**End of Study / Study Closure Document Inventory**

**Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CRO: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Investigator contact information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Site #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ HRPO#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of Study Closure in myIRB: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_**

**SUBJECTS**

Total # Enrolled: \_\_\_\_\_\_\_\_\_\_ (includes all subjects who signed a consent form)

\*All signed informed consent forms are on file and complete \_\_\_\_\_\_\_

Total # LTFU (Lost to follow up): \_\_\_\_\_\_\_\_\_\_

Total # withdrawn (not due to death, and not LTFU): \_\_\_\_\_\_\_\_\_\_

Total # deaths (while enrolled in study) \_\_\_\_\_\_\_\_\_\_

Subject Screening Log: Includes \_\_\_\_\_\_\_\_\_\_ subjects

Subject Enrollment Log: Includes\_\_\_\_\_\_\_\_\_\_ subjects

Complete subject identification code list: \_\_\_\_\_\_\_\_\_subjects

Master Randomization Log: Includes \_\_\_\_\_\_\_\_\_\_ randomized subjects (if applicable)

Record of retained tissue samples/body fluid samples (if applicable) \_\_\_\_\_\_\_\_\_# of samples

**ESSENTIAL DOCUMENTS**

**PROTOCOL AND ALL PROTOCOL AMENDMENTS:**

* Original protocol dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Protocol Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB protocol Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amendment dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Protocol Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB protocol Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amendment dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Protocol Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB protocol Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amendment dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Protocol Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB protocol Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amendment dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Protocol Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB protocol Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**INFORMED CONSENTS**

* Original approved consent form

Version \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amended Consent

Version \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amended Consent

Version \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amended Consent

Version \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Amended Consent

Version \_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**INVESTIGATOR BROCHURE (IF APPLICABLE) / INVESTIGATIONAL PRODUCT**

* IB Original Version \_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* IB Amendment Version \_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* IB Amendment Version \_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signed Signature page\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Instructions for handling of investigational product (if not included in protocol or IB)

Version \_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Shipping/Accountability Records for Investigational Product (IP) \*To document the final

accounting of investigational product(s) received at the site, dispensed to

subjects, returned by the subjects, and returned to sponsor.

Verified, complete and present \_\_\_\_\_\_\_\_\_\_

* Destruction records. Documentation of destruction of unused investigational product by the sponsor or at the site. Verified, complete and present \_\_\_\_\_\_\_\_\_\_\_\_\_
* Decoding/unblinding procedures (if applicable, for blinded trials) to document how, in case of an emergency, identity of blinded investigational product can be identified without breaking the blind for the remaining subjects’ treatment.
* Verified. Unblinding procedures can be found in protocol \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* OR, Unblinding procedures can be found elsewhere (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**\*IDE CLINICAL TRIAL**

* IFU (Instructions for Use) Document

IRB approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 N/A \_\_\_\_\_\_\_\_

* (Full) FDA approval letter dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* CMS approval obtained \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

N/A \_\_\_\_\_\_\_\_

* Annual Report \*Reported to IRB

1 YR APR dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 2 YR APR dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 3 YR APR dated **\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_** date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 4 YR APR dated **\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_** date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 N/A \_\_\_\_\_\_\_\_

* Device Accountability Records. \*To document the final accounting of investigational device(s) received at the site, used for subjects, destroyed and/or returned to sponsor.

Verified and present \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**RECRUITMENT/ADVERTISEMENT**

* Recruitment flyer (if applicable)

Version \_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

IRB Approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Advertisement used for subject recruitment (if applicable)

IRB approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* No Advertising was used for this study \_\_\_\_\_
* Any other written information to be provided to the subject(s)

Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB approval \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**REGULATORY DOCUMENTS**

* Federal Wide Assurance Letter (for IRB membership/composition documentation) \_\_\_\_\_
* Laboratory (as applicable)

Local Laboratory:

* CAP
* CLIA
* Normal values for applicable medical/laboratory tests
* CV and medical license Local Laboratory Director

Verified: All of the above are present \_\_\_\_\_

 Central Laboratory:

* CAP
* CLIA
* Normal values of applicable medical/laboratory tests
* CV (Curriculum Vitae) and medical license Central Laboratory Director

