DEPARTMENT OF STATE HEALTH SERVICES
CENTRAL OFFICE INSTITUTIONAL REVIEW BOARD
REQUEST FOR WAIVER OF CONSENT OR AUTHORIZATION

Protocol #: _____-_____-_____

Project Title: _____

Please describe the risks to subjects involved in this research. Address risks to privacy as well as any others. Explain why these risks are no more than minimal, if that is the case.

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Please check all that apply:
☐ Request a Waiver or Alteration of Consent Requirements (Complete Part A & B)
☐ Request a Waiver of Signed Consent (Complete Part C)
☐ Request a Waiver of Authorization to Use or Disclose Protected Health Information (Complete Part A & D)

Part A:

1. Please justify why the research can not be practicably conducted without the waiver.

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2. Please justify that the rights or welfare of subjects will not be adversely affected by the waiver.

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Part B:

3. Please describe any plan to provide subjects with additional pertinent information after study completion, if appropriate: ☐ Not applicable

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Part C:

4. Is there any link between the subject and the research other than the consent form?
   ☐ Yes (if YES, go to 6) ☐ No

5. Describe the plan to seek participants' wishes on whether they would prefer a signed consent form to document their participation and how their preferences will be addressed.
   (Proceed to Part D, if applicable)

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6. Describe any procedures used in the study and explain why they would not normally require consent outside of the research context.

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Part D:

7. List specifically the PHI that will collected or used. Explain why the research can not be done without access to this information.

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8. Describe the plan to protect identifiers from improper use and disclosure and indicate where PHI will be stored and who will have access (include all entities that may have access, e.g. IRB, sponsors, FDA, etc.)

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9. What will happen to the PHI at the conclusion of the study?
   Will PHI be destroyed at the end of the study? ☐ Yes ☐ No
   If the answer above is NO, explain why the data must be retained and for how long, including whether the data is needed for a health or research purpose, legal or institutional requirement, or other reason. Be specific.

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Written Assurance:

As Principal Investigator, my signature below provides written assurance that identifiable information will not be reused or disclosed except as required by law; for authorized oversight of the research project; or for other research only if that research has been reviewed and approved by the IRB with specific attention and approval to the issue of access to this PHI.

_____ _____

Signature of Principal Investigator Date