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

Convened IRB: Operational Review Policy/Procedure

Internal Approval

SVP, Research Administration

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy describes the conduct of Institutional Review Board (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 convened IRB.

Boston Children's Hospital has established and maintains an Institutional Review Board (IRB). The IRB's primary responsibility is the protection of research subjects.

The IRB reviews research protocols for issues in design and conduct that may potentially affect the safety, rights, and welfare of human subjects. The review procedures comply with federal regulations, state laws, and institutional polices. The IRB has established procedures to ensure a consistent review process for all initial reviews, continuing reviews/administrative updates, amendments/revisions, and unanticipated problems that involve risk to subjects or others.

The convened 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.

In accordance with HHS/OHRP guidance, "convened" IRB meetings may be recognized as those

conducted via video conference call (such as the Zoom platform), provided that each participating IRB member:

i. has received all pertinent material prior to the meeting, and
ii. can actively and equally participate in the discussion of all protocols.

Minutes of such meetings must clearly document if a meeting is held remotely via video conference and if so, that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance, initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues). See IRB police on Convened IRB Minutes for more information.

Procedures

Administrative Pre-Review

The IRB administrative staff will review all protocols for completeness and consistency. They will provide the investigator with feedback, questions, and/or concerns.

1. Prior to the convened IRB meeting, IRB Analysts may request clarifications or further information on aspects of the proposed research, in compliance with IRB institutional policies and HHS/FDA regulations.
2. 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.

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.

1. If an agenda is full, the protocol will be placed on the next open meeting agenda.
2. Deferrals are always placed in the agenda for the next upcoming meeting regardless of the number of new protocols received.

Quorum and Representation

Quorum

For the convened IRB to hold a meeting at which actions can be taken, a quorum of members must be present.

1. A quorum consists of more than half of the IRB members.
2. If a quorum is lost during a meeting, no further actions will be taken.

Remote/video meetings may be held per 45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2):

- IRB members may participate in a convened meeting of the IRB via video conferencing (e.g.,

Zoom) when those members have received in advance of the meeting a copy of the documents for research proposals that are to be reviewed at the meeting.

- IRB members who participate in a convened meeting via video conferencing (e.g., Zoom) may vote and be counted towards the quorum.

Representation

IRB Member representation is important. One member may serve more than one role. Represented roles should include:

1. A scientific member
2. At least one member whose primary concerns are non-scientific
3. One member who is not affiliated with the hospital
4. One member who represents the general perspective of subjects.
5. 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.

Voting Actions and Documentation

Voting Actions

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

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

Conditional Approval: 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 must decide if:

1. the response is sent back to the IRB designated reviewers (i.e. “Conditional Approval Return to Reviewers”)
2. the IRB analysts (who are also IRB members) to confirm all changes and requests have been made (i.e. “Conditional Approval Return to Staff”).

Deferral: When required changes or questions raised by the IRB prevent the IRB from making one or more of the required IRB determinations, reasons may include (but are not limited to):

1. Insufficient information to determine HHS/FDA criteria for approval have been met
2. Concerns regarding the acceptability of the risk and benefit ratio

3. Inadequate privacy and confidentiality protections
4. Inadequate informed consent process

Examples of reasons for deferral 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.
3. More information is required or changes in design and procedures must be implemented.
4. 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 convened IRB for review.

Disapproval*:* The IRB may vote on action to Disapprove a research protocol after prior consultation and communication with the Principal Investigator, whereby the IRB determines that the research presents risks to participants that far outweigh the benefit or value of the knowledge to be gained. Alternatively, the research may raise such serious ethical questions that the IRB ultimately determines the protocol to be unacceptable. In the event disapproval is foreseen, the investigator is invited to attend the meeting to discuss the protocol prior to the Chair calling a vote.

Voting Documentation

1. At the convened IRB meeting, a vote is taken and recorded.
2. The total number of votes is always equal to the total number of members present at the meeting.
3. Minority Reporting: Those members who vote against a majority action on a research protocol is encouraged and is noted within the minutes.

Conflict of Interest (COI)

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.

1. IRB members are expected to inform the IRB if they have a conflict prior to the discussion of any item on the agenda.
    a. In addition, the reviewer worksheets ask IRB members to indicate that they have no COI
2. Any IRB member who has a COI (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 cannot be present during the final discussion and vote.
3. If it is not obvious that an IRB member is 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. The IRB member will be expected to

relinquish responsibility for reviewing the protocol.

Primary & Secondary Reviewers

All new protocols are assigned a primary and a secondary reviewer. The primary and secondary reviewers are responsible for a complete review and summary of the protocol application.

1. Expertise: At least one of the two reviewers must have the appropriate expertise to review the topic of the protocol. If there is not appropriate expertise:
    a. either an outside consultant will be sought, or
    b. the protocol will be rescheduled for review when expertise is obtained.
2. Convened IRB presentation: The primary and secondary reviewers present the protocol to the IRB at a convened meeting.
    a. The primary reviewer presents a brief summary of the protocol, followed by their comments.
    b. The secondary reviewer presents their comments only.
    c. Following presentation by the primary and secondary reviewer, the IRB is invited to provide additional comments.
        i. All members are asked to review all protocols and informed consents in preparation for the discussion.
3. 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 guides the reviewer comments and is structured to discuss the issues within the context of the regulatory criteria.
    c. The worksheet requires that reviewers consider all the regulatory criteria required for approval.

