton 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;

5.3.2. The Creighton 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;

5.3.3. The Creighton University record relating to research contains evidence of legally enforceable rights or obligations of Creighton University; or

5.3.4. The Creighton University record related to research is needed to fulfill statutory and regulatory requirements or a business purpose of the unit.

5.4. 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.

6. DISPOSAL PROCEDURES

6.1. When the prescribed retention period for the Creighton University record relating to research has passed, the Creighton University record must be properly disposed of, unless there is an exception that requires Creighton University to keep the records longer.

6.2. 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.

6.3. 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 Creighton University and the organizational unit, or which are required to be retained under this policy, should be segregated and saved in an appropriate file.

6.3.1. **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.

6.4. 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 Creighton University after they leave the work unit.

7. RESOURCES

Research and Compliance Records Retention Worksheet

8. CONTACTS

The Director of Research 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**
SPONSORED PROGRAMS ADMINISTRATION			
Awards: Awarded Grant Proposal, Award Documents/Records, Cooperative Agreements, Contracts, Purchase Orders, Subagreements	Grants Administration	3 years after the Final Financial Status Report unless contract provisions are more stringent	OMB A-110, OMB A-133, NIH Grants Policy Statement, NSF Grants Policy Manual
Awards: State of Nebraska (LB595, LB692), Health Future Foundation	Grants Administration	3 years after the final progress report	Sponsored Programs Administration Policy
Unfunded Proposals Submitted to External Agencies	Grants Administration	2 years after submission	Sponsored Programs Administration Policy
Grant/Contract Research Data	**Principal Investigator** or Department	3 years after the Final Financial Status Report	OMB A-110, OMB A-133 NIH Grants Policy Statement, NSF Grants Policy Manual
CLINICAL RESEARCH			
Essential Documents* • Regulatory documents • Case histories • Binder documents • Source documents • Original source documents • Paper medical records • Other study material * http://www.fda.gov/cder/guidance/iche6.htm	**Principal Investigator**	3 years following the date of completion of the research study unless contract provisions are more stringent	21 CFR 312.62
HIPAA Authorizations and/or Waiver of HIPAA Authorizations	**Principal Investigator**	6 years following the date of completion of the research study unless contract provisions are more stringent	
Investigational 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	21 CFR 312.62

		not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified	
Investigational 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 • Approval Applications/Forms • Consent Forms • Related Documents (protocol, study-related correspondence, sponsor related documents)	Human Research Protection Program Office	3 years after completion of the activity	21 CFR 56.115
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			
• Approved Application/Forms Protocols	IACUC Office	3 years after completion of the activity	9 CFR. 2.35(f), PHS Policy, IV.E
• Significant Modifications to Protocols	IACUC Office	3 years after completion of the activity	9 CFR. 2.35(f), PHS Policy, IV.E
• IACUC Minutes (attendance, activities, deliberations)	IACUC Office	3 years after completion of the activity	9 CFR. 2.35(f), PHS Policy, IV.E

• Semi-annual Reports	IACUC Office	3 years	9 CFR. 2.35(f), PHS Policy, IV.E
• Assurance	IACUC Office	3 years (ambiguous since Assurance is valid for 5 years)	PHS Policy, IV.E
• USDA Registration	IACUC Office	3 years	Creighton University IACUC Policies and Procedures
• AAALAC records	IACUC Office	3 years	PHS Policy, IV.E
• APHIS Form 7001/VS From 18-1	Animal Resource Facility/ARF	At least 3 years after completion of activity	9 CFR 2.35(f)
• APHIS Form 7005/VS From 18-5	ARF	At least 3 years after completion of activity	9 CFR 2.35(f)
• APHIS Form 7006/VS From 18-6	ARF	At least 3 years after completion of activity	9 CFR 2.35(f)
• Occupational Health & Safety Questionnaire	Research Compliance Monitor/ Auditor Office	Duration of employment plus 7 years	29 USC.§657; CFR §1904.5 (Occupational Safety & Health Act)
• Tetanus Vaccine Record	Research Compliance Monitor/ Auditor Office	Duration of employment plus 7 years	29 USC.§657; CFR §1904.5 (Occupational Safety & Health Act)
• Animal Health/Medical Records and Husbandry documents and other related records	ARF	At least 3 years after completion of activity	9 CFR 2.35(f)
• Research data related to animal protocols	**Principal Investigator**	At least 3 years after completion of activity or per terms of grant/contract	CU Policies and Procedures
INSTUTIONAL BIOSAFETY			
Meeting Minutes, Faculty Registration & Attachments, Membership List, Procedures	IBC Office	3 years	
NIH/OBA Registration, Annual Reports, Notices of New Memberships	IBC Office	Indefinite	NIH
Select Agent and Toxin Registrations	IBC Office	Indefinite	42 CFR 73.3 42 CFR 73.4 9 CFR 121.3

