FUNCTION OF THE INSTITUTIONAL REVIEW BOARD

Akron Children's IRB functions under a federal-wide assurance based on common rule (45 CFR 46) and FDA policies (21 CFR 56).

1. The IRB shall have the responsibility to review and the authority to approve, require modification in, or disapprove all activities and all proposed changes in previously approved activities. In rare circumstances, emergency approval of a research study can be approved for one time use by the Chair prior to full IRB review as discussed below. In the event of disapproval, the investigator shall have the opportunity to appeal the decision to the IRB. IRB approval does not mean the institution must support the study. No one other than the IRB has the authority to approve human subject research at Children's Hospital.

2. The IRB shall initially review and approve human subject research as described in procedures below, consistent with federal regulation.

3. The IRB will provide continuing review of all approved human subject research as described in procedures below, consistent with federal regulation.

4. The IRB will review and approve any changes to research protocols and informed consents or assents as described in the procedures below, consistent with federal regulation.

5. The IRB will receive, review and act upon, if necessary, reports of serious adverse events as described in the procedures below, consistent with federal regulation.

6. In accordance with regulation, all IRB reviews (except exempt, expedited and emergency reviews as defined below must be conducted at a convened meeting at which a majority of voting members (or voting and appropriate alternated members) are present, including at least one member whose primary concerns are in a non-scientific area (a quorum). Approval of research is by a majority vote of the quorum. Should the quorum fail during the meeting, the IRB may not take further votes or actions until the quorum is restored.

7. The IRB shall prepare and maintain adequate documentation of its activities including:

    - Written procedures, a membership list and copies of OHRP certificates of designated individuals.
    - Minutes of meetings in sufficient detail to show voting members and others present, actions taken, and the vote on these actions, including the number of members voting for, against and abstaining. If a member in attendance has a conflicting interest regarding any project, minutes shall document that the member did not participate in the review except to provide information, and did not vote.
    - Copies of all research protocols and investigator brochures, when available, reviewed.
    - Certificates of researcher training for investigators as required by regulation. Completed applications, copies of primary protocol review and consent review forms, and copies of informed consents and assents approved.

- Records of all continuing review documents and review forms and actions, including amendments to protocols, consents and assents, and reportable adverse reactions. A database will be maintained to document all events that were acted on and adverse reactions.
- Copies of all correspondence of the IRB.
- Copies of significant new findings provided to subjects.
- Copies of any recruitment or advertising materials provided to potential subjects.
- Written notification to investigators and the Institutional Official of its decision to approve or disapprove the proposed research.
- All records shall be maintained in an area accessible to review for 3 years following the termination of the last IRB approval. All records will be maintained for 6 years.

8. The IRB shall meet at least quarterly and publish its list of scheduled meetings on a yearly basis.