

**Children's**  
Hospital & Regional Medical Center  
Office of the Vice President for Research

**OPERATING PROCEDURES/POLICIES**

Committee: Institutional Review Board  
Policy Number: IRB-25  
Effective Date: June 20, 2005

**POLICY TITLE:**

**USE OF INVESTIGATIONAL PRODUCTS WHEN RESEARCH PARTICIPANT ENTERS CHILDREN'S AS A SECOND INSTITUTION**

**POLICY:**

**When a research participant receiving an investigational drug or biologic in a research study at another institution is admitted to Children's, the IRB shall be notified in order to render an opinion on the need for Children's IRB review and approval.**

**PROCEDURE:**

- 25.1 The admitting physician shall notify the IRB immediately upon learning that a patient is participating in a research study at another institution, and will continue to receive test drug during his/her stay at Children's.
- 25.2 The admitting physician shall provide the IRB with the following information:
- A. Patient name;
  - B. Admit diagnosis;
  - C. Name, address and phone number of Principal Investigator that enrolled patient in clinical study;
  - D. Name, address and contact information for Principal Investigator's IRB;
  - E. Name, address and contact information for Sponsor;
  - F. Documentation of appropriate FDA clearances; and
  - G. Copy of consent form executed by patient admitted.
- 25.3 The IRB Chair shall determine whether Children's IRB review and approval is necessary based on the following guidance:

