Records and Files

Policy

In accordance with federal regulations (45 CFR 46.115 and 21 CFR 56.115), the Institutional Review Board (IRB) maintains, an organized protocol file. The term "protocol" will be used to designate both paper and electronic format, the necessary and appropriate documentation and records relevant to each study. The protocol is available to members and staff of the IRB and the Office of Clinical Research Compliance for appropriate purposes, and is accessible for inspection and copying by authorized representatives of government oversight agencies and accrediting bodies, as appropriate. Older records are maintained in paper form for a period established by the Director of Clinical Research Compliance, and electronic form, thereafter. Newer records will all be in electronic format

Purpose

The purpose of this policy is to describe the contents of protocol and other files associated with the operation of the IRB, and to outline policies for record access, retention, ownership, copying, and inspection.

Procedures

Contents of Protocols

Upon initial creation of a protocol by the investigator a protocol number is to be assigned and a protocol file started. This protocol is then electronically routed through departmental scientific review and Departmental/ Division sign off. The protocol then arrives in the IRB office electronically and all other IRB associated review and approval processes are followed. The file is to be maintained for the entire period the protocol is active, and all subsequent related documents are to be filed in the order in which they are received. The files are to contain official records, as described below, and may also contain notes that document conversations that take place between the investigator and the IRB administrative staff. IRB administrators and the administrative assistant are responsible for assuring that the appropriate documentation is maintained.

IRB protocol files are to include the following official records and documentation:

- The original research protocol submission and informed consents
- Scientific evaluations and approvals
- Recruitment materials, posters, flyers, letters
- Drug/device/biologic investigational plans, brochures, package inserts, and sample consents, if applicable
- Department of Health and Human Services (DHHS) grant applications, protocols, and consents, if applicable
- Assessments, surveys, and questionnaires
- Correspondence and approval notifications from ancillary reviewers

- Reports of action and responses from investigators
- Continuing renewal forms, correspondence, and subsequent approvals, including updated approved consents and approvals
- Unanticipated problem reports including subject complaints and subsequent correspondence
- Amendments and/or revisions, subsequent correspondence regarding such, and notification of approval
- Reports of any injuries and subsequent correspondence
- Reports of any deviations and violations, and subsequent correspondence
- Reviewer worksheets
- Written documentation of reviewer acceptance of issues handled through expedited review procedures
- Consultant reports, if requested
- Guidance provided by General Counsel
- Notifications of clinical trial agreement approval and subsequent release of IRB approval
- Statements of significant new findings provided to participants
- "Notes to file" or emails that offer additional information relevant to the protocol as determined by the IRB staff

Procedures Associated With Access to Protocol Files

- **Paper protocol files may not be removed from the Institutional Review Board Office,** Any individual who requires access to a file must visit the Institutional Review Board Office.
- **Paper protocols are to be stored in locking file cabinets. Electronic protocol files are to be stored under appropriate institutional electronic security procedures, including password protected access.**
- **Protocols are considered confidential documents**. Only the investigator or individuals listed on the protocol are allowed to access the files. Department and Division Chairs may access protocols for any staff member within their department or division. Other individuals who request access to a protocol require the written approval/email of the investigator. This approval must be stored as part of the protocol file. If an investigator requests access to a protocol a protocol administrator or the Director of Research Compliance is to ascertain whether the file contains confidential "notes to file" to which the investigator is not to be granted access.
- **Requests from the public or the media to access protocol files are not to be honored**.
- **All subpoenas for access to protocol files and for copies of documents must be reviewed and approved by the Office of General Counsel.**
- If an auditor or inspector requests the complete protocol file, the IRB should provide them:

    1. The IRB paper file or access to the electronic file.
    2. A printout of any protocol related materials that may be included in the paper file but are included in the electronic database.

Informed Consent Documents

In addition to paper/electronic copies of approved consent documents, the approved informed consent document(s) is stored in electronic form in the Children's Hospital

Research Informed Consent Library as well as the protocol file. The library is accessible from any hospital computer workstation or from outside if there is VPN access to the Children's Hospital System. The library stores all versions of the consents, however only the most recent is displayed to the user. Investigators are asked to use the informed consent library to assure the most recent version of the consent is always used,

Minutes

Minutes of IRB meetings are the responsibility of the Assistant Director of Clinical Research Compliance. Draft minutes are to be reviewed by the Director of Clinical Research Compliance prior to submission to the IRB.

Minutes are to reflect the agenda of each meeting, and are to record the discussion and action taken on each agenda item. The minutes are to include the following:

- Meeting attendance, including noting when an alternate member replaces a primary member
- The deliberations, actions, and votes on each protocol that is subject to initial, or continuing review, and each amendment or revision that is subject to full Committee review. The votes are numerically recorded as for, against, abstain, left room of conflict of interest (must include name of member) not available during vote (must include name of member present at meeting but was not in the room when the final vote was taken)
- The actions the committee may vote on are
  - Approved
  - Conditionally Approved
  - Deferred for further review by full IRB
  - Disapproved
  - No action taken

