Reviewer guide [[Subpart B](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#subpart-B)]: Pregnant Participants, Fetuses, and Neonates

This reviewer guide should be completed and retained in the study file.

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| **PI Name:** | Click or tap here to enter text. |
| **Protocol Title:** | Click or tap here to enter text. |
| **IRB #:** | Click or tap here to enter text. |
| **IRB Reviewer(s):** | Click or tap here to enter text. |
| **Date Completed:** | Click or tap here to enter text. |

# Pregnant Participants or Fetuses

All must be true as applicable, OR requirements of [46.207](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.207) must be met.

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|  | 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. |
|  | **One** of the following is true**:**   |  |  | | --- | --- | |  | 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. | |  | If there is **no prospect of benefit** to the woman or the fetus:  the risk to the fetus no greater than **minimal risk** AND  the purpose of the research is the development of **important biomedical knowledge** which cannot be obtained by any other means *For DOD-supported research: replace “biomedical” with “generalizable”* | |
|  | Any risk is the least possible for achieving the objectives of the research. |
| **Consent:** | |
|  | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | One of the following is true, and **consent of the mother is obtained** in accordance with [45 CFR 46.116](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.116):   |  |  | | --- | --- | |  | The research holds out the prospect of **direct benefit to the pregnant woman**, OR | |  | The research holds out the prospect of **direct benefit both to the pregnant woman and the fetus**, OR | |  | The research holds out **no prospect of benefit** for the woman nor the fetus AND **risk to the fetus is no greater than minimal risk** AND the purpose of the research is the development of **important biomedical knowledge that cannot be obtained by any other means** | | | | **OR** | | |  | |  |  | | --- | --- | |  | The research holds out the prospect of direct benefit solely to the fetus **AND** | |  | The **consent of the pregnant woman AND the father** is obtained in accordance with [45 CFR 46.116](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.116), 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**. |
|  | For children who are pregnant, assent and permission are obtained in accordance with the provisions of subpart D (Children). |
|  | No inducements, monetary or otherwise, will be offered to terminate a pregnancy. |
|  | Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. |
|  | Individuals engaged in the research will have no part in determining the viability of a neonate. |

**COMMENTS:** Click or tap here to enter text.

# Neonates of uncertain viability and non-viable neonates

All must be true as applicable, OR requirements of [46.207](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.207) must be met.

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|  | Where scientifically appropriate, **preclinical and clinical studies** have been conducted and provide data for assessing potential risks to neonates. |
|  | Each individual providing consent is fully informed regarding the reasonably foreseeable **impact of the research on the neonate**. |
|  | Individuals engaged in the research will have **no part in determining the viability** of a neonate. |
|  | Neonates of uncertain viability *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 conditions have been met:*   |  |  |  | | --- | --- | --- | |  | **One of the following is true:** | | |  |  | 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 | |  | 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 | |  | Consent is obtained in accordance with [45 CFR 46.116](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.116) from **either parent** of the neonate, or either parent’s **legally authorized representative** if **neither** parent is able to consent because of unavailability, incompetence, or temporary incapacity, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. | | |
|  | Non-viable neonates  |  |  | | --- | --- | |  | Vital functions of the neonate will not be artificially maintained | |  | The research will not terminate the heartbeat or respiration of the neonate | |  | There will be **no added risk** to the neonate resulting from the research | |  | The purpose of the research is the development of **important biomedical knowledge** that cannot be obtained by other means | |  | Consent is obtained in accordance with [45 CFR 46.116](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.116) (General requirements) except that the waiver and alteration provisions do NOT apply.   * Consent must be obtained from **both parents**, or from **one parent** if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. * The consent of a **legally authorized representative** of either or both of the parents of a nonviable neonate will **not** suffice. | |

**COMMENTS:** Click or tap here to enter text.

# After delivery: placenta and other material

All must be true as applicable, OR requirements of [46.207](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#46.207) must be met.

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|  | Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state[[1]](#footnote-2), or local laws and regulations regarding such activities. |
|  | If information associated with the material above is recorded for research purposes in a manner that living individuals can be identified (directly or through links), then **those individuals are research subjects** and all Common Rule requirements apply to the individuals. |

1. For MA, see [M.G.L. c. 112 § 12J](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12J) [↑](#footnote-ref-2)