# PROTOCOL INVOLVING PREGNANT WOMEN &/OR FETUSES

**Protocol Title:**

**Principal Investigator:**

**Institution:**

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| **1)** Have similar pre-clinical studies, such as studies on pregnant animals, or studies on non-pregnant women been conducted to provide information for assessing the potential risks for pregnant women and/or fetuses? | Yes |
| No |
| N/A |
|  | |
| **2)** Is it true that the biomedical knowledge or other knowledge to be obtained as a result of this research can be obtained by no other means? | Yes |
| No |
|  | |
| **3)** Does the consent process fully inform the woman recruited of any foreseeable impact of the research on the fetus?  Use the Consent form checklist to review the details of the actual consent document. | Yes |
| No |
|  | |
| **4)** Have the risks to the pregnant woman and fetus been minimized? | Yes |
| No |
|  | |
| **5)** Is the pregnant woman a child, as defined by state law?  If unsure, check state laws to find out what the legal age of adulthood is.  If yes, then regulations for research involving children also need to be complied with.  See [45 CFR 46.402](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402) and [45 CFR Subpart D](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd) | Yes |
| No |
|  |  |
| **6)** Is it stated in the protocol that individuals engaged in research are prohibited from incentives (monetary or otherwise) to encourage termination of the pregnancy? | Yes |
| No |
|  | |
| **7)** Is it stated in the protocol that individuals engaged in research are prohibited from taking part in decisions regarding the timing, method, or procedures to terminate a pregnancy? | Yes |
| No |

**Determination of Who Needs to Give Consent:**

**A.** Only the pregnant woman needs to give consent if any and/or several of the following are true:

The research holds no prospect of direct benefit to the woman or the fetus

The risk to the fetus is not greater than minimal

The purpose of the research is to develop important biomedical knowledge

Look for evidence of each of the items above in the research protocol and other submitted documents.

**B.** Only the pregnant woman needs to give consent if one of both of the following are true:

The research holds the prospect of direct benefit to the pregnant woman only.

The research holds the prospect of direct benefit to both the pregnant woman and the fetus.

**C.** Both the pregnant woman and the father of the fetus need to give consent if the following are true:

The research holds the prospect of direct benefit to the fetus only.

The consent from the father does not have to be obtained if he is unavailable, incompetent, temporarily incapacitated, or if the pregnancy resulted from rape or incest.

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**Key Terms (45 CFR 46.202)**

**Fetus**- The product of conception from implantation until delivery.

**Dead Fetus** - A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

**Delivery**- Complete separation of the fetus from the woman by expulsion or extraction or any other means.

**Pregnancy**- Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**Viable** - As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

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| **Specific Concerns/Items for Board Discussion:** |

**Resources to Guide Review:**

* [Federal Regulations for Research Involving Pregnant Women/Fetuses: 45 CFR 46 Subpart B](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb)
* [CRCAIH Glossary of Human Subjects Protections Terms](http://crcaih.org/assets/Human_Subjects_Protections_Glossary.pdf)