ACMS-IRB Application Form

**Research Involving Pregnant Women, Foetuses and Neonates**

**Protocol Title:**

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| --- |
| Enrolling Pregnant Women, Foetuses or Neonates in research requires that the research meet specific criteria. Please provide protocol specific information explaining how your proposed research project meets **ALL** of the following criteria: |

*Text Field*

1. Describe if appropriate preclinical studies, including studies on pregnant animals and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and fetus.

*Text Field*

1. Describe if the risk to the fetus is the least possible consistent with the research objectives.

*Text Field*

1. Special Informed Consent Requirements

[ ] I will obtain consent from the pregnant woman because (check all that apply):

[ ] Research holds out the prospect of direct benefit to the pregnant woman.

[ ] Research holds out the prospect of direct benefit to both the pregnant woman and the fetus.

[ ] 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.

[ ] I will also obtain consent from the father because the research holds out the prospect of direct benefit solely to the fetus.

[ ] The Informed Consent document(s) will provide information regarding the reasonably foreseeable impact of the research on the fetus or neonate.

1. Assurances by Principal Investigator

[ ] There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.

[ ] Individuals engaged in the research will not have any part in any decisions as to the timing method, or procedures used to terminate a pregnancy.

[ ] Individual engaged in the research will not have any part in determining the viability of a neonate.

1. Describe the additional safeguards that will be provided to protect rights and welfare of the vulnerable subjects.

*Text Field*