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| **Subpart C Opening Checklist (A)** |
| # | Requirement | Checkbox | Route to: |
| 1 | Study involves prisoners as participants | [ ] Yes[ ] No | If yes – route to Prisoner Checklist (B)If no – route to regular checklists |

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| **Prisoners 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 | The study has been reviewed by a prisoner representative | [ ] Yes[ ] No |  |  |
| 2 | Any advantages accrued to the prisoner through participation in the research are not of a magnitude that coerces their ability to weigh the risks of the research against the advantages of participation | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 3 | The risks involved with the research are commensurate with risks that would be accepted by non-prisoner volunteers | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 4 | Procedures for subject selection within the prison are fair to all prisoners | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 5 | Procedures for subject selection within the prison are free from arbitrary intervention by prison authorities or other prisoners | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 6 | Control subjects are randomly selected from the group of available prisoners that meet the inclusion criteria for the control group | [ ] Yes[ ] No[ ] N/A | *Protocol-Specific Finding*  | If yes or N/A - #8If no - #7 |
| 7 | Sufficient justification has been provided by the investigator | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 8 | Information is presented to the prisoners in a language that is understandable | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 9 | Follow-up examinations or care are required for participants | [ ] Yes[ ] No[ ] N/A |  | If yes - #10 -11If no or N/A - #12 |
| 10 | Adequate provisions have been made for follow-up examinations, taking into account length of sentences | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 11 | Participants will be informed of the requirement for follow-up | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 12 | Study is not greater than minimal risk and not more than inconvenience to the participants | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #13 - 14If no - #15 |
| 13 | Study of the possible causes, effects, and processes of incarceration, and of criminal behavior | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 14 | Study is of prisons as institutional structures or of prisoners as incarcerated persons | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 15 | Study is on the conditions particularly affecting prisoners as a class | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes – #16If no - #17 |
| 16 | The DHHS has consulted with the appropriate experts and published notice in the Federal Registrar | [ ] Yes[ ] No |  |  |
| 17 | Study is on practices which have the intent and reasonable probability of improving the health or well-being of the participant | [ ] Yes[ ] No | *Protocol-Specific Finding*  | If yes - #18 -#19If no - #20 |
| 18 | Study requires assignment of control groups | [ ] Yes[ ] No | *Protocol-Specific Finding*  |  |
| 19 | The DHHS has consulted with the appropriate experts and published notice in the Federal Register | [ ] Yes[ ] No |  |  |
| 20 | Informed consent is obtained from participants | [ ] Yes[ ] No |  | If yes – Informed Consent ChecklistIf no - Waiver of Consent Checklist |