Administrative Records Relating to Research: Retention and Disposition Requirements Consolidated View

This is a consolidated view of the Administrative Records Relating to Research: Retention and Disposition Requirements. It is a subset of the list and contains common clinical research record types. **All employees and affiliated persons who handle UCSF records must comply with all retention requirements that apply to each research project. Examples include but are not limited to: FDA-regulated research, enrolled minors, HIPAA, COI disclosures, etc.** For the complete list go to http://www.ucop.edu/research-policy-analysis-coordination/_files/retention_disposition_2015-update.pdf Any questions can be directed to Brenda Gee: Brenda.Gee@ucsf.edu or Carolyn Tuft:	**Guidance:** *1. **Copies:** Copies are considered non-records, and should be retained only until their usefulness has passed, but never any longer than the official record.* *2. **Audit, Investigation, Litigation** : Records and information needed for audit, investigation or litigation must be kept until the matter is resolved. The records and information return to following retention and disposition requirements in the Administrative Records relating to Research: Retention and Disposition Requirements once the matter has ended.* *3. **Medical Records:** *Guidance from the UCSF Health Information Management Services (HIMS) Department states the retention period for medical records as 15 years following last recorded activity, with records of minors set at 15 years plus three years past the age of majority.* *4. **IRB and Academic Research Records:** General Counsel recommends longer retention periods for IRB and academic research records pertaining to children as subjects, (seven years after the children reach the age of majority [18 in California]) and for records pertaining to in vitro studies or pregnant women (25 years). Per the UC Contracts and Grants Manual, 18-272 Records Retention, Inspection and Copying*

Primary Function/Category	Category	Sub-Category	Description	Retention Rule/Description	Records Code	Keywords (sample records)
Research Administration Records	A. Sponsored Project Agreements Records	A.1. Sponsored Projects Proposals that are **not accepted/funded**	Rejected proposals, proposals not funded, withdrawn proposals, not accepted grant proposals	These are considered non-records, and should be retained only until their usefulness has passed.	0012A1	Rejected proposals, proposals not funded, withdrawn proposals, not accepted grant proposals

Research Administration Records	A. Sponsored Project Agreements Records	A.2. **FDA Regulated** Sponsored Projects Agreements Records for **Investigational New Drugs Applications**	Sponsored Projects Agreements Records document the life cycle of sponsored projects: including proposal and submission actions, agreement negotiations, awarding of funding or execution of agreements, issuances of subcontracts or sub-awards, ongoing administration, and termination and close-outs of the agreements. This group of records follows the administration and non-financial reporting activities surrounding sponsored projects.	Marketing Application + 2 years or Investigation discontinued and FDA notified + 2 years, if these activies do not occur, agreement expiration/termination + 6 years unless otherwise specified in the award agreement	0012A2	FDA, Food and Drug Administration, investigational new drugs, agreements for FDA drugs, awards, accepted fda proposals, subcontracts, sub-awards, sub awards, subawards, closeouts, cost sharing, cost- sharing, commitments, certifications, statistical reports, progress reports
Research Administration Records	A. Sponsored Project Agreements Records	A.3. **FDA Regulated** Sponsored Projects Agreements Records for **Investigational Devices**	Sponsored Projects Agreements Records document the life cycle of sponsored projects: including proposal and submission actions, agreement negotiations, awarding of funding or execution of agreements, issuances of subcontracts or sub-awards, ongoing administration, and termination and close-outs of the agreements. This group of records follows the administration and non-financial reporting activities surrounding sponsored projects.	Investigation completed/terminated + 2 years, if no notificatin of these activities, sponsor agreement termination/expiration + 6 years unless otherwise specified in the award agreement	0012A3	FDA, Food and Drug Administration, investigational devices, agreements for FDA devices, awards, accepted fda proposals, subcontracts, sub- awards, sub awards, subawards, closeouts, device, premarket approval, product development protocol, cost sharing, cost-sharing, commitments, certifications, statistical reports, progress reports

Research Administration Records	B. Research Integrity Records	B.1. Research-Related Conflict of Interest records for sponsored projects **funded by governmental bodies**	Research Integrity Records document all activities related to identifying and ameliorating conflicts of interest, as well as the activities related to protecting and assuring compliance under the laws and policies that protect the rights and welfare of human and animal subjects used in UC research. These records may include but are not limited to:• Research-Related Conflict of Interest records, including financial disclosure records, conflict resolution records, reports, and statements;	Retain records for 3 years after the end of the calendar year in which the expiration/termination of the sponsored agreement occurs.	0012B1	Conflict of Interest, conflicts, COI, financial disclosures, resolve, conflicting, governmental bodies
Research Administration Records		B.2. Research-Related **Conflict of Interest records** for sponsored projects **funded by non-governmental bodies**	Research Integrity Records document all activities related to identifying and ameliorating conflicts of interest, as well as the activities related to protecting and assuring compliance under the laws and policies that protect the rights and welfare of human and animal subjects used in UC research. These records may include but are not limited to:• Research-Related Conflict of Interest records, including financial disclosure records, conflict resolution records, reports, and statements;	Retain records for 7 years after the end of the calendar year created.	0012B2	Conflict of Interest, conflicts, COI, financial disclosures, resolve, conflicting, non-governmental bodies

