

Children's

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-18
Effective Date: June 20, 2005

POLICY TITLE:

WAIVER OR MODIFICATION OF INFORMED CONSENT

POLICY:

In accordance with federal regulations the IRB may approve a consent procedure which omits or alters some of the required elements of informed consent or waives the requirement for informed consent. Whenever the IRB approves a waiver or alteration in the informed consent process the IRB must carefully document that the federal regulations allowing such action have been met.

PROCEDURE:

- 18.1 Federal regulations permit modifications of the consent procedure and, under certain circumstances, informed consent may be waived entirely if the research meets one of the following conditions:
- A. The research is to be conducted or subject to the approval of local government officials and is designed to study, evaluate or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs [45 CFR 46.116(c)(1)] and the research could not practicably be carried out without the waiver or alteration [45 CFR 46.116(c)(2)]; or
 - B. The research involves no more than minimal risk to the subjects [45 CFR 46.16 (d)(1)]; and the waiver or alteration will not adversely affect the rights and welfare of the subjects [45 CFR 46.116(d)(2)]; and the research could not practicably be carried out without the waiver or alteration [45 CFR 46.116(d)(3)]; and whenever appropriate,

the subjects are provided with additional pertinent information after participation [45 CFR 46.116(d)(4)].

- 18.2 FDA regulations allow exceptions from the requirements for obtaining informed consent when the use of an FDA regulated test article (investigational drug, biologic, medical device) is needed immediately to meet the health needs of the human subject and consent is deemed infeasible [21 CFR 50.23(a)]. Obtaining informed consent can be considered infeasible provided both the investigator and a physician not otherwise participating in the use of a drug, biologic or device regulated by the FDA certify in writing all of the following *prior to use of the test article*:
- A. The human participant is confronted by a life-threatening situation necessitating the use of the test article [21 CFR 50.23(a)(1)];
 - B. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from the subject [21 CFR 50.23(a)(2)];
 - C. There is not sufficient time to obtain consent from the participant's legal representative [21 CFR 50.23(a)(3)]; and
 - D. There is no alternative method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the life of the participant [21 CFR 50.23(a)(4)].
- 18.3 If, in an investigator's opinion, immediate use of a drug, biologic or device regulated by the FDA is required to preserve the life of a subject, and time is not sufficient to obtain the independent certification as outlined in 18.2, the investigator may proceed with use of the test article but within five (5) working days after its use must obtain a written evaluation from a physician not participating in the clinical investigation [21 CFR 50.23(b)].
- 18.4 Use of a drug, biologic or device regulated by the FDA without obtaining informed consent must be reported to the IRB as soon as possible but no later than five (5) working days after use of the test article. The documentation required in 18.2 and 18.3 above shall be submitted with this report to the IRB [21 CFR 50.23(c)].

Submitting Committee: Institutional Review Board

Approved by:

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| <u>Donald S. Dehena</u> | <u>6/20/05</u> |
| Chair | Date |
| <u>Elizabeth Trigg</u> | <u>6/20/05</u> |
| Manager | Date |