

Status **Active** PolicyStat ID **13321293**



**Boston  
Children's  
Hospital**

Where the world comes for answers

Effective 9/1/2022  
Next Review 1/1/2026

Owner Susan Kornetsky:  
Manager  
Department Research  
Applicability Boston Children's  
Hospital- Policies  
& Procedures

## Records and Files Policy/Procedure

### Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

### Scope

This policy is to describe the research protocol contents and other files associated with the operation of the Institutional Review Board (IRB). It also outlines policies for IRB record access, retention, ownership, copying, and inspection.

### Definitions

**Protocol:** In this policy, the term will be used to designate both paper and electronic format, the necessary and appropriate documentation and records relevant to each study.

### Policy Statements

In accordance with federal regulations (45 CFR 46.115 and 21 CFR 56.115), the Institutional Review Board (IRB) maintains an organized **protocol** file.

Older records are maintained in paper form for a period established by the Senior Director of Clinical Research Compliance. 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.

## External Requests

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.

## Research Record Retention

In accordance with Department of Health & Human Services (HHS) and the U.S. Food & Drug Administration (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.

## Policies and Procedures

The IRB maintains copies of all policies and procedures pertinent to the Boston 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 Boston Children's Hospital.

## Procedures

### 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 electronically arrives in the IRB office and all other IRB associated review and approval processes are followed (i.e. 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.

- a. The files are to contain official records, as described below.
- b. Also, they may contain notes that document conversations that take place between the research team and the IRB administrative staff.
- c. 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:

1. The original research protocol submission and informed consent(s)
2. Scientific evaluations and approvals
3. Recruitment materials (e.g. posters, flyers, letters, etc.)
4. Drug/device/biologic investigational plans, brochures, package inserts, and sample consents
5. Assessments, surveys, and questionnaires
6. Pre-review correspondence and responses
7. Correspondence and approval notifications from ancillary reviewers
8. Reports of action and responses from investigators
9. Continuing renewal/administrative update forms, correspondence, and subsequent approvals, including updated approved consents and approvals
10. Unanticipated problem reports including subject complaints and subsequent correspondence
11. Amendments and/or revisions, subsequent correspondence regarding such, and notification of approval
12. Reports of any injuries and subsequent correspondence
13. Reports of any deviations and violations, and subsequent correspondence
14. IRB Reviewer worksheets
15. Written documentation of reviewer acceptance of issues handled through expedited review procedures
16. Consultant reports, if requested
17. Guidance provided by General Counsel
18. Notifications of clinical trial agreement approval and subsequent release of IRB approval
19. Statements of significant new findings provided to participants
20. "Notes to file" or emails that offer additional information relevant to the protocol as determined by the IRB staff
21. Reliance agreement materials when a single IRB review is used

## 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. 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 Boston Children's Hospital Research Informed Consent Library.

1. The Informed Consent Library is accessible from any hospital computer workstation or externally, if there is VPN access to the Boston Children's Hospital System.
2. The library stores all versions of the consents, however **only** the most recent is displayed to the user.
3. PIs and research teams are asked to use the Informed Consent Library to ensure the most recent version of the consent is always used.

## Expedited Reviews: New, Continuing Review, and Amendments

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

1. 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.

2. 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.

1. The file is to consist of the completed form as well as any additional correspondence, consents, etc.
2. Annual PI verification that the exemption remains unchanged is to be included in the exemption file.

## 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.

## Documentation

Provider documentation, such as patient care documents, assessments of processes, and outcome measures across organizational settings, serve to monitor performance of healthcare practitioners' and the healthcare facility's compliance with standards governing the profession and provision of healthcare.

## References/Citations

45 CFR 46.115

21 CFR 56.115

## Related Content

- IRB Policy: Convened IRB Minutes (For additional information on IRB meeting minutes documentation)

## Approval Signatures

**Step Description**

**Approver**

**Date**