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| **Subpart D Opening Checklist (A)** | | | |
| # | Requirement | Checkbox | Route to: |
| 1 | Study involves children as participants | Yes  No | If yes - #2  If no – route to regular checklists |
| 2 | Study involves wards of the state as participants | Yes  No | If yes – route to Ward Checklist (B)  If no – route to Child Review Checklist (C) |

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| **Ward of the State 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 is related to the participants’ status as wards | Yes  No | Protocol-Specific Finding | Route to Child Review Checklist (C) after completion of this checklist |
| 2 | The study is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards | Yes  No | Protocol-Specific Finding |
| 3 | An advocate is appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as a guardian or in lieu of parents. *(Note: one individual may serve as an advocate for more than one child)* | Yes  No | Protocol-Specific Finding |
| 4 | The advocate is an individual who has the background and experience to act in and agrees to act in the best interest of the child for the duration of the child’s participation | Yes  No | Protocol-Specific Finding |
| 5 | The advocate is not associated in any way with the research, investigators, or guardian organization | Yes  No | Protocol-Specific Finding |

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| **Child 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 | 404: The research presents not greater than minimal risk to children | Yes  No | Protocol-Specific Findings | If yes - #11  If no - #2 |
| 2 | The research presents the prospect of direct benefit to individual subjects (i.e. children) | Yes  No | Protocol-Specific Findings | If yes - #3-4  If no - # 5-10 |
| 3 | The risk is justified by the anticipated benefits to subjects | Yes  No | Protocol-Specific Findings | If yes - #11  If no - #5-10 |
| 4 | The relation of anticipated benefit to risk is at least as favorable to the participants as the available alternatives | Yes  No | Protocol-Specific Findings | If yes - #11  If no - #5-10 |
| 5 | The risk represents a minor increase over minimal risk | Yes  No | Protocol-Specific Findings | If routed here, advance to 11 after completion of these questions |
| 6 | The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in actual or expected medical/dental/psychological/social/educational situations | Yes  No | Protocol-Specific Findings |
| 7 | The intervention or procedure is likely to yield generalizable knowledge about the participants’ disorder or condition which is of vital importance to the amelioration of the disorder or condition | Yes  No | Protocol-Specific Findings |
| 8 | Adequate provisions are made for soliciting assent of children and permission of parents | Yes  No | Protocol-Specific Findings |
| 9 | The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children | Yes  No | Protocol-Specific Findings |
| 10 | If ONLY the above question is yes, then approval has been granted by the DHHS for the study | Yes  No  N/A | Protocol-Specific Findings |
| 11 | Assent will be sought from all participants | Yes  No |  | If yes - #25  If no – #12-16 |
| 12 | The participants (i.e. children) are all under 7 |  |  | If yes - #29  If no - # |
| 13 | The participants (i.e. children) are between 7 and 11 | Yes  No |  | If yes - #17  If no - # |
| 14 | The participants (i.e. children) are over the age of 11 | Yes  No |  | If yes - #17  If no - # |
| 15 | Verbal assent is sought from participants between the ages of 7 and 11 | Yes  No  N/A | Protocol-Specific Findings | If yes - #17  If no - #18 |
| 16 | Written assent is sought from participants over the 11 | Yes  No  N/A | Protocol-Specific Findings | If yes - #17  If no - #18 |
| 17 | An assent form is provided to the participants | Yes  No |  | If yes - #25  If no - #25 |
| 18 | The participants (i.e. children) are cognitively capable of providing assent | Yes  No  N/A | Protocol-Specific Findings | If yes - #19-24  If no - #25 |
| 19 | The research presents no more than minimal risks to participants | Yes  No | Protocol-Specific Findings | If routed here, advance to 29 after completion of these questions |
| 20 | The research could not practicably be carried out without the requested waiver | Yes  No | Protocol-Specific Findings |
| 21 | The research could not practicably be carried out without the use of identifiable information | Yes  No | Protocol-Specific Findings |
| 22 | The waiver will not adversely affect the rights and welfare of the subject | Yes  No | Protocol-Specific Findings |
| 23 | If a waiver of consent is not requested, the participants’ parents or legal guardians will provide consent | Yes  No | Protocol-Specific Findings |
| 24 | Whenever appropriate the participant (i.e. child) will be provided with additional pertinent information after participation | Yes  No | Protocol-Specific Findings |
| 25 | A signed assent form will be collected for children over the age of 11 (note: verbal assent is acceptable for children between the ages of 7-11) | Yes  No | Protocol-Specific Findings | If yes - #29  If no - #26-28 |
| 26 | The only record linking the child AND the research is the informed consent form and the principal risk is breach of confidentiality | Yes  No  N/A | Protocol-Specific Findings | If routed here, advance to 29 after completion of these questions |
| 27 | The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written assent is normally required outside of the research context | Yes  No  N/A | Protocol-Specific Findings |
| 28 | The participant is part of a distinct cultural group or community in which signing forms is not the norm AND the research presents no more than minimal risk to the participants AND an appropriate alterative mechanism for documenting consent is obtained | Yes  No  N/A | Protocol-Specific Findings |
| 29 | Parental permission is required from: | 1 Parent  Both Parents  No Parents | Protocol-Specific Findings | If the 3rd option is checked, the waiver of consent checklist must be filled out. |
| 30 | The study is eligible for expedited review | Yes  No |  |  |