**APPENDIX N: Waiver of Parental Permission Process**

|  |  |
| --- | --- |
|  **IRB Study Number:** | Click or tap here to enter text. |

|  |
| --- |
| Complete the prompts below to request a waiver (permission not obtained) of the parental permission process. If more than one waiver is needed with different rationales, copy and paste this page and submit both. **NOTE: The waiver does not apply to greater than minimal risk to subjects[[1]](#endnote-2)****Review the HRP-416 - CHECKLIST - Children to ensure you have provided sufficient information for the IRB to make these determinations.** |
|  |
| Select one of the following options and address the criteria below for how they are met: |
|  |
| 1. [ ]
 | **Parental permission is not a reasonable requirement to protect the participants**  |
|  | 1. Explain how the research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children).

Click or tap here to enter text. |
|  | 1. Explain how an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted

Click or tap here to enter text. |
|  | 1. Explain how the waiver is not inconsistent with Federal, State, or local law.

Click or tap here to enter text. |
|[ ]  **Minimal risk, non-FDA-regulated research** |
|  | 1. Explain how the research involves no more than minimal risk to the participants.

Click or tap here to enter text. |
|  | 1. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

Click or tap here to enter text.  |
|  | 1. Explain how the research could not practicably be carried out without the waiver or alteration

Click or tap here to enter text.  |
|  | 1. Explain why (for research involving identifiable private information or identifiable biospecimens) the research could not ‘practicably’ be carried out without using such information or biospecimens in an identifiable format. (N/A if research is subject to Pre-2018 Requirements OR if research does not use identifiable private information or biospecimens) [ ]  **NA**

Click or tap here to enter text.  |
|  | 1. Specify whether the participants or legally authorized representatives will be provided with additional pertinent information after participation (e.g., debriefing) and provide the rationale.

Click or tap here to enter text.  |
|[ ]  **FDA-regulated Clinical Investigations Involving No More Than Minimal Risk to Human Subjects** |
|  | 1. Explain how the clinical investigation involves no more than minimal risk [as defined in 21 CFR 50.3(k) or 56.102(i)] to the participants.

Click or tap here to enter text. |
|  | 1. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

Click or tap here to enter text.  |
|  | 1. Explain why the research could not practicably be carried out without the waiver or alteration

Click or tap here to enter text.  |
|  | 1. Specify whether the participants or legally authorized representatives will be provided with additional pertinent information after participation (e.g., debriefing) and provide the rationale.

Click or tap here to enter text.  |
| 1. [ ]
 | **Research or Demonstration Project Conducted by or Subject to the Approval of State or Local Government** |
|  | 1. Explain how the research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

Click or tap here to enter text.  |
|  | 1. Select all that apply:

[ ]  Public benefit or service programs.[ ]  Procedures for obtaining benefits or services under those programs.[ ]  Possible changes in or alternatives to those programs or procedures.[ ]  Possible changes in methods or levels of payment for benefits or services under those programs.1. Explain how the project is designed to study, evaluate, or otherwise examine the selected option.

Click or tap here to enter text.  |
|  | 1. Explain why the research could not ‘practicably’ be carried out without the requested waiver or alteration.

Click or tap here to enter text.  |

1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk. [↑](#endnote-ref-2)