

## Investigator Essential Documents

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Approved by: Interim Vice Chancellor for Research  
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310 AOB (MC 672)  
1737 West Polk Street  
Chicago, IL 60612-7227  
Phone: 312 996-4995 Fax: 312 413-0238  
[www.research.uic.edu/protocolreview/irb](http://www.research.uic.edu/protocolreview/irb)

### POLICY:

- I. UIC PIs are responsible for creating their own filing system of essential documents.
- II. UIC PIs must submit a written request to obtain missing records from UIC OPRS. UIC OPRS will use its discretion as to whether or not to re-release these documents and may need additional information as to the circumstances and a corrective action plan to ensure that further documents are not lost. UIC OPRS takes into account the PIs history of lost documents in its determination.

### PROCEDURE:

- I. UIC PIs are responsible for creating a system of essential documents. The UIC OPRS provides the necessary guidance and support to Investigators, research personnel, and their staff for establishing a system of essential documents.
- II. The essential documents provide the support to ensure the compliance of the PI, research personnel, sponsor, and monitor with applicable regulatory requirements. These documents are also likely to be used by the sponsor and regulatory authorities in an audit to confirm the validity of study conduct and integrity of the data.
- III. The Investigator must create their own filing system of the following essential documents (as applicable):
  - A. Assent form;
  - B. Assurance number and letter re: IRB membership;
  - C. Budget proposal;
  - D. Case report forms;
  - E. Communications;
  - F. Curriculum vitae (CV) of PI and Co-Investigators, Human subjects training certificates, and other credentials (i.e., licenses);
  - G. Drug data sheet;
  - H. Final/Close-Out monitoring report;
  - I. Final study report;
  - J. Financial disclosure;
  - K. Form FDA 1572 (up to date) (1571 if PI is IND Sponsor), if applicable;
  - L. Information given to trial subject;

- M. Informed consent form;
  - N. Investigator's brochure;
  - O. IRB/IEC approvals and correspondence;
  - P. Laboratory (Including: CLIA certification for lab if sponsor requires, normal lab values for the lab and tests to be used);
  - Q. Monitoring log;
  - R. Monitoring reports;
  - S. Pharmacy accountability records;
  - T. Protocol;
  - U. Protocol training;
  - V. Record of retained body fluids and/or tissue samples;
  - W. Screening and enrollment/randomization Logs;
  - X. Serious adverse events and safety reports;
  - Y. Signature and initials key/log including delegation of authority;
  - Z. Signed agreements;
  - AA. Site quality assurance records of activities;
  - BB. Source documents;
  - CC. Standard operating procedures for the protocol at this site;
  - DD. Subject identification code list; and
  - EE. Unblinding procedures (standard and emergency).
  - FF. Appropriate documentation necessary for documenting informed consent authority, including but not limited to a progress note signed by a physician, an assessment by a certified psychiatrist, an applicable court order or finding, advance directives, documentation of appropriate surrogate status.
- IV. Some documents may be combined as long the individual elements are readily identifiable. All documents do not have to be combined in one regulatory file.
- V. A regulatory file of the essential documents must be maintained for each study site of a multi-site trial. The main site may maintain all regulatory files for the affiliated sites if necessary.
- VI. All of the above mentioned documents (in part III above) must be available for audit/inspection by the sponsor and regulatory agencies and/or the UIC HSPP.
- VII. Documents may be saved electronically as appropriate.
- VIII. When the research falls under multiple regulatory governances, the Investigator must always follow the most stringent criteria/guidelines.
- IX. The destruction or retention of informed consents and regulatory documents should follow applicable federal regulations, UIC OVCR policy, sponsor requirements, and other applicable guidelines. PIs must review all applicable sources above and keep records for the longest period of time indicated. For example, if a sponsor agreement requires the longest period of record retention, then its requirements

govern even if the federal regulations state a shorter period of record retention. The Federal Regulations, 21 CFR 56.115(b) and 45 CFR 46.115(b), require IRB records to be retained for at least 3 years after completion of the research. The regulations (21 CFR 312.62(c)) state the data shall be retained for two years following approval of a marketing application for which the drug is being investigated or two years after the investigation is discontinued and FDA notified. Thus an investigator may need to retain the study records for 10 or more years, as the average time to obtain drug approval from Phase I to the submission of the New Drug application (NDA) is 10 years. The NIH regulations [45 CFR 74.53] indicate the NIH grant records must be kept for three years after the submission of the final expenditure report. The HIPAA regulations [45 CFR Part 160] indicate the HIPAA-related records (authorizations, documentation of approval of waivers) must be maintained for 6 years.

- X. Investigator records are subject to inspection by federal agencies, including but not limited to, OHRP and the FDA. A variety of actions and/or penalties may be taken against principal investigators and/or the institution for incomplete or nonexistent records.
  
- XI. For research protocols that are not industry sponsored, not federally funded, not FDA regulated, not involved with the Department of Defense, and HIPAA does not apply due to a lack of PHI, UIC recommends that PIs retain research-related documents for 6 years. Plans for long-term storage may need to be made to ensure the confidentiality and availability of the documents should these documents be requested by regulatory agencies, outside parties with authority, publications, departments, University officials, and/or OPRS.

**REVISION LOG:**

| <b>Version (#, date)</b> | <b>Replaces (#, date)</b> | <b>Summary of changes</b>  |
|--------------------------|---------------------------|--|
| 1.1, 06/18/09            | 1.0, 1/30/09              | Clarified record retention time periods and procedure for re-requesting documents. |
| 1.2, 8/25/09             | 1.1, 06/18/09             | Deleted several citations in Section IV.   |