

Institutional Review Board (IRB) Policies & Procedures Manual



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Convended IRB: Operational Review Procedures

Purpose

This policy describes the conduct of IRB procedures as it pertains to protocols, continuing review, amendments/revisions, and adverse events/unanticipated problems that involve risk to subjects that undergo full committee review by the convended IRB.

Policy

Boston Children's Hospital has established and maintains an Institutional Review Board (IRB). The IRB reviews research protocols for any issues in design and conduct that may potentially affect the safety, rights, and welfare of human subjects.

The IRB's primary responsibility is the protection of research subjects. The IRB establishes procedures to ensure a consistent review process for all initial reviews, continuing reviews, amendments/revisions, and unanticipated problems that involve risk to subjects or others.

The review procedures must comply with federal and state regulations, and with institutional policies.

The convended IRB meets, at a minimum, on the second and fourth Monday of each month. More frequent meetings may be held as required. IRB members are provided protocol materials five to seven days prior to the meeting.

Procedures

Administrative Pre-Review

The IRB administrative staff will review all protocols for completeness and consistency and provide the investigator with feedback, questions, and/or concerns. IRB administrative staff will also provide advice as to what will likely be acceptable within IRB policies and provide input on the protocol prior to being reviewed at the IRB meeting. Before protocols are placed on the IRB meeting agenda, the investigator must respond to the issues raised and changes requested through the pre-review process before protocols are placed on the IRB meeting agenda.

Agenda

After the pre-review process, protocols are placed on the agenda in the order in which they are received, a "first come, first serve" basis. If an agenda is full, the protocol will be placed on the next open meeting agenda.

Deferrals are always placed in the agenda for the next upcoming meeting regardless of the number of new protocols received.

Quorum and Voting

For the convened IRB to hold a meeting at which actions can be taken, a quorum of members must be present. A quorum consists of more than half of the IRB members. And should include:

- A scientific member
- At least one member whose primary concerns are non-scientific
- One member who is not affiliated with the hospital and
- One member who represents the general perspective of subjects.
*One member may serve more than one of these roles.
- A physician member must be present during the review of any clinical research study that involves the use of a Food and Drug Administration-regulated drug, device, or biologic.

In extenuating circumstances only, a member may be permitted to participate in the meeting by telephone conferencing. In such instances, they will receive all the same materials other members receive in preparation for the meeting.

If a quorum is lost during a meeting, no further actions will be taken.

For the research to be approved, it shall receive the approval of the majority of those members present at the meeting.

Actions

Approval: An acceptable risk/benefit ratio exists, and the protocol is approved as submitted.

Conditional Approval: At the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the investigator:

1. Make specified changes to the research protocol or informed consent document(s),
2. Confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or
3. Submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the federal regulations.

When the IRB members determine a protocol is conditionally approved, they also decide if the response is sent back to the primary and secondary reviewers or whether the IRB analysts (who are also IRB members) can confirm all changes and request have been made.

Deferral: The changes proposed, or questions raised by the IRB prevent the IRB from making one or more of the determinations required for approval by the regulations. Due to the lack of information or concerns raised in terms of risks and benefits, the adequacy of privacy and confidentiality protections, and/or the adequacy of the informed consent process, result in the IRB being unable to make the required determinations and specific changes to the research protocol. Examples include:

1. The protocol was poorly written, lacking significant amounts of information regarding scientific justification, procedures, and/or risk reduction.
2. There are significant ethical concerns that do not permit a favorable risk/benefit determination. More information is required or changes in design and procedures must be implemented.

3. There are clarifications and modifications requested directly relevant to determinations required by the regulations such as the data and safety monitoring plan.

All responses to deferrals are placed back before the full IRB for continued review.

Disapproval: After consultation with the investigator, the IRB determines that the research presents subject risks that far outweigh the benefit or value of the knowledge to be gained; or the research raises such serious ethical questions as to be unacceptable. In the event disapproval is foreseen, the investigator is invited to attend the meeting to discuss the protocol.

For additional information, see IRB policy: ***Disapprovals and Appeals.***

Initial Reviews of New Protocols

1. New research protocol applications that do not meet the criteria for exemption or expedited review are placed on the agenda for full IRB review.
2. All protocols are submitted electronically and made available to IRB members through the CHERP system.
 - a. The electronic submission utilizes a series of Smartforms that request specific information for all protocols (e.g. research team, financial disclosure, funding information) and then branch to other forms as necessary for the category of research under consideration.
 - b. There are document uploads in multiple sections of the forms where the research team can provide the complete information required for IRB review in addition to answering the SmartForm questions
 - c. All members have full access to the complete submission under review.
3. Protocols are discussed on an individual basis.

Conflict of Interest

4. IRB members must not be involved in the review of any protocol in the conduct of the research protocol or have any other conflict of interest.
5. IRB members are expected to inform the Committee if they have a conflict prior to the discussion of any item on the agenda. In addition, the reviewer worksheets ask IRB members to indicate that they have no COI
6. Any IRB member who has a conflict of interest (i.e., is involved in the protocol or has other conflicts) may be asked questions about the content of the protocol but cannot be present beyond the discussion of questions and answers and must leave the room during the final discussion and vote.
7. If it is not obvious that a IRB member is, in fact involved in a protocol (i.e., is not listed as a participating investigator), and the protocol is assigned to that member, it is that member's responsibility to inform the IRB administrative office of this situation and to relinquish responsibility for reviewing the protocol.

