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| IRB Reviewer Form: Appendix C (Children) In addition to the protection provided under the Common Rule (45 CFR 46), federal regulations (45 CFR 46 subpart D) provide additional protection for **children** involved in research such as obtaining assent from the child and permission of the parents/guardians. Research involving **viable neonates** must comply with the additional regulatory protections for children.  **For research sponsored by the Environmental Protection Agency (EPA), see 40 CFR 26 Subparts C and D for further information.**  **For research sponsored by the Department of Defense (DoD) see DoD Directive 3216.02 for further information.**  **For assistance in answering the following questions, please refer to the IRB Policy for “Vulnerable Subjects: Children” at** [**http://www.irb.wayne.edu**](http://www.irb.wayne.edu)  **Risk** | | | |
|  | Select the risk category for the child participants that will be studied:  NOTE: If the study will have a control group with children, #1 should be the risk category should be for the children with the condition being studied.  **\* Both parents must give signed informed consent for their child to participant in category 3 research.** | **Category 1 -** Research not involving greater than minimal risk (45 CFR 46.404)  **Category 2 -** Research involving greater than minimal risk but with a potential for direct benefit to the individual participants (45 CFR 46.405)  **Category 3 -** Research involving greater than minimal risk and with no prospect of direct benefit to the child, but likely to yield generalizable knowledge about the child’s disorder or condition (45 CFR 46.406)**\*** | |
| 1. **Control/Placebo Group** (if applicable): Select the risk category for the child participants that will be in a control/placebo group:   **\* Both parents must give signed informed consent for their child to participant in category 3 research.** | **Category 1 -** Research not involving greater than minimal risk (45 CFR 46.404)  **Category 2 -** Research involving greater than minimal risk but with a potential for direct benefit to the individual participants (45 CFR 46.405)  **Category 3 -** Research involving greater than minimal risk and with no prospect of direct benefit to the child, but likely to yield generalizable knowledge about the child’s disorder or condition (45 CFR 46.406)**\*** | N/A  – There will not be a control/placebo group with child participants |

**Parental Permission**

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|  | Select type of **parental permission** that will be used. More than one category may be appropriate:  Note: for Risk level 3 research: BOTH PARENTS MUST GIVE SIGNED INFORMED CONSENT FOR THEIR CHILD TO PARTICIPATE. | |
| **Research Informed Consent Form/Parental Permission** | a. Do you agree with the justification provided by the PI for parental signature requirements?  Yes  No (state reason): |
| **Waiver of Parental Permission**  Note: Parental permission *cannot be waived in FDA*-regulated studies. | ***More than Minimal Risk Studies:***  a. Has the PI provided adequate information about how the choice was made to request this waiver as determined by the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition and has adequate justification been provided by the PI? ?  N/A – Minimal Risk Study  Yes  No (state reason):  b. Are there adequate safeguards for the minor (i.e., assignment of a guardian to safeguard the child’s rights)?  N/A – Minimal Risk Study  Yes  No (state reason):  c. Do you agree with the protocol specific justification provided by the PI for approval of a waiver of parental permission for this study?  N/A – Minimal Risk Study  Yes  No (state reason):    d. State who will be the child advocate, if applicable:  ***Minimal Risk Studies:***  a. If PI is requesting a waiver of consent/parental permission for a minimal risk study, the following must be met:   * The waiver will not adversely affect the rights and welfare of the child * The research could not practically be carried out without the waiver * The parents/child will be informed of pertinent information, if applicable.   Have all of the above criteria for waiver of consent been met?  N/A – More than Minimal Risk Study  Yes  No (state reason):  b. Do you agree with the justification for the waiver of consent provided by the PI?  N/A – More than Minimal Risk Study  Yes  No (state reason): |
| **Oral Parental Consent or Anonymous Information Sheet** | a. Has the PI provided adequate justification for a waiver of the requirement for signed parental permission?  Yes  No (state reason):    b. Is the plan to allow parents to sign a consent form (if the parents choose to do so) appropriate?  Yes  No (state reason): |

**Assent of the Child**

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|  | Do you agree with the method(s) used to obtain child assent? | Yes  No (state reason): |
| a. Is a waiver of assent appropriate? | Yes  No (state reason): |

**Research with Children Conducted Outside of Michigan**

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| 4. | Will research involving children be conducted **outside of Michigan**? | Yes  No **– go directly to #5** |
| a. Did the PI provide a description of who under the law of the local jurisdiction has not reached the legal age to consent to the procedures involved in this protocol? | Yes  No |
| b. Did the PI provide supporting documentation of the above (e.g., copies of national, state, or local law, or opinion of legal counsel)? | Yes  No |
| c. Will a guardian, instead of a parent, be providing permission for a child? | Yes  No **– go directly to #5** |
| d. Did the PI provide a description of who under the law of the local jurisdiction is authorized to consent on behalf of the child? | Yes  No |
| e. Did the PI provide supporting documentation of the above (e.g., copies of national, state, or local law, or opinion of legal counsel)? | Yes  No |

**Children Who Are Wards**

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| 5. | Will children who are wards be enrolled in the proposed research? | Yes  No |
| 1. Is the parental/guardian consent process for wards appropriate? | Yes  No (state reason): |
| 1. Do federal regulations allow for wards to participate in the proposed research? | Yes  No (state reason): |
| 1. Is a child advocate required for this research? | Yes  No |
| 1. Is there an adequate plan for appointing child advocates for each ward? | N/A – A child advocate is not required  Yes  No (state reason): |
| Additional Comments: | | |

Signature of Reviewer:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_