



IRBNet #:

PI:

APPENDIX F – RESEARCH INCLUDING CHILDREN

Complete this appendix only if requesting children be included as subjects in the proposed research.

Section 1 – Regulatory Risk/Benefit Determination Applicable to Children

Federal regulations (45 CFR 46, subpart D) define risk/benefit categories as they apply to children.

- 1.1 Select the category that describes the potential risks and benefits to the children participating in this research.
- (404) Minimal Risk (if applying for expedited review may only be included under this category)
 - (405) Greater than minimal risk, but holds prospect of direct benefit to subjects.
 - (406) Greater than minimal risk, no prospect of direct benefit

1.2 Explain how the proposed research fits the category selected

Section 2 – Parental Consent Requirements

2.1 Indicate plan for obtaining parental consent	Required attachments
<input type="checkbox"/> One parent must give permission Allowable if the research is minimal risk (404) or greater than minimal risk but holds prospect of direct benefit (4050)	Provide a copy of the parental permission form with the IRB application
<input type="checkbox"/> 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. Required if the research is greater than minimal risk and holds no prospect of direct benefit (406)	Provide a copy of the parental permission form with the IRB application
<input type="checkbox"/> The researcher requests a waiver of parental consent. Provide justification below for waiving parental consent:	None



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Section 3 – Assent Requirements – Subjects 8 to 17 Years Old
An assent form should be used for subjects who are 8 to 17 years old. In certain circumstances, assent may be waived and an information sheet used to inform minor participants about the research. Justification for waiver of assent is required.
3.1 Does the proposed research include children between the ages of 8 and 17 years old?
3.2 Are the minor subjects capable of providing assent?
Indicate below when assent will be obtained or if the researcher proposes to waive assent. If requesting to waive assent, indicate whether an information sheet (an assent form without signature lines) will be provided.
Select the option below that describes whether assent will be obtained or waived.
Required attachments

Section 4 – Consenting Subjects Who Reach the Age of Majority
4.1 Will any of the subjects continue to actively participate in this study when they reach the age of majority? (18 years in Colorado)