Full IRB Committee Discussion

Following the full discussion of the convened IRB, the primary and secondary reviewers will suggest a voting action to be taken.

1. The IRB Chair calls for a committee vote.
2. In general, the Chair will continue discussion until it appears that consensus is reached, however a vote may be called at any time.
3. During the review of proposed research, IRB members may express a difference of opinion, or raise issues, questions or concerns that cause debate among the IRB members, or even result in disagreement. Controverted issues are those that cause controversy and dispute among IRB membership. IRB members may resolve controverted issues in a variety of possible ways, such as continued discussion and deliberation, a vote to defer action to seek further clarification from the investigator or sponsor of the proposed research, or decide to settle the issue by vote. The minutes must summarize the IRB's discussion and resolution of any

controverted issues.

Initial Reviews of New Protocols

New research protocol applications that do not meet the criteria for exemption or expedited review are placed on the agenda for convened IRB review. Protocols are discussed on an individual basis.

1. All protocols are submitted electronically and made available to IRB members through the CHeRP system.
    a. All IRB members have full access to the complete submission under review.
    b. 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.
        i. Document uploads are in multiple sections of the SmartForms where the research team can provide complete information required for IRB review.

Amendments/Revisions

All revisions/amendments that do not meet the criteria for expedited review are placed on the agenda for the convened IRB meeting. 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.

1. Each amendment is assigned a primary and a secondary reviewer.
    a. Reviewers get a Reviewer Worksheet that needs to be completed and submitted at the end of the meeting.
2. The CHeRP system allows members to review side-by-side the sections of the SmartForm and attached materials that have been changed.
    a. Revised consents and recruitment notices are submitted in tracked changes to improve efficiency and effectiveness of the review process.
3. The voting procedures listed above apply to the review and voting process for amendments/ revisions.

Continuing Reviews

Continuing reviews that meet the regulatory criteria for expedited review are not placed on the agenda for full IRB review.

1. Each continuing review is assigned a primary reviewer.
    a. A *Reviewer Worksheet* is provided and needs to be completed and submitted at the end of the meeting. The worksheet is structured so that the reviewer can determine whether the regulatory criteria continue to be met.
2. Through the CHeRP system, the primary reviewer is provided with a copy of the continuing review SmartForm. They also have access to the entire protocol, and associated materials,

including study history (i.e. previous continuing reviews and Reportable Events).

3. The procedures listed above apply to the review and voting process for continuing reviews.
4. The IRB determines 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.

Protocols that require continuing review in accordance with the Revised Common Rule, effective January 19, 2019 and the protocols approved prior to that date are referenced in the IRB policy: Continuing Review and Administrative Updates.

Reportable Events

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

1. Each Reportable Event is assigned a primary reviewer.
2. The reviewer will present the event, corrective actions, and provide comments as necessary.
3. Through the CHeRP system, the reviewer has access to the entire protocol file, including previous reportable events.
4. The IRB voting actions are to:
    a. Accept the event
    b. Request additional information (i.e. "Return to IRB" or
    c. Suspend recruitment or terminate entire protocol as necessary in accordance with Suspensions, Terminations, Administrative Closures, and Investigator-Initiated Voluntary Suspension or Termination Policy/Procedure.
5. The IRB will also vote as to whether the event constitutes the following in accordance with Reportable Events: Unanticipated Problems and Adverse Events Involving Risks to Research Subjects and Others policy and Noncompliance: Investigations and Determinations policy:
    a. Unanticipated Problem Involving Risks to Subjects or Others
    b. Serious Noncompliance
    c. Continuing Noncompliance

Reports of Action Procedures

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

1. The Senior Director of Clinical Research Compliance, Director, or IRB Operations Manager are responsible for the final review of all reports of action before they are sent to principal investigators.
2. The IRB Chair and any IRB member may ask to review a draft of the report of action for any protocol, continuing review, or amendment/modification before it is sent to the investigator.

3. As necessary, the IRB staff may ask IRB Chair or members to review reports of action prior to sending them to the investigator.
4. Whenever possible, reports of action are forwarded to investigators within seven days of the convened IRB meeting.
5. Copies of all reports of action included in the CHeRP protocol file.

Related Content

- IRB Policies
    - Amendments and Revisions
    - Continuing Review and Administrative Updates
    - Disapprovals and Appeals (For more information on research protocols that have been disapproved by the IRB)
    - Institutional Review Board Conflict of Interest (For more information concerning COI and IRB members)
    - Convened IRB Meeting Minutes (For more information on voting during the convened IRB meeting)
    - For more information concerning criteria for reporting:
        - 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
- IRB Forms
    - Reviewer Worksheets:
        - Initial Review
        - Amendments
        - Continuing Reviews

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025

Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	2/2/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/1/2025
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Applicability

Boston Children's Hospital- Policies & Procedures