



## OPERATING PROCEDURES/POLICIES

**Committee:** Institutional Review Board  
**Policy Number:** IRB-35  
**Effective Date:** January 8, 2009

### POLICY TITLE:

### PROHIBITION ON THE USE OF ENROLLMENT INCENTIVES TO INDIVIDUALS OR INSTITUTIONS TO RECRUIT PARTICIPANTS IN RESEARCH STUDIES

### POLICY:

**Children's prohibits the use of enrollment incentives paid to investigators, collaborators, intermediaries or subcontractors to recruit participants to take part in a research activity. Such incentives create a potential for conflict of interest and may have deleterious effects on human subjects protections.**

### DEFINITIONS:

***Enrollment incentive*** is any form of direct or indirect inducement offered/received in exchange for enrolling subjects in human subjects research. A reasonable payment made to a researcher in exchange for engaging in an activity that incurs actual cost is not an enrollment incentive. Enrollment incentives do not include reasonable payments paid to participants for taking part in research.

### PROCEDURE:

- 35.1 Enrollment incentives paid to individuals or institutions create a potential for conflict of interest. Such incentives can negatively impact on human subjects protections by their effect on the process of informed consent and enrolling participants who do not meet the eligibility criteria of the research.
- 35.2 Enrollment incentives shall not be allowed in any research activity reviewed and approved under the jurisdiction of Children's IRB or in any research activity involving Children's patients, staff, or facilities that is reviewed by a duly

constituted IRB under a written agreement with Children's.

- 35.3 Enrollment incentives are not allowed in any research agreement between Children's and the sponsors of the research. No acceptance or request for enrollment incentives made be made by Children's, its investigators, or subcontractors.
- 35.4 Children's, its investigators, or subcontractors may accept payment for the actual costs incurred in recruiting research participants as long as these payments represent actual costs and not incentives.
- 35.5 Enrollment incentives prohibited under this policy include but are not limited to:
- A. Any fee to an institution or individual for recruitment that exceeds the actual cost of recruiting research participants;
  - B. Bonuses or other forms of additional payments for timely, early, or over-enrollment of research participants, for retention of participants, or for timely or early IRB approval;
  - C. Use of per subject payment rates that vary based only upon the number of research participants enrolled, including increased per subject rates paid for over-enrollment of research participants that are not made based on the actual costs incurred by such activities;
  - D. Extra contractual benefits such as unrestricted research gifts, medical or office equipment, payment of conference fees, authorship rights, journal subscriptions, educational stipends, software, personal gifts, favors or similar inducements provided in exchange for enrolling research participants;
  - E. Payment of referral or finder's fees in exchange for referral of patients or clients as potential research participants;

Submitting Committee: Institutional Review Board

Approved by:

/s/ Douglas Diekema, M.D., M.P.H., IRB Chair, January 6, 2009

/s/ Laurie Bolton, J.D., OIA Director, January 8, 2009