**PIEC Application Form Annex F**

**– Research involving Pregnant Women, Fetuses and Neonates**

**PROTOCOL TITLE:**

Text Field

|  |
| --- |
| 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. |

This research study involves:

*[ ]  Pregnant Women and Fetuses*

*[ ]  Neonates of Uncertain Viability and/or Nonviable Neonates*

*[ ]  Viable Neonates (Skip this form and complete Annex G - Research Involving Minors)*

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 in order to achieve the research objectives.*

Text Field

1. *Special Informed Consent Requirements:*

*[ ]  I will obtain consent from ONLY the pregnant woman because:*

*[ ]  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 obtain consent from the pregnant woman AND the father of the fetus because the research holds out the prospect of direct benefit solely to the fetus.*

***Note: The Informed Consent document(s) must provide information regarding the reasonably foreseeable impact of the research on the fetus or neonate.***

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

Text Field

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.*

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

|  |  |  |
| --- | --- | --- |
| *Signature* |  | *Date* |
| *Name:* Text Field |  |  |