  Please refer to the definitions of these actions in the policy and procedure "Operational Review Procedures: Full Committee Review"
- Discussions related to adverse events, deviations, violations and whether they are determined to be serious or continuing noncompliance
- Discussions of any noncompliant incidents and whether they are determined to be serious or continuing noncompliance
- Whether any report that was submitted as a 1) serious or unexpected or 2) unanticipated event involving risks to subjects or others were determined to be an unanticipated event involving risks to subjects or others
- Discussion of any administrative issues addressed during the meeting
- Notation of all concerns raised about a protocol, including resolutions
- Summaries of discussions of controversial issues and resolutions
- Specific reasons for required changes to research, or for its disapproval
- Documentation of specific findings related to:
  - Children
    a. A risk/benefit determination including whether the Committee agrees with the investigators determination and justification and/or their own determination and rationale
    b. A determination as to whether assent is required
    c. If the Institutional Review Board agrees that an investigator does not need parental permission for a individual less than 18, the rationale utilized by the IRB. This would include a statement as to whether the

criteria used in subpart D were used to waive parental permission or a determination that for purposes of the study the individual under 18 may be considered an adult by definition in the regulations

d. A determination as to whether permission from one or both parents/ guardians is required

- Prisoners. – A determination as to whether the committee concurs with the investigator's responses and justifications for the seven regulatory additional determinations as specified in the Policy and Procedure for "Prisoners" or a summary of their own determinations and findings
- Pregnant women and fetuses. A determination as to whether the committee concurs with the investigator's responses and justifications for the regulatory determinations as specified in the Policy and Procedure for "Pregnant Women, Fetuses and Neonates"" or a summary of their own determinations and findings. Determinations regarding 112 MGL 12J.
- Waivers and alterations of consent- A determination as to whether the committee concurs with the investigator's responses and justifications for waivers an alterations of consent and consent documents as specified in the Policy and Procedure " Informed Consent" or a summary of their own determinations and findings

- Determinations of Significant Risk and Nonsignificant Risk devices including whether they concur with the sponsor's determination or a summary of their own determination and justification
- Notation of the duration of the approval period granted.(Note the minutes may reflect that unless otherwise noted, approvals for a one year period in the minutes
- If a waiver or alteration of informed consent or informed consent documentation is requested, a determination as to whether the Committee concurs with the justification as provided by the investigator or a summary of their own determination and justification

Copies of draft minutes are to be presented to the full IRB at a convened meeting. Copies of the final IRB meeting minutes are then shared with the Institutional Official.

Policies and Procedures

The IRB maintains copies of all policies and procedures pertinent to the Children's Hospital Human Research Protection Program. These policies and procedures are made available to investigators and research staff on the IRB website. On an annual basis or as deemed necessary or appropriate to ensure fulfillment of institutional responsibilities under the existing assurance, to improve operational efficiency, or to address other concerns that may arise, the policies and procedures may be revised as needed. Policies and Procedures are maintained electronically in a management document retention and storage system supported by the hospital.

Expedited Reviews (New, Continuing Review, and Amendments)

Protocols are to be maintained as referenced above for all expedited review protocols.

Each month a report is to be generated that summarizes the new, continuing review and amendment expedited reviews conducted during the month. This report is to include the category of expedited review for each new protocol, as defined by federal regulation. The report is to be submitted to the full IRB for review at a convened meeting.

For amendments, revisions and continuing reviews conducted by expedited review, a document that includes the title of the protocol, the name of the PI, and a summary of the amendment or revision, is to be submitted each month to the IRB for review at a convened meeting.

Exemptions

Am exemption protocol is to be maintained for each exemption granted. The file is to consist of the completed form as well as any additional correspondence, consents, etc.

Annual PI verification that the exemption remains unchanged is to be included in the exemption file.

Research Record Retention

In accordance with DHHS and Food and Drug Administration regulations, copies of all research-related records, including the protocol, informed consent, continuing reviews, adverse events, all correspondence pertinent to that protocol, and exemptions, must be maintained for at least three years following completion of that research. All other records (e.g., minutes) are to be maintained for three years. Once a protocol is submitted to the IRB it is considered a record and is to be maintained in accordance with the record retention policy, regardless of whether the protocol is cancelled at any point, including a point prior to initiation of the research. Records are not destroyed after the three year period; they are scanned into electronic form and archived.

Inspection and Copying

At reasonable times and in a reasonable manner, all records maintained by the IRB are to be accessible for copying and/or inspection by authorized representatives of federal agencies, accrediting bodies, and departments.

Research Data Ownership and Use

Data collected from research protocols that are conducted under the auspices of Children's Hospital utilizing the resources of the Hospital, and that are maintained at Children's Hospital, are jointly owned by the Hospital and the investigator. In instances of industry sponsor ownership of primary case report forms and other written information, the right of Children's Hospital and investigators to maintain copies of such data is to be preserved in any industry-sponsored clinical trial agreement. Clinical trial agreements are not, through confidentiality provisions or otherwise, to abrogate the ability or responsibility of Children's Hospital, the IRB, or Children's Hospital investigators to use such data to protect and inform research subjects, or to publish results consistent with academic standards, privacy standards, and applicable laws and regulations.

When investigators leave Children's Hospital, arrangements are to be made for the disposition of research data. Department Chairs and Division Chiefs, or the Vice President for Research Administration, are to be contacted to discuss this issue further. Arrangements may consist of providing for reasonable access to the data, or of retaining a copy of the data at the Hospital. Investigators whose research results in the filing of a patent are required to contact the Technology and Innovation Development office to discuss retention of research data, and investigators are encouraged to call this Office if there are other relevant questions or concerns. Any arrangement for the disposition of research data requires that such data be made available to the IRB, upon request, for purposes of exercising its responsibilities under applicable laws, regulations, and policies.

Related Content

1. Document Retention and Destruction: Clinical Research, Investigator Files; pgs. 12 – 15. (CH Compliance Manual, ELibrary)

Document Attributes

Title	Records and Files		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	04/01/05, 06/20/05 03/23/07 03/10/08 03/25/08 03/12/2010 5/1/15
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children's Hospital, 2015	**Last Modified**	8/10/15
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