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| **IRB Meeting Date:** Click or tap to enter a date.**or Date of Review**  | **eBridge #:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text. | **Reviewer Name:** Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which request the inclusion of subjects who are minors. IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research involving Children*

1. **Subpart D (children) Determinations (45 CFR 46 or 21 CFR 50)**

Check the allowable category below that best represents the degree of risk and benefit to which the children in this project will be exposed and explain your choice.

**Note: More than one category may be indicated. If multiple categories are indicated, please answer the additional question after each marked category.**

[ ]  Category 1 (404 or 50.51): The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

[ ]  **Project involves a** **Single Population which falls under this category**

[ ]  **Project includes more than one population;** **this category applies to the following population:**Click or tap here to enter text.

[ ]  Category 2 (405 or 50.52): The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.

[ ]  **Project involves a** **Single Population which falls under this category**

[ ]  **Project includes more than one population;** **this category applies to the following population:** Click or tap here to enter text.

[ ]  Category 3 (406 or 50.53): The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subjects’ conditions.

[ ]  **Project involves a** **Single Population which falls under this category**

[ ]  **Project includes more than one population;** **this category applies to the following population:**Click or tap here to enter text.

[ ]  Category 4 (407 50.54): The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. **Research which meets this category cannot be approved by the IRB and must go for review by Secretary of HHS or the Commissioner of Food and Drug to make a determination as outlined per 50.54.**

[ ]  **Project involves a** **Single Population which falls under this category**

[ ]  **Project includes more than one population;** **this category applies to the following population:**Click or tap here to enter text.

Explain your choice of category: Click or tap here to enter text.

1. **What permission will be obtained from the parents?**

[ ]  Permission from only one parent is being requested

[ ]  Permission will be obtained from both parents where possible.

Note: ***2 parent signatures are required for any project which meets category 3 (406 or 50.53).***

[ ]  A waiver of parental permission is being requested

[ ]  Informed Consent/Parental Permission has already been obtained

(i.e., previously IRB approved bank, incoming data from another institution, etc.)

[ ]  None of the Above – the project qualifies for exempt review. Select the level of contact

 [ ]  Project will not have direct contact with subjects, and an informed consent process or document is not required

 [ ]  Project will have direct contact with subjects, and an informational letter will be provided

1. **Please indicate whether the children in this project are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:**

 [ ]  All are capable

 [ ]  None are capable; explain: Click or tap here to enter text.

 [ ]  Some are capable; explain: Click or tap here to enter text.

1. **For subgroups of children capable of assent, how will assent be solicited?** Click or tap here to enter text.
	1. [ ]  A waiver of assent is being requested
	2. [ ]  Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
2. **For subgroups of children capable of assent, how will assent be documented?** Click or tap here to enter text.
	1. [ ]  A waiver of assent is being requested
	2. [ ]  Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
3. **Has the project team developed a plan to consent subjects who reach the age of majority?** [ ]  Yes [ ]  No [ ]  N/A
	1. **Describe the proposed plan:** Click or tap here to enter text.

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| **Reviewer Comments**  |
| Click or tap here to enter text. |

Reviewer Name:Click or tap here to enter text. Date: Click or tap to enter a date.