Records and Files

Purpose

This policy is to describe the research protocol contents and other files associated with the operation of the IRB. It also outlines policies for IRB record access, retention, ownership, copying, and inspection. The following topics are provided:

1. Protocol Lifecycle
2. Protocol Contents
3. Access to Protocol Files
4. Informed Consent Library
5. Convened IRB Minutes
6. Expedited Review
7. Exemption Determinations
8. Research Record Retention
9. Inspections and Copying
10. Policies and Procedures

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.

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 be in electronic format.

Protocols are available to IRB members and administrative staff and the Office of Clinical Research Compliance. As appropriate, protocols are accessible for inspection and copy by authorized representatives of government oversight agencies and accrediting bodies.

Procedure

Protocol Lifecycle

1. Upon initial creation of an electronic protocol by the Principal Investigator (PI) a protocol number is to be assigned and a protocol file started.
2. This protocol is then electronically routed through departmental scientific review and departmental/division sign off.
3. The protocol then arrives in the IRB office electronically and all other IRB associated review and approval processes are followed (e.g. required ancillary reviews).

4. 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:
   a. Official records, as described below. Also, they may contain notes that document conversations that take place between the research team and the IRB administrative staff.
   b. IRB administrative staff are responsible for assuring that the appropriate documentation is maintained.

Protocol Contents

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
- Assessments, surveys, and questionnaires
- Pre-review correspondence and responses
- Correspondence and approval notifications from ancillary reviewers
- Reports of action and responses from investigators
- Continuing renewal/administrative update 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
- Reliance agreement materials when a single IRB review is used
- Documentation of non-compliance.

Access to Protocol Files

Paper protocol files

1. May not be removed from the IRB Office. Any individual who requires access to a file must visit the IRB Office.
2. 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.

1. Only the PI and individuals listed on the protocol can access the files.
2. Department/Division Chairs may access protocols for any staff member within their department or division.
3. Other individuals who request access to a protocol require the written approval/email of the PI or Division Chief/Department Chair. This permission must be stored as part of the protocol file.
4. If a PI requests access to a protocol (the view the IRB administrative staff have) the Director of Research Compliance is to ascertain whether the file contains confidential "notes to file" to which the PI is not to be granted access.
5. **Requests from the public or the media to access protocol files are not to be honored**.
6. **All subpoenas for access to protocol files and for copies of documents must be reviewed and approved by the Office of General Counsel.**
7. If an auditor or inspector requests the complete protocol file, the IRB should provide:
    a. The IRB paper file or access to the electronic file.
    b. A printout of any protocol related materials that may be included in the paper file but are included in the electronic database.

Informed Consent Library

In addition to paper/electronic copies (in the protocol file) of approved consent documents, the approved informed consent document(s) is stored in electronic form in the BCH Research Informed Consent Library.

The Informed Consent Library is accessible from any hospital computer workstation or externally, if there is VPN access to the BCH System.

The library stores all versions of the consents, however only the most recent is displayed to the user.

PIs and research teams are asked to use the Informed Consent Library to ensure the most recent version of the consent is always used.

Convened IRB Minutes

For the policy concerning the convened IRB meeting minutes documentation, see ***IRB Meeting Minutes***.

Expedited Reviews: New, Continuing Review, and Amendments

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

IRB Records for initial and continuing review of research by the expedited procedure include:

- The justification for using the expedited procedure.
- Justification that the criteria for approval are met.
- Actions taken by the reviewer.
- Any findings required by laws, regulations, codes, and guidance to be documented.

The Reviewer Worksheet New Protocols: Expedited Review serves to document:

- The rationale for conducting continuing review on research that otherwise would not require continuing review.
- The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

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 title of the protocol, the name of the PI, a summary of the amendment or revision, and the category of expedited review for each new protocol as defined by federal regulations.

The report is to be submitted to the full IRB for review at a convened meeting.

Exemption Determinations

An exemption protocol is to be maintained for each exemption determination. 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 HHS and FDA 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.

Records are not destroyed after the three-year period; they are scanned into electronic form and archived.

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 prior to the initiation of the research.

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, monitors and departments.

Policies and Procedures

The IRB maintains copies of all policies and procedures pertinent to the BCH's 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 BCH.

Related Content

IRB Policy

IRB Meeting Minutes

Document Attributes

Title	Records and Files		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/1/2005 6/20/2005 3/23/2007 3/10/2008 3/25/2008 3/12/2010 5/1/2015 8/10/2015
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