DEA Controlled Substance Records	**Principal Investigator**	Indefinite	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			
• Results of surveys and calibrations	Radiation Safety Office	3 years	NRC 20.2103(a)
• Results of surveys to determine dose from external sources		Duration of License	NRC 20.2103(b)(1)
• Results of measurements and calculations used to determine individual intakes		Duration of License	NRC 20.2103(b)(2)
• Results of air samplings, surveys, and bioassays		Duration of License	NRC 20.2103(b)(3)
• Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		Duration of License	NRC 20.2103(b)(4)
• Determination of prior occupational dose		Duration of License	NRC 20.2104
• Planned special exposure		Duration of License	NRC 20.2105
• Individual monitoring results		Duration of License	NRC 20.2106
• Dose to individual members of the public		Duration of License	NRC 20.2107
• Waste disposal		Duration of License	NRC 20.2108
• Records of receipt of byproduct material		Duration of Possession and 3 years after transfer	NRC 30.51(a)(1)
• Records of transfer of byproduct material		3 years after transfer	NRC 30.51(a)(2)
• Records of disposal of byproduct material		Duration of License	NRC 30.51(a)(3)
• Authority and responsibilities of Radiation Protection Program		5 years	NRC 35.2024
• Radiation Protection Program changes		5 years	NRC 35.2026
• Written directives		3 years	NRC 35.2040

• Procedures for administrations requiring a written directive		Duration of License	NRC 35.2041
• Calibrations of instruments used to measure activity of unsealed byproduct material		3 years	NRC 35.2060
• Radiation survey instrument calibrations		3 years	NRC 35.2061
• Dosages of unsealed byproduct material for medical use		3 years	NRC 35.2063
• Leak tests and inventory of sealed sources and brachytherapy sources		3 years	NRC 35.2067
• Surveys for ambient radiation exposure rate		3 years	NRC 35.2070
• Release of individuals containing unsealed byproduct material or implants containing byproduct material		3 years	NRC 35.2075
• Mobile medical services		3 years	NRC 35.2080
• Decay-in-storage		3 years	NRC 35.2092
• Molybdenum-99 or strontium-82 or strontium-85 concentrations		3 years	NRC 35.2204
• Safety instruction		3 years	NRC 35.2310
• Surveys after source implant and removal		3 years	NRC 35.2404
• Brachytherapy source accountability		3 years	NRC 35.2406
• Calibration measurements of brachytherapy sources		3 years	NRC 35.2432
• Decay of strontium-90 sources for ophthalmic treatments		Life of Source	NRC 35.2433
• Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units		3 years	NRC 35.2605
Radiation Survey Usage	**Principal Investigator**	7 years	
ACCOUNTING SERVICES			
Grant/Contracts Financial Status Reports (SF269 or 269A), Federal Cash Transaction Reports (SF272)	Accounting Services	3 years from date of submission of final financial reports	NIH Grants Policy Statement; OMB Circular A-133
Property Inventory	Accounting Services – Property Office	5 years after final disposition of property	NIH Grants Policy Statement; OMB Circular A-133
Personnel Activity Report Forms	Accounting Services	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	Accounting Services	3 years from date of submission of final financial report	NIH Grants Policy Statement; OMB Circular A-133
Vendor Invoices	Accounting Services	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	Accounting Services	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	Accounting Services	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	Accounting Services	3 years	Fair Labor Standards Act
Employee Action Forms	Accounting Services	3 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)
RESEARCH AND COMPLIANCE			
Compliance Reviews	Research and Compliance Office	3 years, 3 months	Per Federal regulatory authority for Grants/Contracts, IRB, IACUC, IBC, and other regulatory areas, when files for these areas are destroyed, these compliance review files will be destroyed.
Auditing and Monitoring Reports	Research and Compliance Office	3 years, 3 months	Per Federal regulatory authority for Grants/Contracts, IRB, IACUC, IBC, and other regulatory areas, when files for these areas are destroyed,

			these auditing and monitoring report files will be destroyed.