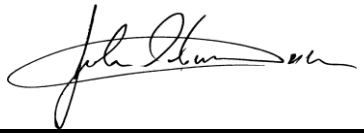
KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Research Involving Pregnant Women as Participants	**POLICY # 5012**
APPROVED: **Richard J. Greene, M.D., Ph.D.** **IRB Chair**  **John DeLuca, Ph.D.** **Vice President for Research** 	**EFFECTIVE DATE:** **January 1, 1998** **REVISED DATE:** **June 19, 2014**

I. PURPOSE

To provide guidelines for conducting research studies involving pregnant women as participants.

II. POLICY

Kessler Foundation, as required by the Department of Health and Human Services (DHHS), agrees to all provisions of 45 CFR 46, Protection of Human Subjects, including Subparts A-D. Subpart B specifically addresses additional protection for pregnant women who participate in research.

> "Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. DHHS regulations require that, when appropriate, subjects be provided a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is, or may, become pregnant) which are currently unforeseeable as part of the informed consent process (45 CFR 46.116(b)(1).
>
> IRBs must judge whether the mother's participation would pose any risk to the fetus or nursing infant. In some studies, IRBs may need to ensure that non-pregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. Furthermore, where appropriate, subjects should be advised to notify the investigator immediately should they become pregnant. In some instances, there may be potential risk sufficient to justify requiring that pregnant women either be

specifically excluded from the research or studied separately." (From IRB Guidebook: Chapter VI Special Classes of Subjects DHHS-OHRP)

In studies involving medications or procedures that may pose a risk to the fetus, pregnant women should be excluded from study participation. In such cases (e.g. when MRI scans are required) women of childbearing potential should be required to have a negative pregnancy test before they are permitted to participate in the study.

III. PROCEDURE

A. No pregnant woman may be involved as a subject in a research study unless: (a) the purpose of the study is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (b) the risk to the fetus is minimal.

B. A pregnant woman may be involved as a subject in a research study only if she and the father of the fetus are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if (a) the purpose of the study is to meet the health needs of the mother; (b) his identity or whereabouts cannot reasonably be ascertained; (c) he is not reasonably available; or (d) the pregnancy resulted from rape.