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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 - #2  If 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 checklist  If 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 – 7  If 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 - #8-12  If 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 - #19  If no - #15 – 18 |
| 15 | Consent is obtained from the mother | Yes  No | *Protocol-Specific Finding* | If yes - #16  If no – #18 and/or Waiver of Consent checklist |
| 16 | Consent is obtained from the father | Yes  No | *Protocol-Specific Finding* | If yes - #18  If 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 - #7  If 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 - #7  If 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 - #8-9  If 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 Checklist  If no - Waiver of Consent Checklist |