Institutional Review Board Policies and Procedures Manual

SECTION 3: IRB RECORDKEEPING AND IRB FILES

3.1 IRB RECORDKEEPING AND IRB FILES

In compliance with federal regulations (45 CFR 46.115 and 21 CFR 56.115), the ORIC office maintains files on all protocols. The term "protocol file" refers to both the paper and electronic documents pertaining to each study. The protocol file is accessible to IRB members and ORIC staff to perform their responsibilities. They are also available for inspection and copying by authorized representative of government oversight agencies and accrediting entities, as appropriate. Older records, including records of studies that are no longer active, may be stored off-site and/or on remote servers.

The purpose of this chapter is to describe the protocol file and other IRB files related to IRB operations, and to address record access, retention, ownership, copying, and inspection.

A. Protocol File

When a protocol is initially submitted to the IRB, it is assigned a protocol number and a file is opened. The file is maintained for the entire duration of the study while it is active. The file will contain all official documents and correspondence. The administrative staff is responsible for appropriately maintaining the documents and files. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records may include the following:

i. Copies of the original protocol submission, informed consent/assent documents, and the sponsor protocol document,

ii. Scientific evaluations and approvals, (e.g. Lurie Cancer Center Review),

iii. Recruitment materials,

iv. Investigator Brochures, and package inserts if applicable,

v. IRB analyst and reviewer checklists, and ORIC/IRB correspondence with PI (including comments/responses within the electronic IRB system),

vi. Letters of support if applicable,

vii. Consultant reviews or reports, and/or guidance from General Counsel as applicable,

viii. Copies of IRB approvals from other study sites as applicable,

ix. IRB approval documents (approval letters, IRB stamped consent/assent documents, etc.),

x. All protocol renewal submissions, correspondence and subsequent approvals including stamped consent/assent forms,

xi. All unanticipated problem reports, protocol violations/deviation, adverse events, subject complaints and related correspondence that meet the reporting criteria and subsequent IRB acknowledgments or approvals,

xii. All protocol modifications, subsequent correspondence and IRB approvals, including modified consent/assent forms,

xiii. Letters or statements describing new findings provided to subjects if applicable,

xiv. Data and safety monitoring reports, if applicable,

xv. Reports from study monitoring by sponsor or other agency,

xvi. Any notes to file or emails containing additional relevant protocol information.

B. Access to Protocol Files

Hard copies of any protocol files may not be removed from the ORIC office except for purposes of an IRB meeting. An individual requiring access to the file must visit the ORIC office.

Paper files are stored in locked file cabinets and electronic files are stored in the electronic IRB system, with access to staff appropriate to their responsibilities. Email correspondence is stored in an internal and password protected mailbox.

The protocol file is confidential. Excluding the IRB/ORIC staff and members, and authorized individuals, request for access from any other individual who is not the PI for access to a protocol file is to be obtained from ORIC staff and the PI. Requests from the public or the media to access protocol files are not honored.

Subpoenas for access to the protocol files and copies of documents are reviewed and approved by the Office of General Counsel.

For auditors and inspectors, such as FDA and OHRP, the individual(s) must show appropriate identification and documentation.

C. Informed Consent and Assent Documents

Copies of the approved consent and assent documents are stored in the paper file, in the electronic IRB system, and/or an internal hospital drive.

D. Meeting Agenda

The IRB meeting agenda is compiled by the ORIC staff and reviewed by the Director and IRB Chair. The IRB Chair has the ultimate authority to decide what is placed on the agenda and the IRB reviewer assignments. A report and the proposed management of any financial conflicts of interest, unanticipated problems, and/or non-compliance are also included in the agenda for discussion and deliberation and/or vote by the convened board. In addition, administrative business (i.e., review and approval of previous meeting minutes, etc.) is included on the agenda under General Administrative Business. The agenda and meeting materials are available to all IRB members at least 10 days before the meeting.

E. Meeting Minutes

The IRB meeting minutes are compiled by the ORIC staff, reviewed by the Director and IRB Chair, prior to submission to IRB members for approval. All IRB actions that occur outside of the convened meeting (i.e., between meetings) are reported to the full board and included on the minutes (i.e., approval via the expedited review process, exempt determinations, etc.). The minutes reflect the agenda of the meeting and document the discussion, deliberations, and action taken on each item, and include the following:

i. Meeting attendance, including documentation of any alternates replacing a primary member, staff, and guests;

ii. IRB Chair's request for conflict of interest and disclosures;

iii. Review and vote of previous meeting's minutes;

iv. Deliberations, actions and votes on each agenda item requiring IRB action;

v. Summaries of discussion related to controversial issues and resolutions;

vi. Documentation and summaries of discussions related to protocol issues, including the risk determination, waivers of consent/assent, and requirements of one or both parents/guardians' signatures on consent forms;

vii. Documentation of determinations of Significant Risk and Non-significant Risk devices including concurrence or non-concurrence with the sponsor's determination;

viii. Documentation of the duration of the IRB approval period – note that unless stated otherwise, the approval period is for one year;

ix. Loss of quorum;

x. Numerically recorded votes and indication of number of votes for, against, or abstentions;

xi. Committee actions:

a. Approve

b. Approve with minor directed contingencies where the response from the PI may be approved via expedited review

c. Deferred for further review by the convened IRB

d. Disapproved

e. No action taken

xii. Discussion related to any adverse events, deviations, violations, noncompliance, including a discussion of whether noncompliance is considered to be serious or continuing noncompliance; this also includes discussion of any actions taken;

xiii. The use of the consultant and the written report prepared by the consultant; and

xiv. Discussion of any administrative business or issues addressed in during the meeting.

F. IRB Regulatory Records

IRB records are maintained electronically. These include the agenda, minutes, and attendance sheet for each meeting.

G. Policies and Procedures

All IRB policies and procedures are available to all investigators and hospital staff on the hospital portal and/or website.

H. Research Record Retention

In compliance with HHS and FDA regulations, copies of all research related records, including protocols, consent forms, renewals, adverse events, and correspondence pertinent to a given protocol are maintained for three years following completion of the research. All other IRB records (e.g. minutes) are maintained for three years. Once a

protocol is approved by the IRB, the study record is maintained in accordance with this policy regardless even if it is never initiated by the investigators.

I. Research Data Ownership and Use

Data collected from research protocols that are conducted under the auspices of the Institution are owned by the Institution. For industry sponsored protocols ownership is addressed in the clinical trial agreement.

When investigators leave the Institution, arrangements are made for the disposition of the research data. The investigator is to contact their Department Chair/Division Chief and the Senior Vice President and Chief Operating Officer, to discuss the arrangements and access to the data or retaining a copy of the data.