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

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

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| **ADDENDUM: INFORMED CONSENT ALTERATION/WAIVER –**  **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 no 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.
* **Basic elements of informed consent:**
* A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
* A description of any reasonably foreseeable risks or discomforts to the subject;
* A description of any benefits to the subject or to others which may reasonably be expected from the research;
* A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
* A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
* For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
* An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
* A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
* **Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:**
* A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
* Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
* Any additional costs to the subject that may result from participation in the research;
* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
* A statement that significant new findings developed during the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
* The approximate number of subjects involved in the study.

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| **SECTION 1. REQUESTING ALTERATION OF INFORMED CONSENT 45 CFR 46.116(f)(3)** |

1. **Is this research requesting alteration of informed consent?**

**☐ No**

**☐ Yes**

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

1. **Please describe which elements of consent will be altered, and/or omitted, and justify the alteration:** [REQUIRED FIELD]
2. **Will the research involve no more than minimal risk to the subject? Provide justification:** [REQUIRED FIELD]
3. **Whenever relevant, will the subject be provided with additional pertinent information after they have participated in the study? Please explain:** [REQUIRED FIELD]

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| **SECTION 2.**  **WAIVER OF DOCUMENTATION OF INFORMED CONSENT 45 CFR 46.117(c)** |

1. **Is this research requesting waiver of documentation of informed consent?**

**☐ No**

**☐ Yes**

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

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]

***PLEASE NOTE:***

*The IRB cannot waive the requirement for documentation or alter the consent form for FDA* *regulated research under this condition*

1. **Does the research involve procedures that are minimal risk except for the linking of the consent document to private information? If so, please describe the potential harm a subject may experience as a result of a breach in confidentiality:** [REQUIRED FIELD]
2. **Will the research present no more than minimal risk to the subject and involve no procedure for which written consent is normally required? Provide justification:** [REQUIRED FIELD]

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| **SECTION 3. WAIVER OF INFORMED CONSENT PROCESS 45 CFR 46.116(f)(3)** |

1. **Is this research requesting waiver of informed consent process?**

**☐ No**

**☐ Yes**

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

1. **Will the research involve no more than minimal risk to the subject? Provide justification:** [REQUIRED FIELD]
2. **Whenever relevant, will the subjects be provided with additional pertinent information after they have participated in the study? Provide justification:** [REQUIRED FIELD]

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| **SECTION 4. HIPAA WAIVER OR ALTERATION 45 CFR 164.512(i)(2)(ii)** |

1. **Is this research requesting HIPAA Waiver or alteration?**

**☐ No**

**☐ Yes**

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

1. **Will PHI will be accessed for activities preparatory to research, and are the following representations true?**

* **The use or disclosure of the PHI being sought is solely for the purposes of designing the study or for assessing the feasibility of conducting the study.**
* **The PHI will not be removed from the covered entity.**

**Describe how the PHI will be used in preparation for research:** [REQUIRED FIELD]

1. **Are you requesting a waiver of authorization for access to medical records?**

**☐ No**

**☐ Yes**

***If yes****,* ***complete (i-viii).***

***PLEASE NOTE:***

*Waivers of consent and authorization are governed by HIPAA (*[*45 CFR 164.512[i]*](https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.2.164&rgn=div5#se45.2.164_1512)*), the Common Rule (*[*45 CFR 46*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)*), and the Washington State Health Care Information Act (*[*RCW 70.02*](https://app.leg.wa.gov/rcw/default.aspx?cite=70.02)*).*

1. **The access of PHI without authorization/consent present no more than minimal risk to the subjects and their privacy because:** [REQUIRED FIELD]
2. **The waiver will not adversely affect the rights and welfare of the subject because:** [REQUIRED FIELD]
3. **The research could not practicably be conducted without the waiver because:** [REQUIRED FIELD]
4. **Access and use of the PHI is necessary to conduct this research because:** [REQUIRED FIELD]
5. **The risks to the subjects and their privacy are reasonable in relation to the anticipated benefits of this research because:** [REQUIRED FIELD]
6. **List the steps taken to protect the privacy and confidentiality of the data and to protect identifiers from improper use or disclosure:** [REQUIRED FIELD]
7. **I plan to destroy identifiers at the earliest opportunity, no later than:** [REQUIRED FIELD]
8. **I will not destroy the identifiers for the following scientific or health-related reasons:** [REQUIRED FIELD]