**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

|  |  |
| --- | --- |
| **Principal Investigator:** | [REQUIRED FIELD]  |
| **Study Title:** | [REQUIRED FIELD]  |
| **IRB #:** |  |

|  |
| --- |
| **ADDENDUM: INFORMED CONSENT WAIVER –** **MORE THAN MINIMAL RISK** |

**Instructions:**

* Read the guidance provided below before answering the questions.
* Do not leave questions/[REQUIRED FIELD] blank; write or check "**N/A**" if not applicable.

**Guidance:**

* If you are requesting waiver of the informed consent process, the IRB will **consider** your request provided that the appropriate conditions below apply to your research and are justified:
* The research involves more than minimal risk to the subject.
* Whenever relevant, the subject will be provided with additional pertinent information after they have participated in the study.
* The IRB does not approve alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations. Contact the IRB office for regulations that apply to single emergency use waiver or acute care research waiver.

|  |
| --- |
| **SECTION 1. REQUESTING**  **WAIVER OF DOCUMENTATION OF INFORMED CONSENT PROCESS 45 CFR 46.117(c)(1)(i)** |

1. **Is this research requesting waiver of documentation of informed consent process for more than minimal risk research?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (a-c).***

***PLEASE NOTE:***

*Under this condition, each participant must be asked whether they want to sign a consent form; if the participant agrees to sign a consent form, only an IRB approved version should be used.*

1. **Will the only record linking the subject and the research be the consent document, and will the principal risk be potential harm resulting from a breach of confidentiality? Provide justification:** [REQUIRED FIELD]
2. **Does the research involve procedures that are minimal risk except for the linking of the consent document to private information?**

**☐ No**

**☐ Yes**

1. **Describe the potential harm a subject may experience as a result of a breach in confidentiality:** [REQUIRED FIELD]