P

P

1. Pregnant women or fetuses may be involved in federally funded projects only if the IRB finds that all of the ten (10) elements outlined in 45 CFR 46.204 are met. The same ten (10) elements should be evaluated for all other projects, but are not binding.
2. The Investigator must address all ten (10) elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist*.

N

1. Neonates of uncertain viability and nonviable neonates may be involved in a research project only if the IRB finds that all four (4) of the elements required in 45 CFR 46.205 are met for federally funded projects. The same four (4) elements should be evaluated for all other projects, but are not binding.
2. The Investigator must address all four (4) elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*

N

1. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in a research project unless the IRB finds that the two (2) additional elements are met for federally funded projects. The same two (2) additional elements should be evaluated for all other projects, but are not binding.
2. The Investigator should address the two (2) additional elements in their eBridge SmartForm application to allow the IRB to evaluate and document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*

N

1. After delivery, a nonviable neonate may not be involved in research project unless the IRB finds that all of the five (5) additional elements required under 45 CFR 46.205 (c) are met for federally funded projects. The same five (5) additional elements should be evaluated for all other projects, but are not binding. he Investigator should address the five (5) additional elements in their SmartForm application to allow the IRB to document the protocol-specific findings supporting that conclusion for each condition via the *IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist.*
    a. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph 46 CFR46.205(c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
    b. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph 45 CFR 46.205(c)(5).
    c. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

N

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 subparts A and D. *See IRB Member SOP: Research Involving Children*

1. Documentation of the member's review will be uploaded to the workspace within eBridge prior to the convened Committee IRB meeting.
2. The assigned reviewer will structure and focus their review of the project around meeting the requirements of Subpart B. The recommendations will be discussed and a final decision made by the IRB Committee.

45 CFR 46 Subpart A
45 CFR 46 Subpart B
45 CFR 46.116
45 CFR 46 Subpart D
45 CFR 46.204
45 CFR 46.205
45 CFR 46.205 (c)
45 CFR 46.205 (c)(5)
45 CFR 46.404-407
45 CFR 46.408-409
21 CRF 50.50-56
40 CFR 26

IRB SOP: Use of Human Fetal Tissue in Research
IRB Member SOP: Research involving Children
IRB Member Form: Research involving Pregnant Women and Fetuses (subpart B) Checklist
IRB Member Form: Additional Federal Agency Requirements Checklist

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