Clinical Research Billing Compliance Frequently Asked Questions

Clinical Study Record Retention Requirements

1. What are the UC and UC Irvine Study record retention policies?

UC policy on record retention related to research can be found here: http://www.ucop.edu/research-graduate-studies/_files/research/policies/documents/retention_disposition_reqs.pdf

UCI Health's record retention policy, including research records as part of the medical record can be found here: https://intranet.ha.uci.edu/sites/policiesandprocedures/hospital/General%20Administrative%20Policies/Privacy%20and%20Security%20Policies/Document%20Retention.pdf

2. **How long should the investigator retain study related records at the completion of a clinical study?**

   The investigator must retain all study–related records for the designated period required by all applicable law, regulation, policy, or award terms/sponsor contract.

3. **What types of specific documents should the investigator retain at the completion of a clinical study with an IND (Investigational New Drug) Application?**

   All study documents should be retained by the Investigator, including, but not limited to:

   - All Case Report Forms (CRFs/eCRFs), data Clarification forms collected
   - Complete subject identification list
   - Audit certificate (if required)
   - Final trial close out monitoring report
   - Randomization/Treatment allocation and decoding document
   - IRB communications and Final report to IRB/IEC
   - Clinical study report
   - Records of disposition of the drug, including dates, quantity, and use by subjects
   - Clinical case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
   - Any clinical records used to support billing submitted and payments received for protocol services

4. **What types of records are considered part of each subject's case history as defined by federal regulations?**

   Case histories are defined in 21 CFR §812.140(a)(3) and include the case report forms and supporting data including, signed and dated informed consent forms and medical records including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

5. **What type of records does the FDA require the investigator to retain for studies involving Significant and Non-Significant Risk devices?**

   The investigator must maintain accurate and complete records relating to the investigation. These records include:

   - All correspondence with the sponsor, other PIs, the IRB, FDA and other regulatory correspondence, etc.

- Records of receipt, use, or disposition of the investigational device
- The protocol and documentation (date and reason) for each deviation from the protocol (if any)
- Case report forms and supporting data
- Signed and dated consent forms and research record notations demonstrating that informed consent was obtained prior to participation in study
- Medical records (including progress notes of the physician, hospital chart(s), and nurses' notes) and any other records that the FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation

6. How long does the FDA require the Investigator to retain documents on a clinical study with an Investigational Device Exemption (IDE)?

The documents should be retained:

- At least 2 years after the last approval of a marketing application or
- Until at least 2 years have elapsed since the formal discontinuation of clinical development of the product, and the FDA is notified.

NOTE: UC or UCI record retention policies may require retention for a longer period of time.

7. How long does the FDA require the Investigator to retain documents on a clinical study with an Investigational New Drug (IND)?

The documents should be retained for a period of:

- At least 2 years 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 if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

NOTE: UC or UCI record retention policies may require retention for a longer period of time.

8. Does the US Department of Health and Human Services (DHHS) have regulations regarding clinical study record retention that apply to studies that are not FDA-regulated?

Yes, DHHS' regulations on the protection of human research subjects apply even if the study is not FDA-regulated. DHHS' study record retention regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three (3) years after completion of the research. Retained records must include the signed informed consent form or the short form with written research summary, unless the IRB waived the requirement for informed consent or the requirement for documentation of

informed consent. The “study completion date” as defined in the ClinicalTrials.gov glossary, is the date that the final data for a clinical study were collected because the last study participant has made the final visit to the study location (that is, 'last subject, last visit').

9. How long is the investigator contractually obligated to retain Industry-sponsored clinical study related records?

The period of records retention to which the investigator is contractually obligated to a study sponsor can vary depending on the nature of the clinical study and the agreed terms of the contract. Read the contract carefully for specific record retention obligations that may extend beyond the period required by policy, laws, rules, and regulations.

10. How does the Investigator know when the Industry sponsor no longer requires the study records be retained?

The sponsor informs the investigator(s)/institution(s) in writing of the need for record retention and notifies the investigator(s)/institution(s) in writing when the trial related records are no longer needed and the FDA has been notified.

11. Can the investigator invoice record retention costs to the study sponsor?

Yes, the investigator can claim record retention costs. These costs are typically captured in the study contract costs as negotiated items.

12. Could Medicare request study records related to claims submitted for protocol services?

Yes, when performing a billing audit, Medicare may request billing records up to 10 years. In the event the billing review involved claims for protocol services, study-related records could be needed to understand the billing.

13. Do the Department of Health and Human Services (DHHS) regulations require that investigators retain original hardcopy records?

Yes, if investigators have been designated to retain certain records on behalf of the institution per DHHS regulations, they must retain the original consent documents, with the other study records in some form. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of DHHS at reasonable times and in a reasonable manner. Retention of multiple copies of each record is not required.

14. Who is responsible for retaining the clinical study records when the investigator leaves the institution?

The successor Investigator and the Institution are responsible for retaining the clinical study records when the Investigator leaves the Institution. Investigators should follow the institution's policies and procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records for the period of time required.

15. Is there FDA guidance concerning retention of Electronic Case Report Forms (eCRFs)?

Yes, in September 2013, the FDA released a guidance entitled "Electronic Source Data in Clinical Investigations". Based on this document, the clinical investigator should retain control of the records (i.e., completed and signed eCRF or certified copy of the eCRF). If requested, the clinical investigator should provide the FDA with access to the records that serve as the electronic source data. When data elements are transcribed from paper sources into an eCRF, the clinical investigator(s) must also retain the paper sources, or certified copies.

Back to top