**APPENDIX M: Waiver of Consent/Parental Permission Documentation**

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

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| Complete the prompts below to request a waiver of consent and/or parental permission documentation for the proposed research. The Common Rule regulations permit waivers of documentation of the consent and parental permission process if the research meets certain conditions. Common Rule and FDA regulations differ regarding when an IRB may waive the requirement to document the informed consent process. **Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information.** |
|  |
| Select one of the following options and address the criteria below for how they are met (note that option 1 below is the most used): |
|  |
|[ ]  **Option 1 (only option acceptable for FDA regulated research):** |
|  | 1. The research presents no more than minimal risk to the participant.

Click or tap here to enter text. |
|  | 1. The research involves no procedures for which written consent is normally required outside of the research context.

Click or tap here to enter text.  |
|[ ]  **Option 2:** Under this option, each participant (or legally authorized representative) must be asked whether they want to sign a consent document; if the participant agrees to sign a consent document, only an IRB-approved version may be used. Address how the following conditions are met. |
|  | 1. The only record linking the participant, and the research would be the consent document.

Click or tap here to enter text.  |
|  | 1. The principal risk of a signed consent document would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).

Click or tap here to enter text. |
|[ ]  **Option 3:** |
|  | 1. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

Click or tap here to enter text.  |
|  | 1. The research presents no more than minimal risk to the participant.

Click or tap here to enter text.  |
|  | 1. There is an appropriate alternative method for documenting that informed consent was obtained.

Click or tap here to enter text.  |