For additional information, see IRB policy: ***Institutional Review Board Conflict of Interest***

Primary & Secondary Reviewers

8. All new protocols are assigned a primary and a secondary reviewer.

- a. At least one of the two reviewers must have the appropriate expertise to review the topic of the protocol.
 - b. If there is not appropriate expertise, either an outside consultant will be sought, or the protocol will be rescheduled for review when the expertise is obtained.
 - c. The primary and secondary reviewers are responsible for a complete review and summary of the protocol application.
 - d. These reviewers present the protocol to the IRB at a convened meeting.
 - i. The primary reviewer presents a brief summary of the protocol, followed by their comments.
 - ii. The secondary reviewer presents their comments only.
 - iii. Following presentation by the primary and secondary reviewers, the full IRB is invited to provide additional comments. All members are asked to review all protocols and informed consents in preparation for the discussion.
9. Primary and secondary reviewers receive a reviewer worksheet that must be completed and uploaded in IRB electronic system prior to IRB meeting.
- a. The use of this worksheet is mandatory.
 - b. The worksheet requires that reviewers consider all the regulatory criteria required for approval.
 - c. The worksheet guides the reviewer comments and are structured to discuss the issues within the context of the regulatory criteria.

Full Committee Discussion

10. Following the full discussion, the primary and secondary reviewers will suggest an action to be taken, see **Actions**, listed above.
11. The IRB Chair calls for a committee vote. In general, the Chair will continue discussion until it appears that consensus is reached but a vote may be called at any time.

Continuing Review and Minority Reporting

12. In addition, the IRB will determine the time frame for the subsequent continuing review.
 - a. The continuing review time period must be set to occur within 1 year of the approval date.
 - b. The default is one year, unless the IRB votes otherwise.
13. The preparation of minority reports by those members who vote against a majority action on a research protocol is encouraged and will be noted within the minutes.

Voting

14. A vote is taken and recorded. The total number of votes is always equal to the total number of members present at the meeting.

For additional information, see IRB policy: **Convened IRB Meeting Minutes**

Amendments/Modifications

All revisions/amendments that do not meet the criteria for expedited review are placed on

the agenda for the convened IRB meeting.

1. Each amendment is assigned a primary and a secondary reviewer.
2. Reviewers get a reviewer worksheet that needs to be completed and submitted at the end of the meeting.
3. All members are provided with a copy of the amendment/revision request form with the proposed changes listed along with the rationale for the change.
4. The electronic CHeRP system allows members to review side-by-side the sections of the SmartForm and attached materials that have changed.
5. Revised consents and recruitment notices are submitted in tracked changes to improve efficiency and effectiveness of the review process.
6. The voting procedures listed above apply to the review and voting process for revisions/amendments.

For more detailed information, see IRB policy: ***Amendments and Revisions***.

Continuing Reviews

Except for those continuing reviews that meet the regulatory criteria for expedited review, all continuing reviews are placed on the agenda for full IRB review.

For protocols that require Continuing Review in accordance with the Revised Common Rule, effective January 19, 2019 and the protocols approved prior to that date, see IRB policy: Continuing Review.

1. Each continuing review is assigned a primary reviewer.
2. A reviewer worksheet is provided and needs to be completed and submitted at the end of the meeting.
3. The worksheet is structured so that the reviewer can determine whether the regulatory criteria continue to be met.
4. Through the electronic CHeRP system, the primary reviewer is provided with a copy of the Continuing Review SmartForm and has access to the entire protocol and associated materials, including previous Continuing Reviews and Reportable Events.
5. The procedures listed above apply to the review and voting process for continuing reviews.
6. In addition, the Committee determines the time frame for the subsequent continuing review.

For more detailed information, see IRB policy: ***Continuing Review***.

Unanticipated Events (UAP)

Unanticipated events that have been reviewed by the IRB chair and determined to require the convened IRB's review are placed on the agenda.

1. Each UAP is assigned a primary reviewer.
2. The reviewer will present the event, corrective actions, and provide comments as necessary.
3. Through the electronic CHeRP system, the reviewer has access to the entire protocol file including previous reportable events.
4. The IRB votes to either:
 - a. Accept the event
 - b. Request additional information **or**

- c. Suspend recruitment or the entire protocol as necessary.
5. The IRB will also vote as to whether the event meets the Criteria for Reporting.

For more information, see IRB policy:

- ***Noncompliance: Investigations and Determinations***
- ***Reporting***
- ***Suspensions, Terminations, Administrative Closures, Investigator-Initiated Voluntary Suspension or Termination***
- ***Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events***

Reports of Action

A written report of action is prepared by the IRB administrative staff for all actions mentioned above.

The Director of Clinical Research Compliance or Assistant Director are responsible for the final review of all reports of action before they are sent to principal investigators.

The IRB Chair and any IRB member may ask to receive and review a draft of the report of action for any protocol, continuing review, or amendment/modification before it is sent to the investigator.

As necessary, the Director of Clinical Research Compliance, Assistant Director and the IRB administrative staff may ask IRB members and the Chair to review reports of action prior to sending them to the investigator.

Whenever possible, reports of action are forwarded to investigators within seven days of the IRB meeting. Copies of all reports of action included in the CHERP electronic protocol file.

Related Content

IRB Policies

Amendments and Revisions

Continuing Review and Administrative Update

Convended IRB Meeting Minutes

Disapprovals and Appeals

Institutional Review Board Conflict of Interest

Noncompliance: Investigations and Determinations

Reportable Events

Suspensions, Terminations, Administrative Closures, Investigator-Initiated Voluntary Suspension or Termination

Unanticipated Problems Involving Risks to Research Subjects and Others Including Adverse Events

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