Administrative Records Relating to Research	Conflict of Interest (COI) Records	COI Records For **NSF-funded** research	Records of all financial disclosures and of all actions taken to resolve conflicts of interest. Includes NSF funded research, FDA funded research, PHS funded research (includes NIH awards)	Retain records for 3 years after the end of the calendar year in which the expiration/termination of the sponsored agreement occurs.	None	UC Records Retention Schedule, 0012B1* NSF Grant Policy Manual Chapter V Section 510, g, UC Records Retention Schedule, 0012B1* UC Records Retention Schedule, 0012B1* 42 CFR 50.604(i)
Administrative Records Relating to Research	Conflict of Interest (COI) Records	COI for research **funded by non-governmental sponsors**	(as covered by the California Political Reform Act §18755): original reports or statements (including 700-U forms)	Retain records for 7 years after the end of the calendar year created. (Record may be retained on microfilm or other space-saving material after a period of 2 years – Government Code 81009(g))	None	UC Records Retention Schedule, 0012B2* California Political Reform Act California Government Code 81009€
Administrative Records Relating to Research	Conflict of Interest (COI) Records	COI Records: For research **funded by non-governmental organizations**	(as covered by the California Political Reform Act §18755): copies of reports or statements (including 700-U forms)	Retain records until superseded or 5 years after the end of the fiscal year in which the certification was made, unless a longer period is specified in the legal requirements. Legal requirement is: Not less than 4 years Provided that retention of more than one copy is not required (Record may be retained on microfilm or other space-saving material after a period of 2 years – Government Code 81009(g))	None	UC Records Retention Schedule, 0006C* California Political Reform Act California Government Code 81009(f)

Administrative Records relating to Research	Agreements, Awards, Contracts	Financial records pertinent to an award (Federal, State and Private)	Financial records pertinent to an award (Federal, State and Private)	Retain records for 6 years after the expiration/termination of the sponsored activities; or the period stated in the award document - whichever is longer.	None	UC Records Retention Schedule, 0005A1*
Administrative Records relating to Research	Agreements, Awards, Contracts	Fiscal Reports, Federal Research	Fiscal Reports, Federal Research	Retain records for 6 years after the expiration/termination of the sponsored activities; or the period stated in the award document whichever is longer	None	UC Records Retention Schedule, 0005A1*
Administrative Records relating to Research	Agreements, Awards, Contracts	Statistical records and supporting documents pertinent to an award for **FDA Regulated Sponsored Projects for Investigational New Drugs Applications**	Statistical records and supporting documents pertinent to an award (Federal, State and Private) for FDA Regulated Sponsored Projects for: Investigational New Drug Applications or Investigational Devices	Marketing Application + 2 years or Investigation discontinued and FDA notified + 2 years, if these activies do not occur, agreement expiration/termination + 6 years unless otherwise specified in the award agreement	None	UC Records Retention Schedule, 0012A2*, UC Records Retention Schedule, 0012A3*
Administrative Records relating to Research	Institutional Review Board (IRB) Records	IRB and academic research records pertaining to **children as subjects**	IRB and academic research records pertaining to children as subjects	7 years after the child reaches the age of maturity (18 in California)	None	UC Contracts and Grants Manual 18-272
Administrative Records relating to Research	Institutional Review Board (IRB) Records	IRB and academic research records pertaining to **in vitro studies or pregnant women**	IRB and academic research records pertaining to in vitro studies or pregnant women	25 years	None	UC Contracts and Grants Manual 18-272

Administrative Records relating to Research	Institutional Review Board (IRB) Records	Reviewed **research proposals**	Reviewed research proposals, Scientific evaluations, Approved sample consent documents, Progress reports, Reports of unanticipated problems involving risks to subjects or others, Meeting minutes, records of continuing review activities, correspondence between investigators and IRB, written IRB procedures	Retain records for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.	None	UC Records Retention Schedule, 0012B5* 45 CFR 46.115(b) Protection of Human Subjects* 21 CFR 56.115(b) IRB Records
Administrative Records relating to Research	Institutional Review Board (IRB) Records	IRB records **relating to VA research,** including the investigator's research records	IRB records relating to VA research, including the investigator's research records	These records are considered Federal Records and are currently considered unscheduled Federal Records. As unscheduled records, the original format of the record must be retained as the official recordkeeping copy until a proposed record retention and disposition schedule is submitted for review, appraisal, and approval by NARA.	None	UC Records Retention Schedule, 0012B6* Template Memorandum of Understanding between Veterans Health Administration (VHA) Central Office and {Name of Local Veterans Affairs (VA) Facility} and {Name of Local VA Nonprofit Corporation} Guidance on VA Research Records and the Impact of the Federal Records Act, Office of Research and Development, Veterans Health Administration's, dated March 8, 2013
Administrative Records Relating to Research	Health Insurance Portability and Accountability Act (HIPAA) Records	**HIPAA-related documents**, as specified (policies and procedures, communications etc.)	HIPAA-related documents, as specified (policies and procedures, communications etc.)	6 years (from the date of creation or the date when it last was in effect, whichever is later)	None	45 CFR 164.530(j)(2)

Administrative Records Relating to Research	Research Misconduct Records	**Research misconduct** proceedings records, as specified	Research misconduct proceedings records, as specified	Retain records for 7 years after the end of the fiscal year in which the specific final report is issued or all specific activity has ended, whichever is longer.	None	UC Records Retention Schedule, 0006B* 42 CFR 93.317(b)
Administrative Records Relating to Research	Food and Drug Administration (FDA) Records	Investigational New Drug Records	Investigational New Drug Applications Records of drug disposition (to be retained by investigator), Case histories (to be retained by investigator), Records of receipt, shipment or disposition of an investigational new drug (to be retained by sponsor), Records showing any financial interest (to be retained by sponsor)	Marketing Application + 2 years or Investigation discontinued and FDA notified + 2 years, if these activies do not occur, agreement expiration/termination + 6 years unless otherwise specified in the award agreement	None	UC Records Retention Schedule, 0012A2* 21 CFR 312.62(c)