



STRUCTURE OF THE INSTITUTIONAL REVIEW BOARD

1. Akron Children's IRB is a committee of the hospital Board of Trustees. Therefore, the IRB reports its activities and has its policies and procedures reviewed by the Board. It reports through an institution official who is an officer of Akron Children's, has completed mandated OHRP training and is the signatory official of the Akron Children's Hospital Federal Wide Assurance (FWA). The institutional official is the individual to whom concerns or complaints about IRB functions or decisions are directed. The institutional official oversees the appointment of the IRB Chair and IRB Coordinator and assures appropriate institutional support of its activities.
2. Akron Children's IRB has a Chair, as specified in the FWA, who has completed mandated OHRP training. The Chair is a member of the hospital staff and is responsible for initial review of any materials submitted to the IRB and presiding at convened IRB meetings. If needed, the Chair may delegate the above duties to an IRB voting member.
3. Akron Children's IRB has an IRB Coordinator, as specified in the FWA, who has completed mandated OHRP training. The Coordinator is the contact person for investigators and regulatory agencies. The Coordinator addresses questions concerning human subject research, provides materials and guidance to investigators, develops meeting agendas and materials to be distributed and maintains IRB records and files.
4. Akron Children's IRB is a federally registered IRB and has a composition that meets federal regulations described in 21 CFR 56.107, which briefly stated are:
 - At least 5 voting members
 - Diversity of membership: no IRB can consist entirely of one gender or entirely of one profession
 - At least one member who has primary expertise in scientific areas and at least one member with primary concerns in nonscientific areas
 - At least one member who has no affiliation with institution
 - Members of the IRB have sufficient knowledge and expertise to evaluate studies submitted
 - No IRB member may be involved in evaluation of a study with which a conflict of interest exists

In practice, the IRB comprises 8-12 voting members and 1-4 alternate members chosen to comply with the above regulations and provide appropriate expertise. Voting members are asked to attend all meetings and have a vote. Alternate members are asked to attend all meetings and are matched by expertise to a class of voting members (e.g. physician, non-physician scientist, non-scientist) and vote only if a voting member to whom they are matched is absent. Other individuals who provide specialized expertise may be invited to attend and assist the IRB.

Akron Children's Hospital is committed to ensuring members of the IRB have appropriate training to perform their function. Institutional support for appropriate continuing education is provided and attendance at such is documented. New IRB members will be provided with a copy of the Akron Children's Hospital Assurance and a copy of the IRB policy and procedures, which they will document they have reviewed prior to participating in IRB activities. The IRB will hold annual "Special Meetings" to provide continuing education to IRB members and perform procedure review.