

**Reviewer:**

**PRO #:**

**PI:**

**This checklist must be completed by an IRB member with sufficient expertise. In order to approve the use of pregnant women, fetuses, or neonates, responses must be “yes” unless not applicable:**

**1. General Limitations – Women, Fetuses, Neonates**

- |  |     |    |    |
|--|-----|----|----|
| 1. Appropriate studies on animals and non-pregnant individuals have been completed.  | Yes | No | NA |
| 2. Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.  | Yes | No | NA |
| 3. Individuals engaged in the activity will have no part in (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy. | Yes | No | NA |
| 4. No procedural changes, which may cause greater than minimal risk to the fetus or the pregnant woman, will be introduced in the procedure for terminating the pregnancy solely in the interest of the activity.                            | Yes | No | NA |
| 5. No inducements, monetary or otherwise, may be offered to terminate pregnancy for the purposes of the activity.  | Yes | No | NA |

**2. Pregnant Women**

- |   |     |    |    |
|---|-----|----|----|
| 1. The purpose of the activity is to meet the health needs of the mother and the fetus.   | Yes | No | NA |
| 2. An activity may be conducted only if the mother and father 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: (check at least one)<br>the purpose of the activity is to meet the health needs of the mother;<br>his identity or whereabouts cannot reasonably be ascertained;<br>he is not reasonably available; or<br>the pregnancy resulted from rape. | Yes | No | NA |

**3. Fetus in Utero**

- |   |     |    |    |
|---|-----|----|----|
| 1. The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only the minimum extent necessary to meet such needs.             | Yes | No | NA |
| 2. The risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. | Yes | No | NA |

<p>3. An activity may be conducted only if the mother and father 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: (check at least one)</p> <ul style="list-style-type: none"> <li>the purpose of the activity is to meet the health needs of the mother;</li> <li>his identity or whereabouts cannot reasonably be ascertained;</li> <li>he is not reasonably available; or</li> <li>the pregnancy resulted from rape.</li> </ul>	Yes	No	NA
<b>4. Fetus ex Utero</b>			
<p>1. The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only the minimum extent necessary to meet such needs.</p>	Yes	No	NA
<p>2. The risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.</p>	Yes	No	NA
<p>3. An activity may be conducted only if the mother and father 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: (check at least one)</p> <ul style="list-style-type: none"> <li>the purpose of the activity is to meet the health needs of the mother;</li> <li>his identity or whereabouts cannot reasonably be ascertained;</li> <li>he is not reasonably available; or</li> <li>the pregnancy resulted from rape.</li> </ul>	Yes	No	NA
<b>5. Fetus ex Utero – uncertain viability / non-viable</b>			
<p>1. Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity unless:</p>			
<p>1. There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.</p>	Yes	No	NA
<p>2. The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.</p>	Yes	No	NA
<p>2. No non-viable fetus will be involved as a subject in an activity unless vital functions of the fetus will not be artificially maintained, experimental activity which of themselves would terminate the heartbeat or respiration of the fetus will not be employed and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.</p>	Yes	No	NA
<p>3. An activity may be conducted only if the mother and father 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: (check at least one)</p> <ul style="list-style-type: none"> <li>the purpose of the activity is to meet the health needs of the mother;</li> <li>his identity or whereabouts cannot reasonably be ascertained;</li> <li>he is not reasonably available; or</li> <li>the pregnancy resulted from rape.</li> </ul>	Yes	No	NA
<p>4. For non-viable neonates, consent waiver and alteration provisions are not applied.</p>	Yes	No	NA