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| --- | --- | --- | --- |
| Study ID |       | PI |       |

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

[ ]  Scientifically appropriate

[ ]  Not scientifically appropriate

*Why does the research meet this criterion?*

1. Select one:

[ ]  The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus

*Why does the research meet this criterion?*

[ ]  If there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

 [ ]  No intervention with the fetus

[ ]  Other, please explain why the research meets this criterion?

1. Any risk is the least possible for achieving the objectives of the research.

*Why does the research meet this criterion?*

1. Does the research hold out:
* prospect of direct benefit to the pregnant woman [ ]  No [ ]  Yes
* prospect of a direct benefit both to the pregnant woman and the fetus [ ]  No [ ]  Yes
* no prospect of benefit for the woman nor the fetus when 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 [ ]  No [ ]  Yes

If yes, check the boxes to confirm:

[ ]  The pregnant woman’s consent will be obtained in accord with informed consent provisions of subpart A (45 CFR 46)

[ ]  Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate

1. Does the research hold out the prospect of direct benefit solely to the fetus? [ ]  No [ ]  Yes

If yes, check the boxes to confirm:

[ ]  Consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A (45 CFR 46), except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

[ ]  Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

1. Will children who are pregnant be subjects in this study? [ ]  No [ ]  Yes

If yes, check the boxes to confirm:

[ ]  Assent will be obtained in accord with subpart D (45 CFR 46)

[ ]  Parental permission will be obtained in accord with subpart D (45 CFR 46)

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

[ ]  No intervention with the fetus

[ ]  Intervention with the fetus, please explain why this criterion is met:

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

[ ]  No intervention with the fetus

[ ]  Intervention with the fetus, please explain why this criterion is met:

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

[ ]  No intervention with the fetus

[ ]  Intervention with the fetus, please explain why this criterion is met:

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| --- |
| IRB determination made by: |
| [ ]  Expedited reviewer | Name: |       | Date: |       |  |
|  |
| [ ]  Full board | Name of individual completing this form: |       | Meeting date |       |
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