

Children's

Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee:	<u>Institutional Review Board</u>
Policy Number:	<u>IRB-16</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

ENGAGEMENT BY MEMBERS OF CHILDREN'S WORKFORCE IN RESEARCH ACTIVITIES THAT REQUIRE IRB REVIEW

POLICY:

Children's IRB review is required when a member of Children's work force is engaged in research activities involving human subjects.

DEFINITIONS:

Engaged in research. An institution becomes "engaged" in human subjects research when members of its work force or persons acting as agents of the institution intervene or interact with living individuals for research purposes or obtain individually identifiable private information about living or deceased individuals for research purposes. An institution automatically is engaged in human subjects research when it receives direct funding to support human subjects research activities. [OHRP Guidance Document "Engagement of Institutions in Research", January 1999.] (Appendix 7)

PROCEDURE:

- 16.1 Children's IRB shall review all research involving human subjects that falls within its jurisdiction as defined in IRB policy 2.
- 16.2 Children's IRB shall review all research in which members of Children's work force are defined as **engaged** in the research activity.

16.3 When Children's IRB review is required, Children's institutional officials may enter into institutional agreements for IRB review with other duly constituted IRBs that have a federal wide assurance and the experience necessary to review research involving children.

16.4 Examples to illustrate when members of Children's workforce are considered **engaged** in a research activity include:

- A. Members of Children's work force are acting as members of the research team or as representatives of the research project and intervening with research participants by performing procedures for research purposes, e.g., collecting biological specimens, administering tests or exams, administering treatments.
- B. Members of Children's work force are acting as members of the research team or representatives of the research project and interacting with individuals for research purposes, e.g., conducting interviews, obtaining consent or assent from participants or their legal representatives, screening or recruiting potential research participants.
- C. Members of Children's work force are receiving private information that is individually identifiable (either directly or indirectly) for research purposes. IRB policy 31 lists potential identifiers (direct and indirect).
- D. Members of Children's work force are manipulating the environment for research purposes, e.g., making audio or video recordings, controlling environmental light, sound or temperature, presenting sensory stimuli.
- E. Members of Children's work force are establishing a statistical center for multi-site research and are receiving private information about individuals enrolled in the research that is individually identifiable (either directly or indirectly). The statistical center is responsible for protecting the privacy and confidentiality of the data.
- F. Members of Children's work force are establishing a coordinating center ("operations center") for multi-site research. The Coordinating Center is responsible for developing operating procedures to protect the research participants at all sites including data and safety monitoring, documentation of informed consent, documentation of IRB approval, confidentiality of research data.
- G. Members of Children's work force have been awarded funding to conduct human subjects research.

16.5 Children's IRB review is not required when members of Children's work force

are involved in activities that pertain to research but the level of involvement would not be considered **engaged** in the research activity.

16.6 Examples to illustrate when members of Children's workforce are considered not engaged in a research activity include:

- A. Members of Children's work force are acting as consultants on the research but will not have access to or receive individually identifiable private information on research participants. Consultants may receive coded information for analysis if there is a written agreement that strictly prohibits the release of identifying codes to the consultant.
- B. Members of Children's work force perform commercial services for a research project in which they will not receive professional recognition or publication privileges and they will adhere to commonly recognized professional standards for maintaining privacy and confidentiality.
- C. Members of Children's work force inform prospective participants (subjects) about a research project but are not involved in the consent of research participants nor act in any way as a representative of the research project. Members of Children's work force may inform prospective subjects about a research project by i) distributing written information about the research project; ii) providing contact information to prospective participants so they may initiate contact with researchers directly; or iii) obtaining permission from prospective participants to release their contact information to researchers.
- D. Members of Children's work force who release private, individually identifiable health information to a research project, with written permission, i.e., authorization from the individuals. For example, a clinician releases protected health information from the patient's medical record to researchers after receiving documentation of the participant's written authorization to release their private health information to researchers for a specific research project.
- E. Members of Children's work force who distribute banked research data or biological specimens provided i) there is Children's IRB approval for the research repository; ii) banked data or specimens are distributed to researchers in a non-identifiable manner; and iii) the recipients (researchers) of the banked data or specimens provide written documentation of IRB approval or IRB determination of exempt review status for their research project prior to the release of the banked specimens or data.

Submitting Committee: Institutional Review Board

Approved by:	<u>Douglas S. Dehene</u>	<u>6/20/05</u>
	Chair	Date
	<u>Elizabeth Trias</u>	<u>6/20/05</u>
	Manager	Date