TEXAS HEALTH RESOUCES
Table 17-III. Record Retention Schedule
Human Subject Research Records and Documents
Approved by THR System Performance Council (SPC): 19 January 2010
Effective Date: October 14, 2013

Record or Document Type	Retention Period	Relevant Legal Citation(s)
IRB Records: • Training Records; • IRB Correspondence (other than protocol-related); • IRB Research Application (Protocol) Files; • Research (Protocol) Tracking System; • Documentation of Exemptions and Exceptions; • Documentation of Expedited Reviews; • Documentation of Review by Another Institution's IRB; and • Adverse Event Reports • Protocol Amendments • Unanticipated problems/protocol violations. • Non-compliance issues • Report(s)/form(s) submitted to any Government agency • Any other document(s) deemed appropriate for retention by the THR IRB.	*Unapproved research records (studies involving adults and minors) – 10 years from last Principal Investigator response (that would affect course of study) to the IRB. *Approved research records Studies involving adults – 10 years after completion of the research. Studies involving minors - Age 21 or 10 years after completion of the research whichever date is later.	45 CFR 46.115; 21 CFR 56.115
IRB Records: • Written Operating Procedures/Guidances; • Policies and Procedures; • Organizational Chart • IRB Membership Rosters; • IRB Membership Documentation (i.e., appointment letters, contracts); • Any other document(s) deemed appropriate for retention by the THR IRB.	IRB records will be retained by the IRB for 10 years after the year the record or document is no longer considered current.	See above
IRB Records: • Documentation of Convened IRB Meetings – Minutes; • Internal/External Audit Reports, related documentation and work product • Report(s)/form(s) submitted to any Government agency • Any other document(s) deemed appropriate for retention by the THR IRB.	IRB records will be retained by the IRB for 10 years after the year the record or document is finalized.	See above

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Investigator Records:: Protocol documents and records: • Study Protocol • Study Protocol Amendments • Signed Protocol or Amendment Signature Pages • Signed Non-Disclosure (Confidentiality) Agreement • Investigator Drug Brochure • Device Instructions for Use • Breaking the blind procedures 1572/Regulatory Forms/CV/Study Personnel: • Form FDA 1572 • Curricula Vitae for all principal and sub-investigators and site staff (updated every two years) • Medical Licenses/Medical licensure number, medical specialty, and board certification number (if applicable) for all principal and sub-investigators • ID Investigators/Credentials • Financial Disclosure Agreement(s) • Training Informed Consent and Other Related Documents: • Approved Informed Consent(s), Assent form(s) Addendum (a), Information sheet, HIPAA authorization, and Assent script. • Signed informed consent forms (if filed elsewhere, please provide memo stating the location of the signed forms) IRB Approvals and Correspondence: • IRB/IBC/RAC Approvals for Protocol, Amendments, Advertisements, Renewals • IRB Correspondence (Progress reports, letters of submission for approval, IRB notification, responses to SAE reports, and IND Safety Reports, Etc.) • HIPAA/Privacy Waiver • IRB Membership Information or General Assurance Number • National Health Authority Approval • Close out/final report notice Laboratory Records: • Lab Certifications (CAP & CLIA) • Laboratory Normal Ranges • CV pathologist/CV Director (signed and dated	Unapproved Research Records (adults and minors): At least 10 years from last communication (that would affect course of study) to the THR IRB. Approved research records: Studies involving Adults – At least 10 years after completion of the research. Studies involving minors: At least age 21 or 10 years after completion of the research whichever date is later.	FDA Regulated Research: 21 CFR 312.57, 21 CFR 313.62 and 21 CFR 812.140. For Federally Funded: 45 CFR 46.115.

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within the last two years) <u>Research Study Logs</u>: • Investigator Personnel Team Signature Page • Clinical Trials Responsibility Log—list name, signature, and initials of all personnel who perform study-related procedures • Site Visit Logs • Site Signature Logs • Master Subject Logs • Screening Logs • Training Logs (Site initiation Visit attendance log & training certificates) • Randomization, screening and enrollment reports • Enrollment confirmation faxes • Records of retained/stored body fluids/tissue samples • Patient/subject tracking logs • Temperature logs (see product accountability) <u>Correspondence:</u> • Study related correspondence between the site, sponsor, CRO,etc <u>Serious Adverse Events (SAE):</u> • Master SAE Reporting Form and Instructions • Blank SAE Forms • IND Safety Letters • Completed SAE Reports Related Correspondence <u>Product Accountability</u>: • Study Product Receipt/packing Invoices • Study Product Accountability Form(s)/Log(s) • Study Product Supply Form(s)/Log(s) • Study-agent order forms • Disposition and/or return of unused or damaged study kit records • Policies and Procedures for dispensing, security, and storage of study drug <u>Clinical Trial Agreements:</u> • Signed Clinical Trial Agreement <u>Regulatory Inspections/Audits:</u> • Correspondence relating to inspections and audits <u>Guidelines:</u> • Specific regulations/guidelines • Declaration of Helsinki • ICH/ISO guidelines (when applicable)		

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• Site Standard Operating Procedures <u>Case Report Forms (CRF):</u> • CRF transmittal(s) and corresponding source documentation <u>Miscellaneous</u>: • Miscellaneous (CRF transmittal logs, letters, memorandums, written documentation of telephone conversations, facsimiles, notes to file, newsletters, copies of electronic correspondence, IRB attestation form, qualified investigator undertaking and or clinical trial site information form) between the site and sponsor, coordinating center, contract research organization, etc. • Monitoring Report Copies		
Investigator Records: HIPAA Authorizations	Signed Privacy Rule Authorizations must be retained for at least six years from the time the Authorization is signed by the human subject.	45 CFR 164.530(j)(1)(ii)
Investigator Records: • HIPAA Alterations and Waivers	At a minimum, retained by the covered entity, for at least 6 years from the waiver effective date or the date the waiver was last in effect, whichever is later.	45 CFR 164.530(j)
<u>Litigation, Investigation or Audits</u> Any record involved in litigation, investigation, claim, or audit that is started before the expiration of the 10-year period or when there is reason to believe an investigation, litigation or audit will occur.	Records shall be retained indefinitely until all litigation, investigation, claims or audit findings involving the records have been resolved and final action taken (see also Research Misconduct section below). When the litigation, investigation or audit is complete, the normal retention schedule will apply depending on the document category.	None

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Research Misconduct • Records or documents involved in proceedings related to an allegation of research misconduct	Records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the THR proceeding or the completion of any proceeding by another agency or regulatory body (i.e., PHS or other agency) involving the research misconduct allegation.	42 CFR 93.317
Official Transfer of Records: When investigator records are officially transferred to or maintained by the Federal awarding agency or other appropriate entity. (Note: Official transfer would not occur until THR and non-THR appropriate officials/committees agree via written documentation that the transfer is acceptable.)	The 10-year retention requirement is not applicable to the recipient. The recipient will follow its own retention schedule as appropriate.	None
Research Administration • Financial records, supporting documents, statistical records, and all other records pertinent to an award or receipt of monies to conduct a research study. Examples of documents include the study contract, study grant and Medicare related documentation. • Other research administration records	Unapproved research records – 10 years from last communication (that would affect course of study) from the principal investigator/study staff. Approved research records – 10 years after research is complete, final expenditure report submitted, and all audit issues resolved; whichever period is longer.	Office of Management and Budget (OMB) Circular A-110, Section 53b 45 CFR 74.53 2 CFR 215.53

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