**Institutional Review Board**

**Research Involving Children**

IRB Members should use this worksheet to determine if the criteria for involving children in research are met as per 45 CFR 46 Subpart D. Minnesota considers anyone under the age of 18 as a minor, for whom to use this worksheet. If the study involves an international population for which there is no legal definition of age of majority, researchers must rely on community standards and practices to determine whether subjects are considered children or adults.

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| Protocol ID |  |
| Title of Protocol |  |
| PI/Researcher(s) |  |
| Average Age of Participants |  |

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| **The research must meet all the following criteria:** |
|[ ]  The research falls into one of the risk categories involving children |
|  |[ ]  Section A |[ ]  Section C |
|  |[ ]  Section B |[ ]  Section D |
|[ ]  One of the following is true: |
|  |[ ]  The research does not involve wards |
|  |[ ]  The research involves wards AND falls into risk categories Section C or D (Section E) |
|[ ]  Assent will be obtained from the children (Sections F, G, and H) |
|[ ]  Permission will be obtained from the parents / legally authorized representative (LAR) (Sections A-D or I-J) |

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| **Section A: Research under 45 CFR 46.404** |
|[ ]  Research is no greater than minimal risk |
|  |[ ]  If true, permission from one parent or LAR is sufficient using informed consent |

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| **Section B: Research under 45 CFR 46.405 (all must be checked)** |
|[ ]  Research involves greater than minimal risk |
|[ ]  Research presents the prospect of direct benefit for the individual subject |
|[ ]  One of the following is true |
|  |[ ]  Risk is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject |
|  |[ ]  Risk is presented by a monitoring procedure that is likely to contribute to the subject’s well-being |
|[ ]  The risk is justified by the anticipated benefit |
|[ ]  The relation of the anticipated benefit to the risk is at least favorable to the subjects  |
|  |[ ]  If true, permission from one parent or LAR is sufficient using informed consent |

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| **Section C: Research under 45 CFR 46.406 (all must be checked)** |
|[ ]  Research involves greater than minimal risk to children that is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject |
|[ ]  Risk represents a minor increase over minimal risk |
|[ ]  The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations |
|[ ]  The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition |
|  |[ ]  If true, permission from both parents is required using informed consent unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child |

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| **Section D: Research under 45 CFR 46.407 (all must be checked)** |
|[ ]  Does not meet the requirements of Section A (46.404), Section B (46.405), or Section C (46.406) |
|[ ]  The research presents a reasonable opportunity to further the understanding, prevention, alleviation of a serious problem affecting the health or welfare of children |
|[ ]  The research will be conducted in accordance with sound ethical principles |
|  |[ ]  If true, permission from both parents is required using informed consent unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child |

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| **Section E: Wards of the state or any other agency, institution, or entity may be involved in research that falls under Sections C and D only if: (all must be checked)** |
|[ ]  One of the following is true: |
|  |[ ]  The research is related to their status as wards |
|  |[ ]  The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards |
|[ ]  An advocate is appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis  |
|[ ]  The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research |
|[ ]  The advocate is not associated in any way (except in role as advocate or IRB member) with the research, the investigator(s), or the guardian organization |

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| **Section F: Adequate Provisions for Soliciting Assent from Children** |
|[ ]  The absence of dissent is not a sign of child’s assent |
|[ ]  Assent will be obtained from  |
|  |[ ]  All children  |
|  |[ ]  None of the children (complete Section G) |
|  |[ ]  Some of the children (complete Sections G and H) |

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| **Section G: Assent is not a necessary condition for research when: (all must be checked)** |
|[ ]  One of the following is true: |
|  |[ ]  The capability of some or all of the children (taking into account age, maturity, psychological state) is so limited that they cannot reasonably be consulted |
|  |[ ]  The intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research |
|[ ]  The research fits the criteria for waiving assent (all must be checked) |
|  |[ ]  The research involves no greater than minimal risk |
|  |[ ]  It is not practicable to conduct the research without the waiver or alteration |
|  |[ ]  Waiving or altering assent will not adversely affect the subjects’ rights and welfare |
|  |[ ]  Pertinent information will be provided to the subjects later, if appropriate |
|[ ]  Adequate provisions have been made for children who decide not to participate |

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| **Section H: Documentation of Assent** |
|[ ]  The PI/Researcher will consider the child’s age, maturity, and degree of literacy when creating the Assent Form |
|[ ]  Other: Click or tap here to enter text. |

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| **Section I: Waiver of Parental or Guardian Permission (all must be checked, if using)** |
|[ ]  The research is not FDA regulated |
|[ ]  The research fits the criteria for waiving consent (all must be checked) |
|  |[ ]  The research involves no greater than minimal risk and involves no procedures for which consent is normally required outside the research environment |
|  |[ ]  It is not practicable to conduct the research without the waiver or alteration |
|  |[ ]  Waiving or altering assent will not adversely affect the subjects’ rights and welfare |
|  |[ ]  Pertinent information will be provided to the subjects later, if appropriate |
|[ ]  The documentation of consent is the only record linking the child to the research, and the principle risk would be potential harm resulting from a breach of confidentiality [ ]  N/A |
|[ ]  The subjects or the LARs are members of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained [ ]  N/A |
|[ ]  The protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children) AND |
|  |[ ]  An appropriate mechanism for protecting the subjects is substituted for assent |
|  |[ ]  The waiver is not consistent with Federal, state, or local law |
|[ ]  The parents will be notified about the proposed research AND be given the opportunity to decline their children’s participation |

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| **Section J: Parental or guardian permission for students to participate in research CANNOT be waived if: (all must be checked)** |
|[ ]  The research is conducted and/or funded under an applicable program of the Department of Education |
|[ ]  The research asks students about one of the following eight sensitive topics: |
|  |[ ]  Political affiliations |
|  |[ ]  Mental and psychological problems potentially embarrassing to the student and his/her family |
|  |[ ]  Sex behavior and attitudes |
|  |[ ]  Illegal, anti-social, self-incriminating and demeaning behavior |
|  |[ ]  Critical appraisals of other individuals with whom respondents have close family relationships |
|  |[ ]  Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers |
|  |[ ]  Religious practices, affiliations, or beliefs of the student or student’s parent |
|  |[ ]  Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program) |