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Pregnant Women Checklist ▾

REVIEWER CHECKLIST
PREGNANT WOMEN and HUMAN FETUSES

Please indicate in each section whether the statement is "True" or "False." If the response to any of the below is "False", the research is not approvable by the IRB at this time. Please indicate any revisions or clarifications if any of the statements below cannot be determined.

<p>True False Clear</p>	<p>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.</p>
<p>True False Clear</p>	<p>One of the following is true:</p> <p>The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman or fetus.</p> <p>All of the following are true:</p> <ul style="list-style-type: none"> • There is no prospect of direct benefit for the woman or the fetus; AND • The risk to the fetus is not greater than minimal; AND • The purpose of the research is the development of important biomedical knowledge; AND • The biomedical knowledge cannot be obtained by any other means.
<p>True False Clear</p>	<p>Any risk is the least possible for achieving the objectives of the research.</p>
<p>True False Clear</p>	<p>One of the following options is true:</p> <p>The research holds out the prospect of direct benefit to the pregnant woman and the woman's consent will be obtained.</p> <p>The research holds out the prospect of direct benefit to both the pregnant woman and the fetus and the woman's consent will be obtained.</p> <p>All of the following statements are true:</p> <ul style="list-style-type: none"> • The research holds out no prospect of benefit for the woman or the fetus; AND • 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; AND • The woman's consent will be obtained. <p>The research holds out the prospect of direct benefit solely to the fetus and the consent of the pregnant woman and the father will be obtained. (Exception: 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.)</p>
<p>True False Clear</p>	<p>Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.</p>
<p>True False Clear</p>	<p>One of the following is true:</p> <p>The research does NOT involve pregnant women under 18 years of age (i.e. children) participants.</p> <p>The requirements for research involving children are met. (Please complete the Children's Checklist if you have not already done so.)</p>

True	False	Clear	No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
True	False	Clear	Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
True	False	Clear	Individuals engaged in the research will have no part in determining the viability of a fetus.

FINAL DETERMINATION

The proposed involvement of pregnant women and fetuses is Approvable.

The proposed involvement of pregnant women and fetuses cannot be determined at this time and needs the clarifications noted below.

The proposed involvement of pregnant women and fetuses is Not Approvable.

Clear

Requested Revisions/Clarifications: Provide more information if you answered "False" to any statements above.

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