Institutional Review Board

Checklist: Research Involving Pregnant Women

NUMBER | HRP-316

IRB Number:	
Protocol Number:	
Investigator:	

Research must meet one of the following three sets of criteria in Sections 1, 2 or 3.

Section 1 Non-Federally Regulated Minimal Risk[1] Research (All must be Yes)	
☐	The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS, or Environmental Protection Agency (EPA).
☐	The research involves no more than Minimal Risk to pregnant women and fetus.
☐	The research is not funded by Department of Defense, or does not involve interventions/invasive procedures to the woman or fetus, and does not involve babies as subjects.
Section 2 Research Involving Pregnant[i] Women (45 CFR §46.204) (subject to regulation by DHHS) (Check if "**Yes**" or "**N/A**". All must be checked).	
☐	Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses (babies). **(N/A if not scientifically appropriate.)** ☐ **N/A**
☐	One of the following is true**: (Check box that is true)** ☐ The risk to the fetus[ii] is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. ☐ If there is no such prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means
☐	Any risk is the least possible for achieving the objectives of the research.
☐	Consent of the mother is obtained under these situations: • If the research holds out the prospect of direct benefit to the pregnant woman, or • If the research holds out the prospect of a direct benefit both to the pregnant woman and the fetus, or • if there is no prospect of benefit for the woman nor the fetus, and when the risk to the fetus is **NOT** greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means. **(N/A if research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.)** ☐ **N/A**
☐	If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman *and* the father is obtained, except that the father's consent need **NOT** be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. **(N/A if research does not hold out the prospect of direct benefit to the fetus.)** ☐ **N/A**

[1] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons.

☐	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
☐	For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(N/A if research does not enroll children who are pregnant.)☐ N/A**
☐	No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
☐	Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
☐	Individuals engaged in the research will have no part in determining the viability of a neonate.

Section 3 Research Involving Pregnant Women that is NOT Otherwise Approvable (45 CFR §46.207)[2] (All must be "Yes")

☐	The research does NOT meet the requirements of 45 CFR §46.204 or §46.205, *(i.e., the research is not conducted, funded or otherwise subject to regulation by DHHS, or EPA)*.
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

At this time, I recommend the research be:

(Please check one, and sign/date)

- ☐ APPROVED.
- ☐ Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office. *Note conditions below*
- ☐ Approved with Conditions, Major Clarifications and/or Modifications back to the Full IRB Meeting. *Note conditions below*
- ☐ Do Not Recommend approval at this time. List Reasons.
  (Convened board must agree by a vote if study is not approved.)

Comments Section:

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(Name) (Signature) (Date)

[i] "Pregnancy" encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

[ii] "Fetus" means the product of conception from implantation until delivery

[2] For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed only after the Director, Defense, Research and Engineering has reviewed and approved the research For all other research, the research may proceed only after Organizational Officials have conducted a review in accordance with the SOP – Not Otherwise Approval Research and approved the research.