



Committee on Clinical Investigation: Selection and Evaluation

Policy

- Children's Hospital maintains an Institutional Review Board (IRB) that includes members with the appropriate expertise to review the wide variety of research protocols commonly conducted by Children's Hospital, as well as members who fairly represent the interests of the community.
- The IRB members will be knowledgeable about regulatory requirements, and will review individual research protocols objectively and impartially.
- Individuals who serve research business and research development roles for the hospital are not permitted to serve as IRB members or administrators for the IRB operations.
- No IRB member, IRB staff, ex officio member or guest present at the meeting will be permitted to contribute to the meeting proceedings in any manner which may influence IRB member decision making because of business associated goals of the hospital

The purpose of this policy is to outline the process for appointing IRB members, and to assure appropriate representation on the IRB.

Procedures

Appointment

The Medical Staff Executive Committee appoints Members of the Committee on Clinical Investigation (CCI). The Medical Staff Executive Committee will consider the recommendations of the Vice President of Research, the CCI Chair, and the Director of Clinical Research Compliance. Members are appointed for a three-year term with renewable terms for an undefined period of time. As terms end and vacancies are established, the goals of both consistency of members and the need for new ideas are taken into consideration. The Medical Staff Executive Committee will receive the CV and/or resume of any individual who is recommended. Copies of the CV and/or resume of will be submitted to the Office of the Director of Clinical Research Compliance.

Membership is established in compliance with the existing regulations of the Department of Health and Human Services (45 CFR 46), the Food and Drug Administration, and the State.

Composition

- Members are selected to assure continual diversity and experience on the CCI, and are to include both males and females of various backgrounds and professions. Children's Hospital has many different disciplines. Committee members are selected from departments that have the most active clinical research programs; however, the Committee also keeps in mind the need for expertise in all areas and makes sure they have appropriate representation. In particular, consideration will be given to the local patient and community populations to achieve membership that is representative of the community. The following characteristics will be taken into consideration, in addition to the regulatory requirements:
 1. The need to have representatives from the major disciplines that conduct clinical research at Children's Hospital.
 2. At least one member and their immediate family members must be unaffiliated with the Hospital, and one must belong to a nonscientific profession. It is desirable to have at least two to three Committee members with these qualifications.
 3. The need to have individuals who understand the psychological, emotional, and behavioral needs of children.
 4. The need to have individuals who are capable of determining whether a specific location is safe to perform research in children.
 5. The need to have individuals of multiple ethnic and cultural backgrounds.
 6. For research sponsored by the Department of Education, and funded by the National Institute on Disability and Rehabilitation Research, when the IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB will include at least one person primarily concerned with the welfare of these research subjects..
- The Chair serves as a voting member, but is to abstain from voting except in the event of a tie.
- Regulatory expertise on the Committee as it pertains to human research protections is provided by the Director of Clinical Research Compliance. This individual is considered a voting member of the IRB and is the alternate member for the Chair.
- No IRB member, IRB staff, ex officio member or guest present at the meeting will be permitted to contribute to the meeting proceedings in any manner which may influence IRB member decision making because of business associated goals of the hospital . The purpose of this policy is to prevent competing business interests from influencing the IRB review process
- The Vice President for Research Administration, the General Counsel, the Director of the Clinical Research Program, and the Investigational Drug Pharmacist are nonvoting members. Additional nonvoting members may be appointed from time to time.
- The Committee on Clinical Investigation operates on a primary and alternate member system. Each primary Committee member is allowed to request that an alternate member be appointed in the event they need to be absent. Alternates are selected to represent the same expertise as the primary

member they will replace. Alternates are allowed to attend and contribute to all meetings; however, they may not vote if the primary member is also present. Members are not required to have an alternate member but are encouraged to do so if they feel they cannot make the majority of Committee meetings.

- IRB members are assigned to serve as either primary or secondary reviewers for new protocols, three year rewrites, continuing review, amendments/revisions, adverse event reports, and other administrative and ethical issues pertinent to human subject protections. All members are expected to read all protocols before a meeting, and to participate in meeting discussions.
- The Administrative Staff of the CCI assigns reviewers based on the member's knowledge and expertise, and is responsible for ensuring that at least one member attending the meeting has the necessary knowledge and expertise to review the protocol. When the agenda includes protocols that involve vulnerable populations, the Administrative staff is responsible for ensuring that at least one member attending the meeting has knowledge and experience in working with the study population. Children's reserves the right to reschedule protocols for review based on the experience and expertise of the members attending the IRB meeting and to seek expert consultation if deemed necessary
- If an IRB member is unable to attend a meeting, he or she is to contact his or her alternate as soon as possible, and is to inform the IRB administrative office as to whether the alternate will attend. The protocol materials will then be delivered to the alternate member. If it is determined that a member cannot attend after the protocols are distributed, there are two possible options:
 - The member who cannot attend may review the protocol and submit written comments. (This will not be included in a quorum.)
 - The member may ask the alternate to attend, and is then responsible for delivering the protocol materials to the alternate. This option is preferable.
- Nonaffiliated members are offered an honorarium of \$100 and a parking voucher for each meeting they attend. All other members do not receive any monetary compensation.
- On an annual basis, statistics regarding the activities of the Committee on Clinical Investigation are compiled and reviewed with the Chair, the Director of Clinical Research Compliance, and the Institutional Official.
- The roster of IRB membership and the CVs are maintained in the Clinical Investigation Office. Membership updates are sent to OHRP as changes in membership occur. The Director of Clinical Research Compliance is responsible for reporting the changes to OHRP

Evaluation of IRB

On an annual basis the CCI Chair and the Director of Clinical Research Compliance meet to discuss the membership of the CCI IRB to determine if the membership includes individuals with varying backgrounds and the experience and expertise needed to review the scope of biomedical and behavioral research conducted at

Children's. In addition the Chair and Director of Clinical research Compliance will provide a written evaluation to all members which will include, the number of meetings they have attended during the year, whether their reviewer worksheets are completed and turned in, timeliness to review responses to conditional approvals and whether they contribute to the regulatory and ethical discussion of protocols at the meeting. In addition, if there are specific concerns about any member, the Committee Chair will confidentially speak with the individual member.

In addition to individual member reviews, IRB members will be asked to complete an anonymous questionnaire regarding the how the Chair functions. the administrative support members receive from the IRB office, how the committee functions as a whole and their perceived needs for additional training. Survey results will be aggregated and shared with the full committee so that any necessary discussions and improvements can be made. This information will also be shared with the Institutional official .

Related Content

Document Attributes

Title	Committee on Clinical Investigation: Selection and Evaluation		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05, 06/20/05 03/15/07 07/17/07 07/23/07 3/25/08 05/28/2010
Reviewed/ Revised by	Susan Kornetsky		
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