SOP: Record Retention Timeframe – Investigators				
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1 PURPOSE

1.1 This procedure establishes the timeframe study Investigators must maintain Human Research records.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Maintain all Human Research records, including signed and dated ICFs (including HIPAA authorizations, as applicable). Refer to the IRB's File Review and Participant File self-audit tools and Post-Approval Responsibilities for more information about what records should be maintained. These records are to be maintained for **a minimum of 7 years after the study has been closed out in the IRB office**, and in accordance with the following timeframes as follows:

3.1.1 Sponsored Research: The investigator will be responsible for maintaining research records as agreed to in the clinical trial agreement with the study sponsor and in accordance with applicable federal and state law regarding record retention.

3.1.2 Investigational Drugs: In accordance with 21 CFR 312.57(c) the investigator, or sponsor is to retain the records and reports required by Subpart D of the section for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.[1]

3.1.3 Investigational Devices: In accordance with 21 CFR 812.140 the investigator, or sponsor, is to maintain the records required by Subpart G of the section during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is closed 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.[2]

3.1.4 Other: In all other studies that do not have a clinical trial agreement, or are not regulated by the FDA, the investigator will be required to maintain research records for 7 years after s/he has closed the study with the IRB.

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm