

	CHECKLIST: Research Involving Pregnant Women			IRB # \$\$IRB Number\$\$
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving Pregnant Women.

- For initial review, modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the IRB Analyst completes this checklist.
- For expedited reviews: the Designated Reviewer reviews the completed checklist and it is retained in the protocol file.

For review using the convened IRB: the IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes to document determinations required by the regulations, in which case this checklist does not need to be retained.

Minimal Risk¹ Research (All must be Yes)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is NOT conducted, funded, or otherwise subject to regulation by DHHS, or Environmental Protection Agency (EPA).
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research involves no more than <u>Minimal Risk</u> to pregnant women and fetuses.
<input type="checkbox"/> Yes <input type="checkbox"/> No	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 fetuses or neonates as subjects.

1 Research Involving Pregnant² Women (45 CFR §46.204) (All items in the left most columns must be “Yes”)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	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. (N/A if not scientifically appropriate.) <input type="checkbox"/> N/A <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	One of the following is true: (Check box that is true) <input type="checkbox"/> The risk to the fetus ³ is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus. <input type="checkbox"/> 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 <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any risk is the least possible for achieving the objectives of the research. <i>Provide protocol specific findings justifying this determination:</i>

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.

² *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.

³ *Fetus* means the product of conception from implantation until delivery

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<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>If the research holds 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 when 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, consent of the mother is obtained. (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.) <input type="checkbox"/> N/A</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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.) <input type="checkbox"/> N/A</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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.) <input type="checkbox"/> N/A</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>No inducements, monetary or otherwise, will be offered to terminate a pregnancy.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Individuals engaged in the research will have no part in determining the viability of a neonate.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>

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2 Research Involving Pregnant Women that is NOT Otherwise Approvable (45 CFR §46.207)⁴ (All must be “Yes”)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The research does not meet the requirements of 45 CFR §46.204 or §46.205. <i>Provide protocol specific findings justifying this determination:</i></p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>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. <i>Provide protocol specific findings justifying this determination:</i></p>

⁴ 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