 Verified: All of the above are present \_\_\_\_\_

* CV and/or other relevant document demonstrating qualifications (signed and dated every 2 years)

Principal Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 Subsequent updated CV dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Medical License (Renewed Yearly)

Principal Investigator: License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

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Sub Investigator License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

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Sub Investigator License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

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Sub Investigator License dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

 dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_; dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Financial Disclosure Forms signed and dated

Principal Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sub Investigator dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* FDA form 1572 original dated \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Revision date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Revision date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Revision date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

* Delegation of Authority Log

Complete, with all signatures and dates. Verified, complete \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**TRAINING DOCUMENTATION**

* Appropriate training logs/documentation is verified and complete for all applicable study personnel \_\_\_\_\_\_\_\_\_\_
* Retain copy of: (Required for IND studies)
* Manual of Operations \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Pharmacy Manual \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* CRF Instructions \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Related Procedural Manuals \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB ANNUAL RENEWAL(S)** (as applicable)

* Annual Renewal (1) IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* Annual Renewal (2) IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* Annual Renewal (3) IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* Annual Renewal (4) IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* Annual Renewal (5) IRB approval date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**MONITORING**

* Site Visit Log is present and complete \_\_\_\_\_\_\_\_\_\_
* Final trial close-out monitoring report. Verified, present and complete \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CASE REPORT FORMS**

* All CRFs are complete. Verified, complete \_\_\_\_\_\_\_\_\_\_\_\_
* All CRFs have been monitored. Verified, monitored \_\_\_\_\_\_\_\_\_\_\_
* All CRFs queries have been resolved and documented. Verified, resolved \_\_\_\_\_\_\_\_\_\_
* All CRFs have been reviewed and signed by the Principal Investigator.

Verified, reviewed and signed by PI \_\_\_\_\_\_\_\_\_\_

**SOURCE DOCUMENTS**

* Source documents for all individual subjects:
* The original documents, data, and records containing clinical findings, observations, or other activities that allow for the reconstruction and evaluation of the study. (i.e., hospital records, clinical and office charts, laboratory notes, X-rays, memoranda, subject diaries, pharmacy dispensing records, etc.)

 Verified: Source documents are present in individual subject records

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Additionally, retain all pertinent study correspondence
* IRB correspondence
* Sponsor ↔ Site correspondence
* Subject correspondence

**ADVERSE EVENTS/SERIOUS ADVERSE EVENTS/RECORDING AND REPORTING**

* All unanticipated problems have been captured by study staff \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* All Unanticipated problems have been reported according to HRPO policies and procedures. Verified, reported per policy \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB NOTIFICATION OF STUDY CLOSURE**

* Closure submitted to IRB \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
* IRB closure acknowledgement provided to sponsor (as applicable) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

**UNUSED STUDY SUPPLIES**

* All unused study supplies including investigational product, unused CRFs, laboratory supplies must be returned to the sponsor or destroyed per instructions of the sponsor.
* Investigational Product:

\_\_\_\_\_\_\_\_\_\_verified, all IP has been (returned / destroyed) as directed by the study sponsor. *Keep all related documentation.*

* Unused Laboratory Supplies:

\_\_\_\_\_\_\_\_\_\_verified, all laboratory supplies have been (returned / destroyed) as directed by the study sponsor.

* Unused Study Documents:

Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Verified, unused study documents have been (returned / destroyed) as directed by the study sponsor.

* Unused “Other” Study Supplies: (Specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_verified, all laboratory supplies have been (returned / destroyed) as directed by the study sponsor.

**DOCUMENT RETENTION**

* Consider plans for record retention
* Note location of all study records. File together and categorize as needed.
* Follow all federal, state, and local government as well as institutional policies for record retention (these may vary). ***The most stringent requirement would apply.***
* All study records must be kept in their original format for at least 6 years from the completion of the study. (HRPO Policy)
* For research conducted under an IND, the clinical research records must be retained for a minimum of two years after the marketing application is approved. Alternatively, if no application will be filed or if the application is not approved for the requested indication, the records must be retained for a minimum of two years after the investigation is discontinued and FDA is notified.
* For research conducted under an IDE the investigatoris required to retain records for a period of two [2] years after: the date on which the investigation is terminated or completed; or, the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
* Additionally, before destroying any records, sponsor approval/documentation must be obtained.