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|  | Diagram  Description automatically generated | **FORM: Children Supplement** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

**Instructions:**

Complete and attach this supplement to your submission in Hutch IRB to provide supporting information.

If different categories of children (e.g., transplant recipient versus transplant donor) will fall into different research risk categories, complete a separate Children Supplement for each of the different categories of children involved in the research.

1. What research risk category are the children in (regulation 45 CFR 46 404 – 407 or FDA 21 CFR 50.51 – 54)?

[ ]  *Category 1 -* Research not involving greater than minimal risk to the individual child (404/50.51). For example, chart reviews, data analysis, certain blood draws.

Additional notes for category 1:

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[ ]  *Category 2 -* Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (405/50.52). For example, therapeutic trials, transplant recipients.

Explain why the risks are justified by the anticipated direct benefit to the child:

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Explain how the relationship between research risk and prospective benefit is at least as favorable as presented by available alternative approaches. If the relationship is not as favorable as standard care, special justification is necessary, and you should contact IRO@fredhutch.org for assistance:

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Additional notes for category 2:

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[ ]  *Category 3 -* Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition (406/50.53).

Explain why the risk represents only a minor increase over minimal risk.

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Explain how the procedures in this research are reasonably commensurate with those inherent to the child’s situation outside research (for instance, an oncology patient would be expected to have more risky procedures than a flu patient):

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Explain what generalizable knowledge will be gained through the research and why it is of “vital importance” (45 CFR 46.406.c/21 CFR 50.53.c) to the understanding of the subject’s underlying disease or condition:

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What alternative methods were considered to gain the knowledge?

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Additional notes for category 3:

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[ ]  *Category 4 -* Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (407/50.54). Requires sign-off by the Director of Health and Human Services or the Commissioner of Food and Drugs; contact IRO@fredhutch.org for assistance.

Additional notes for category 4:

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2. Will assent be obtained from all children?

[ ]  Yes – All children will provide assent → Go to Question 3.

[ ]  No – Not all children will provide assent (waiver of assent requested) → Respond to Questions 2.a. – 2.b.

2.a. Will any of the children provide assent?

[ ]  Yes – Certain children will provide assent. Explain your assenting plan below including which children will provide assent, then go to Question 2.b.

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[ ]  No – None of the children will provide assent.

2.b. Why is a waiver of assent appropriate for this research? *Check all that apply:*

[ ]  The children for whom assent is waived are not capable of providing assent.

Explain:

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[ ]  The intervention or procedures in the research hold the prospect of direct benefit to the child and are only available in the context of clinical research.

Explain:

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[ ]  There are other reasons to waive assent in the research. *For this category, the IRB must find the research to be minimal risk; the waiver will not adversely affect the rights and welfare of the child; the research could not practicable be carried out without a waiver of assent; when appropriate, the children will be provided with additional information after their participation; and, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.*

Explain:

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3. How will the child’s assent be documented? *Check all that apply:*

[ ]  Children aged 0-6: Requesting a waiver of assent due to lack of capacity.

[ ]  Children aged 7-12: Assent documented by signing a separate assent form (submit a copy)

[ ]  Children aged 7-12: Requesting a waiver of assent.

[ ]  Children aged 13-17: Assent documented by signing the parental permission form (e.g., consent form) along with parents or legal guardian.

[ ]  No children will document assent: Requesting a full waiver of assent.

[ ]  Other plan and/or different age groupings →

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4. How will parents or legal guardians provide permission to enroll their child in research?

[ ]  Only one parent or legal guardian will sign the parental permission form (e.g., consent form). *Applicable only for child risk category 1 and 2*.

[ ]  Both parents will sign the parental permission form (e.g., consent form) unless one parent is deceased, unknown, incompetent, readily unavailable, or only one parent has legal custody. *Required for child risk categories 3 and 4*.

[ ]  No parental permission will be documented: Requesting a full waiver of consent.

[ ]  Other strategy → Explain.

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5. Will this study consent child participants to continued research interventions, procedures, use of their specimens and/or data, or long-term follow-up when they reach the legal age to consent in the jurisdiction in which the research is conducted?

[ ]  Yes → Submit the Informed Consent document that will be used for this purpose. This can be the main consent form, or a shorter document with the required elements of consent requesting the child’s consent to remain in the research.

[ ]  No → Explain why you will not seek consent from the children when they reach the legal age to provide consent. Submit a [*HRP-256 - FORM - Consent Supplement*](https://extranet.fredhutch.org/en/f/irb/waiver-consent.html) and, if needed, [*HRP-257 - FORM - HIPAA Supplement*](https://extranet.fredhutch.org/en/f/irb/hipaa-supp-waiver-authorization.html)*.*

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6. Are any of the children wards of the state?

[ ]  Yes

[ ]  No