**APPENDIX O: Waiver or Alteration of Informed Consent Process**

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

|  |
| --- |
| Complete the prompts below to request a waiver (consent not obtained) or alteration (consent obtained, but not all elements included) of the consent process. If more than one waiver is needed with different rationales, copy and paste this page and submit both. If the research will involve the use of deception or the use of an opt-out enrollment process, these criteria must be met. Note: The waivers do not apply to greater than minimal risk research. **Review the HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process 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. [ ]
 | **Minimal Risk FDA-Regulated Research** |
|  | 1. Explain how the research (or research activities to which the waiver/alteration of consent applies) involves no more than minimal risk to participants.

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. 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.

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. 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. [ ]
 | **Minimal Risk Non-FDA-Regulated Research** |
|  | 1. Explain how the research (or research activities to which the waiver/alteration of consent applies) involves no more than minimal risk to participants.

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. 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. 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. 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.  |
|[ ]  **Minimal Risk FDA-Regulated Research Involving Anonymous/Deidentified Tissue Specimens** |
|  | 1. Explain how the research does not involve Human Subjects as Defined by DHHS.

Click or tap here to enter text.  |
|  | 1. Describe how the study involves an in vitro diagnostic device investigation.

Click or tap here to enter text.  |
|  | 1. Explain how the testing is noninvasive.

Click or tap here to enter text.  |
|  | 1. Explain how the testing does not require an invasive sampling procedure that presents significant risk.

Click or tap here to enter text.  |
|  | 1. Explain how the testing does not by design or intention introduce energy into a participant

Click or tap here to enter text.  |
|  | 1. Explain how any device testing result used for diagnostic purposes will have confirmation of the diagnosis by another, medically established diagnostic product or procedure.

Click or tap here to enter text.  |
|  | 1. For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, explain how all labeling bears the statement, prominently placed: “For Research Use Only. Not for use in diagnostic procedures.”

Click or tap here to enter text.  |
|  | 1. For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), explain how all labeling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.”

Click or tap here to enter text.  |
|  | 1. The study will use the following: (Check all boxes that are true and explain. One must be checked.)

[ ]  Specimens collected for routine clinical care or analysis that would have been discarded. Click or tap here to enter text. [ ]  Specimens obtained from specimen repositories. Click or tap here to enter text. [ ]  Leftover specimens that were previously collected for other research purposes. Click or tap here to enter text.  |
|  | 1. Explain how the identity of the participants is not known to the investigator or any other individuals associated with the investigation, including the sponsor (e.g., neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the participants)

Click or tap here to enter text. |
|  | 1. Check all boxes that are true and explain. (One must be checked.)

[ ]  Specimens are not coded where “Coded” means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.Click or tap here to enter text. [ ]  Neither the investigator(s) nor any other individuals associated with the investigation, or the sponsor, can link the specimen to the participant from whom the specimen was collected, either directly or indirectly through coding systems. Click or tap here to enter text.  |
|  | 1. Check all boxes that are true and explain. (One must be checked.)

[ ]  The specimens are not accompanied by clinical information.Click or tap here to enter text.[ ]  Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.Click or tap here to enter text.  |
|  | 1. Explain how the individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.

Click or tap here to enter text.  |
|  | 1. Describe how the specimens are provided to the investigator(s) without identifiers.

Click or tap here to enter text.  |
|  | 1. Explain how the supplier of the specimens has established policies and procedures to prevent the release of personal information.

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.  |