**IRB Member Checklist for Projects involving Pregnant Women and fetuses (subpart B)**

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| IRB Meeting Date or EXR Review Date:Click or tap to enter a date. | eBridge #:Click or tap here to enter text. |
| Principal Investigator: Click or tap here to enter text. | Reviewer:Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which request the inclusion of pregnant women and fetuses. IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research with Pregnant Women and Fetuses.*

This project involves the following (check as many as apply):

[Section: Pregnant women or fetuses (45 CFR 46.204](#Pregnant_Women_204)):

[Section: Neonates of Uncertain Viability (45 CFR 46.205 (a) and (b))](#Neonates_205a)

[Section: Nonviable neonates (45 CFR 46.205 (c))](#Neonates_205c)

Reviewers must then complete the corresponding section(s) below, along with [final comments and recommendations.](#Final_Recommendations)

# **Section: Pregnant women or fetuses (45 CFR 46.204):**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

**If yes**, pregnant women or fetuses may only be involved in the project if the following 10 elements are satisfied.

**If no,** the IRB may choose to waive some of the identified elements, with justification.

1. Does the application identify where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. 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; or, 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;  Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.
2. Any risk is the least possible for achieving the objectives of the research;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or 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, her consent is obtained in accord with 45 CFR 46.116 and 117

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. If the research holds the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with 45 CFR 46.116 and 117, 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.

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under items 5 or 6 is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D; *See IRB Member Form: Research Involving Children (subpart D) Checklist*

Yes  No  N/A  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

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

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

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; and

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

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

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

# **Section: Neonates of Uncertain Viability (45 CFR 46.205 (a))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

**If yes,** neonates of uncertain viability and non-viable neonates may only be involved in the project if the following 4 elements are satisfied.

**If no**, the IRB may choose to waive some of the identified elements, with justification.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. Each individual providing consent under paragraph [45 CFR 46.205(b)(2) or (c)(5)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

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

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The requirements of paragraph [45 CFR 46.205(b) or (c)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section have been met as applicable.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

# **Section: Neonates of uncertain viability (45 CFR 46.205 (b))**

1. Is this project receiving federal funding for the conduct of the research?

Yes No

**If yes**, until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional 2 conditions have been met.  
**If no**, the IRB may choose to waive some of the identified elements, with justification.

1. (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of either parent of the neonate or, if neither parent can consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accordance with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

# **Section: Nonviable neonates (45 CFR 46.205 (c))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

**If yes**, nonviable neonates may only be involved in the project if the following 5 elements are satisfied.   
**If no**, the IRB may choose to waive some of the identified elements, with justification.

1. Vital functions of the neonate will not be artificially maintained

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The research will not terminate the heartbeat or respiration of the neonate

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. There will be no added risk to the neonate resulting from the research.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

1. The legally effective informed consent of both parents of the neonate is obtained in accordance with 45 CFR 46 subpart A except that the waiver and alteration provisions of 45 CFR 46.116(e) and (f) do not apply.

Yes  No  IRB Chooses to Waive, provide justification: Click or tap here to enter text.

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| **Reviewer Comments** |
| Click or tap here to enter text. |

Reviewer Name: Click or tap here to enter text. Date:Click or tap to enter a date.