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| **Subpart B Opening Checklist (A)** |
| # | Requirement | Checkbox | Route to: |
| 1 | Study involves pregnant women, fetuses, or neonates as participants | [ ] Yes[ ] No | If yes - #2If no – route to regular checklists |
| 2 | Study involves neonates as participants | [ ] Yes[ ] No | If yes – route to Neonate Checklist (B)If no – route to Child Review Checklist (C) |

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| **Neonates Checklist (B)** |
| # | Requirement | Checkbox | Protocol-Specific Finding *(a free text box must be placed and labelled “Protocol-specific findings” in any spot listed “Protocol-Specific Findings” in the chart below)* | Route to: |
| 1 | Viable neonates will be participants | [ ] Yes[ ] No |  | If yes – fill out child checklistIf no - #2 - #4 |
| 2 | Preclinical and clinical studies have been conducted and data is provided to assess risk | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 3 | Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 4 | Individuals engaged in the research will have no part in determining the viability of the neonate | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 5 | Neonates of uncertain viability will be participants in the study | [ ] Yes[ ] No |  | If yes - #6 – 7If no - #8 |
| 6 | The research holds out the direct prospect of enhancing the probability of survival to the point of viability and the risk to neonate is the least possible for achieving that objective | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 7 | The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and there will be no additional risk to the neonate | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 8 | Nonviable neonates are participants | [ ] Yes[ ] No |  | If yes - #8-12If no - #13 |
| 9 | Vital functions of the neonate will not be artificially maintained | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 10 | The research will not terminate the heartbeat or respiration of the neonate | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 11 | There will be no added risk to the neonate resulting from the research | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 12 | The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 13 | Consent is obtained from both parents | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #19If no - #15 – 18 |
| 15 | Consent is obtained from the mother | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #16If no – #18 and/or Waiver of Consent checklist |
| 16 | Consent is obtained from the father | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #18If no - #17 |
| 17 | The father is unavailable, incompetent, incapacitated, or the pregnancy resulted from rape or incest | [ ] Yes[ ] No | Protocol-Specific Finding  |  |
| 18 | Consent is obtained from legally-authorized representative/guardian | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 19 | Individuals engaged in the research will have no part in determining the viability of a neonate | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |

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| P**regnant Women and Fetuses Review Checklist (C)** |
| # | Requirement | Checkbox | Protocol-Specific Finding *(a free text box must be placed and labelled “Protocol-specific findings” in any spot listed “Protocol-Specific Findings” in the chart below)* | Route to: |
| 1 | Preclinical and clinical studies have been conducted and data is provided to assess risk | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 2 | The research holds the prospect of direct benefit to the fetus | [ ] Yes[ ] No[ ] N/A | *Protocol-Specific Finding*  | If yes or N/A - #7If no – #3-5 |
| 3 | The risk to the fetus is not greater than minimal | [ ] Yes[ ] No[ ] N/A | *Protocol-Specific Finding*  |  |
| 4 | The purpose of the research is the development of important biomedical knowledge, which cannot be obtained by other means | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 5 | The consent of the pregnant woman and the father is obtained | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #7If no - #6 |
| 6 | The father is unavailable, incompetent, incapacitated, or the pregnancy resulted from rape or incest | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 7 | The research holds the prospect of direct benefit to the pregnant woman | [ ] Yes[ ] No[ ] N/A | *Protocol-Specific Finding*  | If yes - #8-9If no - #10 |
| 8 | The risk to the pregnant woman is not greater than minimal | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 9 | The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 10 | Any risk is the least possible for achieving the objectives of the research | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 11 | Money or inducements are offered to terminate a pregnancy | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 12 | Individuals engaged in the research will have a part in any decisions as to timing, method, or procedures used to terminate a pregnancy | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 13 | Consent is obtained | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  If yes – Informed Consent ChecklistIf no - Waiver of Consent Checklist |