UIC UNIVERSITY OF ILLINOIS AT CHICAGO

Office for the Protection of Research Subjects
Institutional Review Board

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Investigator Essential Documents

Version: 1.3
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Approved by: Human Protections Administrator
AAHRPP REF#: 133

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) that include, but are not limited to:
   A. All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities, including, but not limited to, the IRB, OHRP, and the FDA;
   B. Assent form (IRB approved – all versions);
   C. Assurance number and letter re: IRB membership;
   D. Budget proposal;
   E. Case report forms;
   F. Communications (i.e.,IRB sponsor, CRO, subjects;
   G. Curriculum vitae (CV) of PI and Co-Investigators, Human subjects training certificates, and other credentials (i.e., licenses or credentials to perform job designated by PI);
   H. Drug data sheet;
   I. Delegation of informed consent;

J. Delegation log of responsibilities of research team;
K. HIPAA Authorization;
L. Final/Close-Out monitoring report;
M. Final study report;
N. Financial disclosure;
O. Clinical research only: Form FDA 1572 (up to date) (1571 if PI is IND Sponsor), if applicable;
P. Information given to trial subject (Recruitment, Questionnaires, etc);
Q. Informed consent form - all IRB approved versions);
R. Original signed informed consent forms;
S. Investigator's brochure;
T. IRB approvals, approved documents, and all correspondence (including submissions);
U. For clinical trials only: Laboratory (Including: CLIA certification for lab if sponsor requires, normal lab values for the lab and tests to be used);
V. Monitoring log;
W. Monitoring reports;
X. Parental Permission
Y. Pharmacy accountability records;
Z. Protocol (all versions);
AA. Protocol training;
BB. Record of retained body fluids and/or tissue samples;
CC. Records of audits and outcome by any oversight entity, including, but not limited to, FDA and OHRP;
DD. Screening and enrollment/randomization logs;
EE. Serious adverse events and safety reports;
FF. Signature and initials key;
GG. Other signed agreements with the subject;
HH. Site quality assurance records of activities;
II. Source documents;
JJ. Standard operating procedures for the protocol at the site;
KK. Subject identification code list; and
LL. Unblinding procedures (standard and emergency).
MM. 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, although signed informed consents, parental permissions, child assents, and any other agreements with patients or their legally authorized representative must be saved in original format.

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.

XII. **VA Research.** In addition to the list in Section III above, the following documents must be maintained so that they may be audited by the facility RCO or other entities according to applicable sponsor, local, VA, and other federal

requirements (for more information on record retention and control, see VA Protocol Submission Packet, p. 6, Paragraph 22). :

A. The following documentation must be retained on each subject including, but is not limited to:

1. Informed consent process;

2. All signed and dated informed consent forms, parental permissions, child assents, and HIPAA authorization forms (containing the original signature) must be in the research files, easy to access, and secure.

3. Interactions with subjects by telephone or in person;

4. Observations;

5. Interventions; AND

B. Other data relevant to the research study, including, but not limited to:

1. Progress notes;

2. Research study forms;

3. Surveys; and

4. Questionnaires.

5. Reports of adverse events;

6. Data analysis;

7. Reports including, but not limited to, abstracts and other publications;

8. All correspondence including, but not limited to, that with the funding source or sponsor and with applicable oversight entities including, but not limited to, R&D Committee, and ORO.

9. A master list of all subjects for whom informed consent has been obtained in the study (unless the IRB has determined otherwise);

C. An Accounting of Disclosure must be maintained for each and every disclosure of information from this study to a non-VA entity. Please refer any questions to the JBVAMC facility Privacy Officer for assistance in developing a way to account for this disclosure.

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
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.
1.3 1/20/11	1.2, 08/25/09	Modified portions of Section III to clarify requirements further. Added entire Section XII to comply with VHA Handbook 1200.05, dated October 15, 2010, effective March 2011.