**RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY**
**GUIDANCE FOR INVESTIGATORS**

**Recordkeeping and Record Retention Requirements**

**RECORDS RETENTION AT-A-GLANCE:** Below is the minimum requirement for research record retention. However, the University recommends maintaining these records indefinitely.

<table>
<thead>
<tr>
<th>Category</th>
<th>Study Type</th>
<th>Retention Period</th>
<th>Relevant Source/Citation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-funded, non-FDA regulated, non-published</td>
<td>Three (3) years after completion of the research</td>
<td>45 CFR 46.115(b) Protection of Human Subjects&lt;sup&gt;1&lt;/sup&gt;</td>
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<tr>
<td>2</td>
<td>Funded, non-FDA regulated</td>
<td>Minimum of five (5) years after completion of the study or publication of the results, whichever is later, and preferably indefinitely</td>
<td>Legacy UMDNJ Guidelines&lt;sup&gt;2&lt;/sup&gt;</td>
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<tr>
<td>3</td>
<td>HIPAA authorization</td>
<td>Minimum of six (6) years or until authorization expires</td>
<td>45 CFR 164.530 Security and Privacy&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td>4</td>
<td>FDA regulated – Investigational drug or device</td>
<td>Two (2) years after the investigation is discontinued and FDA is notified, following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or the application is not approved for such indication</td>
<td>21 CFR 312.62 FDA - Investigational New Drug Application&lt;sup&gt;4&lt;/sup&gt;</td>
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<tr>
<td>5</td>
<td>ICH compliant</td>
<td>Two (2) years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor.</td>
<td>ICH E6 4.9.5 GCP: Investigator – Records and Reports&lt;sup&gt;5&lt;/sup&gt;</td>
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<tr>
<td>6</td>
<td>Pediatric/Minor Research</td>
<td>Until age 18 or in accordance with guidelines listed above whichever is later</td>
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**GENERAL GUIDANCE:**
Investigators are required to maintain records of their human-subjects research activities. Good records are essential for verifying the quality of study data produced and demonstrating investigator compliance with good clinical practice guidelines and applicable regulatory requirements. In general, investigators should establish two sets of files for each study:

- Regulatory documents
- Study subject information
I. Regulatory Documents. Regulatory documents should be maintained for all studies, regardless of sponsor/funding source, or whether the research is funded. These documents are typically organized within a regulatory binder, either paper or electronic. Some documents that may be common to more than one study, such as CVs and professional licenses, may be filed centrally. The regulatory binder should contain the essential documents listed below.

Basic regulatory documents required for all studies (non-funded, non-FDA-regulated, non-published):

a. Personnel:
   i. CVs document qualifications and eligibility to conduct a study and provide supervision of subjects. CVs should be signed and dated. It is recommended that CVs be updated every two years to verify that the information is accurate and current.
   ii. Valid licenses and certifications for all professional study staff
   iii. Mandatory human subjects protection training such as CITI.
   iv. Institution’s financial disclosure form: signed/dated copies of financial disclosure for all investigators and staff listed on the protocol.
   v. Staff Signature/Delegation of Responsibility log: documents the signature and initials for all staff that collect and record study data, and lists the study-related procedures each has been delegated by the Principal Investigator

b. Protocol: all versions should be numbered and dated
   i. Initial submission; Continuing reviews; Modifications/Amendments
   ii. Copy of all IRB-approved versions of the consent form and assent form (if applicable).
   iii. Blank copies of all data collection forms, questionnaires, CRFs, and/or study instruments.
   iv. Recruitment materials
   v. Educational materials or other study information designed for subjects

c. IRB Correspondence:
   vi. All IRB correspondence including approval letters and/or notifications
   vii. IRB-approved recruitment materials
   viii. IRB-approved educational materials or other study information distributed to subjects

d. Monitoring Records: document any study-related activity performed to monitor study progress or the accuracy and completeness of study records.
   i. Data Safety and Monitory Board (DSMB) reports
   ii. Sponsor monitor reports
   iii. Audit reports, internal and/or external

e. Laboratory documents (if applicable): These materials document the competency of all lab facilities being used in the study and support the reliability of test results.
   i. Updated copies of laboratory certification,
ii. The Lab Director’s CV
iii. The normal lab/reference values

f. Reportable Events:
   i. Any study violations/deviations
   ii. “On-site” adverse events
   iii. Unanticipated problem reports

g. Others (if applicable):
   i. IBC
   ii. Radiation Reports

Additional regulatory documents required for Funded, non-FDA regulated studies:
   h. NIH/Funding agency grants applications and progress reports.
   i. Correspondence/contract with study sponsor/funding agency.

Additional regulatory documents required for FDA-regulated investigational drug or device studies:
   j. Policies and procedures for dispensing, security, and storage of study drugs/devices.
   k. Copies of all Form FDA 1572s (Statement of Investigator) and Form FDA 1571s (Investigational New Drug Application), if applicable.
   l. Drug/device shipment and receipt records (may be maintained by the Research Pharmacy or Investigational Drug Service (IDS)).
   m. Drug/device accountability log (drug accountability log may be maintained by the Research Pharmacy or IDS).

II. Study Subject Information

   n. General Subject Information
      i. Potential subject/Screening log: captures all potential subjects who appear to be qualified for the study.
      ii. Enrollment/Randomization log: captures all subjects who have signed an IRB-approved consent form or, with IRB approval, have given verbal consent or had informed consent waived; and have been randomized if applicable.

   o. Individual Subject Files: There should be a separate file for each subject enrolled in or screened for a study. The following documents are placed in each file:
      i. An eligibility checklist, signed and dated by the person determining eligibility, lists specific inclusion/exclusion criteria. Copies of source documentation to support medical criteria should be available in the subject’s medical record, and retained to corroborate entries on the data collection instruments.
      ii. Original signed and dated consent form
      iii. Individual case report forms (CRF)
      iv. Study instrument(s) used to capture all data required by protocol for each subject, such as data collection forms, questionnaires, and/or subject diaries
Citations:


