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*