

Office of Research and Project Administration (ORPA)
Record Retention

Records To Be Kept	Governing Law	Time Period	Responsible for Retention
Rejected proposals	Not specifically defined	Two years after proposed start date (destroyed or returned to department upon request)	ORPA
Rejected proposals – data	Not specifically defined	Data from rejected proposals, indefinitely	Department
Retired grants and contracts	Office of Management and Budget (OMB) Circular A110, “Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations”	Three years after end of project period or receipt of final payment, which ever comes last	ORPA (will remain in active files until termination, then into ORPA retired files. An additional four years worth of retired files are stored in the Administration Building, for a total of seven years worth of files)
Retired grants and contracts and accompanying data (<u>all</u> department-generated records)	OMB Circular A110	Three years after completion of the entire research <u>project</u>	Department

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Clinical trials: Original contract and indemnification	Food and Drug Administration (FDA) Notice: “Good Clinical Practices: Consolidated Guidelines”	Three years after completion of clinical trial	ORPA (like other contracts, clinical trial contracts remain in active files until termination, then go to ORPA retired files. An additional four years worth of retired files are stored in the Administration Building for a total of seven years)
Clinical trials – “all relevant records” ¹	FDA Notice: “Good Clinical Practices, etc.”	Three years after completion of clinical trial	Research Subjects Review Board and Western Institutional Review Board
Essential documents for the conduct of a clinical trial ²	FDA Notice: “Good Clinical Practice, etc.”	At least two years after the last approval of a marketing application or at least two years after formal discontinuation of clinical development of the investigational product or longer if required by contract	Investigator/Institution

¹ Written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings and correspondence.

² Prior to start of trial, includes Investigator’s Brochure, signed protocol and amendments and sample case report form (CRF), information given to human subject, informed consent, any other written information, advertisement for subject recruitment (all kept by IRB, too), plus all IRB membership, etc. information previously mentioned, financial records, insurance statement (where required), signed agreement between involved parties (kept by ORPA), FDA approval, where required, CV’s and other documents evidencing qualifications of investigators and subinvestigators, normal values/ranges for procedures and tests included in protocol, sample of label attached to investigational product container, instructions for handling investigational product(s) and trial-related materials, shipping records, certificate of analysis for shipped investigational product, decoding procedures for blinded trials, master randomization list, and trial initiation monitoring report. During the trial, Investigator’s Brochure updates, any revisions to protocol, CRFs, informed consent form, any other written information provided to subjects, advertisement for subject recruitment, additional reviews, correspondence from IRB, CV’s for new investigators or subinvestigators, updates to normal values/ranges, updates of procedures/tests, documentation of shipments, relevant

Records To Be Kept	Governing Law	Time Period	Responsible for Retention
For your information: Patent files Data in support of patent	U.S. Patent Law	17 years from date of patent application	Office of Technology Transfer, patent files Inventor and Department maintain data in support of patent

communications other than site visits signed informed consent forms, source documents, signed, dated and completed CRFs, documentation of CRF corrections, notification to sponsor of serious adverse events, notification by sponsor and/or investigator to regulatory authorities and IRB of unexpected serious adverse drug reactions and other safety information, interim or annual reports to IRB, subject screening log, subject identification code list, subject enrollment log, investigational product accountability at the site, signature sheet, and record of retained body fluids/tissue samples (if any). At completion or termination of the trial, investigational product accountability at site, documentation of investigational product destruction, completed subject identification code list, final report by investigator to IRB or regulatory authority, clinical study report. Most of these items are kept by sponsor also.