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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.