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Pregnant Women Checklist ▾

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**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.

<input type="radio"/> True <input type="radio"/> False <span style="color: orange;">Clear</span>	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.
<input type="radio"/> True <input type="radio"/> False <span style="color: orange;">Clear</span>	One of the following is true: <input type="checkbox"/> The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman or fetus.  All of the following are true: <input type="checkbox"/> <ul style="list-style-type: none"> <li>• There is no prospect of direct benefit for the woman or the fetus; <b>AND</b></li> <li>• The risk to the fetus is not greater than minimal; <b>AND</b></li> <li>• The purpose of the research is the development of important biomedical knowledge; <b>AND</b></li> <li>• The biomedical knowledge cannot be obtained by any other means.</li> </ul>
<input type="radio"/> True <input type="radio"/> False <span style="color: orange;">Clear</span>	Any risk is the least possible for achieving the objectives of the research.
<input type="radio"/> True <input type="radio"/> False <span style="color: orange;">Clear</span>	One of the following options is true: <input type="checkbox"/> The research holds out the prospect of direct benefit to the pregnant woman and the woman's consent will be obtained. <input type="checkbox"/> 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.  All of the following statements are true: <input type="checkbox"/> <ul style="list-style-type: none"> <li>• The research holds out no prospect of benefit for the woman or the fetus; <b>AND</b></li> <li>• The risk to the fetus is not greater than minimal; <b>AND</b></li> <li>• The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means; <b>AND</b></li> <li>• The woman's consent will be obtained.</li> </ul> <input type="checkbox"/> 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.)
<input type="radio"/> True <input type="radio"/> False <span style="color: orange;">Clear</span>	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
	One of the following is true:  The research does NOT involve pregnant women uner 18 years of age (i.e.

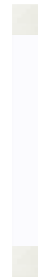
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	<input type="checkbox"/> children) participants. <input type="checkbox"/> The requirements for research involving children are met. (Please complete the Children's Checklist if you have not already done so.)
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	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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**REVIEWER CHECKLIST  
RESEARCH INVOLVING NEONATES**

**IRB REVIEWER:** Please answer and follow the directions for each of the three required (asterisked) questions. Then complete the Final Determination question below..

\* 1) The research involves neonates where it will not be ascertained whether a neonate is viable:

True  False [Clear](#)

If False, please skip to the next section below.

The following statements must be true to approve the research involving neonates of uncertain viability:

<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Each individual engaged in the research will have no part in determining the viability of a fetus.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Either of the following is true: <input type="checkbox"/> The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability and any risk is the least possible for achieving that objective. <input type="checkbox"/> The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Either of the following is true: <input type="checkbox"/> The legally effective informed consent of either parent of the neonate will be obtained. (Exception: the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.) <input type="checkbox"/> If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative will be obtained. (Exception: the consent of the father's legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.)

**Requested Revisions/Clarifications:** Provide more information if you answered "False" to any statements above or if you are unable to make a determination. Please indicate your final determination at the end of this checklist.

\* 2) The research involves neonates ascertained to be non-viable:  True  False [Clear](#)

If False, please skip to the next section below.

**The following statements must be true to approve the research involving non-viable neonates:**

<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Individuals engaged in the research will have no part in determining the viability of a neonate.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	Vital functions of the fetus will not be artificially maintained.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research will not terminate the heartbeat or respiration of the fetus.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	There will be no added risk to the fetus resulting from the research.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.
<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The legally effective informed consent of both parents will be obtained. (Exception: the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.) The informed consent of one parent will suffice if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity. (The consent of a legally authorized representative of either or both of the parents of a nonviable neonate is not permitted.)

**Requested Revisions/Clarifications:** Provide more information if you answered "False" to any statements above. Please indicate your final determination at the end of this checklist.

\* 3) The research involves neonates ascertained to be viable:  True  False [Clear](#)

The following statements must be true to approve the research involving viable neonates:

<input type="radio"/> True <input type="radio"/> False <a href="#">Clear</a>	The research meets the regulatory requirements (please see the Children's Checklist).
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**Requested Revisions/Clarifications:** Provide more information if you answered "False" to any statements above. Please indicate your final determination at the end of this checklist.

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**FINAL DETERMINATION**

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- 
- The proposed involvement of neonates is Approvable.

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  - The proposed involvement of neonates cannot be determined at this time and needs further clarification noted above in the appropriate section(s).

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  - The proposed involvement of neonates is Not Approvable.

[Clear](#)

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