**Research Involving Pregnant Women or Fetuses Checklist**

**Reference: IRB Policy 17.8**

1. **Preclinical and clinical studies have been conducted and provide data for assessing potential risks to pregnant women and fetuses, where scientifically appropriate.**

   ☐Yes
   ☐No
   ☐N/A

2. **The IRB requirements for the level of risk to the subjects are met.**
   ☐The research holds out the prospect of direct benefit for the pregnant woman or the fetus, AND any risk is the least possible for achieving the objectives of the research.

   OR

   ☐The research holds out no prospect of direct benefit for the woman or the fetus, BUT 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, AND any risk is the least possible for achieving the objectives of the research.

3. **Adequate provisions are made for soliciting consent/permission.**
   ☐The consent/permission of the pregnant woman is sufficient. Condition applies when the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit to both the pregnant woman and the fetus, or no prospect of benefit to neither the pregnant woman nor the fetus when the risk to the fetus is not greater than minimal and the research's purpose is to develop knowledge that cannot be obtained by any other means.

   OR

   ☐The consent/permission of both the pregnant woman and the father is required, because the prospect of direct benefit exists solely for the fetus.

   OR

   ☐The consent/permission of only the pregnant woman is sufficient, because the prospect of direct benefit exists solely for the fetus, AND the father is unable to consent (because of unavailability, incompetence or temporary incapacity), or the pregnancy resulted from rape or incest.

4. **Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.** Review the proposed informed consent process to ensure this criterion is met.

☐Yes
☐No

5. **Adequate provisions are made for involving pregnant children.**
☐Research will not include any pregnant children.

OR

☐Research involves children who are pregnant AND all requirements for research involving children are met. In summary, Arkansas law allows pregnant minors to provide permission on behalf of the fetus for research participation. However, for her own participation, parental permission must be obtained. See the "Research Involving Children" policy and checklist.

6. **No inducements, monetary or otherwise, will be offered to terminate a pregnancy.**

☐Yes
☐No
☐N/A

7. **Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.**

☐Yes
☐No
☐N/A

8. **Individuals engaged in the research will have no part in determining the viability of a neonate.** [Yes/No/NA]

☐Yes
☐No
☐N/A