|  |  |
| --- | --- |
| PI Name:  | IRB#:  |
| Protocol/Project Title:  |

|  |
| --- |
| **Appendix V(D): Special Protections for Children in Research** |

**A. Regulatory Risk/Benefit Determinations.** Federal regulations ([45CFR46, subpart D](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd)) define risk/benefit categories as they apply to children. Select the category that describes the potential risks and benefits to children participating in this research:

|  |  |
| --- | --- |
|  | Minimal Risk *(for expedited review, children may only be included under this category)* |
|  | Greater than Minimal Risk, but holds prospect of direct benefit to participants. |
|  | Greater than Minimal Risk, no prospect of direct benefit to participants.\* |

 *\*Currently not permitted at RFUMS, contact IRB office for additional information*

 Explain how the research fits the category selected above:

|  |
| --- |
|  |

**B. Parental Consent Requirements:** Indicate the plan for obtaining parental consent here.

*Attach a copy of the parental consent form with the application*:

|  |  |
| --- | --- |
|  | One parent must give permission. *This is allowable if the research is minimal risk or greater than minimal risk but with the prospect of direct benefit to participants.* |
|  | Both parents must give their permission 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. *This is required if the research is greater than minimal risk and holds no prospect of direct benefit to participants.* |
|  | The PI requests a waiver of parental consent *(provide justification below)* |

 Explain why a waiver of parental consent is necessary:

|  |
| --- |
|  |

**C. Assent Requirements:** Indicate the plan for obtaining assent below. *Assent is generally required for participants 8-17 and recommended for younger participants who are able to provide assent.*

|  |  |
| --- | --- |
|  | Assent will be obtained. *The PI confirms that the minor participant may choose not to participate and their dissent will be honored. Attach a copy of the assent form.*  |
|  | An information sheet will be provided in place of an assent form (assent waiver is requested). *Attach a copy of the information sheet to be provided.* |
|  | The PI will not obtain assent nor provide an information sheet (assent waiver is requested) |

 If requesting a waiver of assent, provide justification here:

|  |
| --- |
|  |

**D. Consenting Participants who reach the age of majority.** Will any of the participants continue to actively participate in this study when they reach the age of majority (Illinois = 18 yrs)?

|  |  |
| --- | --- |
|  | No: If checked, the Appendix is complete. |
|  | Yes: If checked, complete the following item: |

 Describe the plan to re-consent participants once they turn 18 *(must follow adult guidelines):*

|  |
| --- |
|  |