**This form should be used when a Waiver of Consent, Waiver of Alteration of Consent, Waiver of Documentation of Informed Consent, or Alteration/Waiver of Protected Health Information (PHI) Authorization is needed. Only fill out the section(s) that apply to your study.**

|  |
| --- |
| **Basic Information** |
| **Short Title:** |       |
| **Principal Investigator Name:** |       |
| **Section 1: Waiver or Alteration of Consent**  |
| **A. Waiver of Informed Consent or Alteration of Consent 45 CFR 46.116(f) Complete this section if you are requesting a Waiver of Consent or a Waiver of an Element of Consent, otherwise leave blank.**  |
| **Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject:**      |
| **Explain why the waiver/alteration will not adversely affect the rights and welfare of the subjects:**       |
| **Explain why it is impracticable to conduct this research when informed consent is required:**      |
| **Explain, if appropriate, how the subjects will be provided with additional pertinent information about the research after participation. If not appropriate, explain why:**       |
| **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format:**       |
| **B. Waiver of Documentation of Informed Consent Complete this section if you are requesting to omit the signature requirement during the consenting process. Complete *only one* Subpart.**  |
| ***Subpart 1****: Waiver of Documentation of Informed Consent 45 CFR 46.117(c)(1)(i)* |
| **Explain how the consent document is the only record linking the subject and the research:**      |
| **Explain how the principal risk would be the potential harm resulting from a breach of confidentiality:**      |
| ***Subpart 2****: Waiver of Documentation of Informed Consent 45 CFR 46.117(c)(1)(ii)* |
| **Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject**      |
| **Describe how the research involves no procedures for which written consent is normally required outside the research context:**      |
| ***Subpart 3****: Waiver of Documentation of Informed Consent 45 CFR 46.117(c)(1)(iii)* |
| **Explain how subjects or legally authorized representatives are members of a distinct cultural group or community in which signing a from is not the norm:**      |
| **Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to subject:**      |
| **Section 2: Waiver or Alteration of Protected Health Information (PHI)** |
| **Waiver or Alteration of PHI 45 CFR 164.512(i) Complete this section if you are requesting a Waiver of PHI authorization to access the medical records for research purposes.** |
| **A.** Describe the PHI being used or disclosed in your study  |
| [ ]  Patient/subject name[ ]  Address street location[ ]  Address town or city[ ]  Address state[ ]  Address zip code[ ]  Elements of dates (except year) related to an individual (i.e., DOB, admission/discharge dates, date of death)[ ]  Telephone number[ ]  Fax number[ ]  Electronic mail (email) address[ ]  Social security number[ ]  Medical record numbers[ ]  Health plan beneficiary numbers[ ]  Account numbers[ ]  Certificate/license numbers[ ]  Vehicle identification numbers and serial numbers including license plates[ ]  Medical device identifiers and serial numbers[ ]  Web URLs[ ]  Internet protocol (IP) address[ ]  Biometric identifiers (finger and voice prints); specify:      [ ]  Full face or comparable photographic images[ ]  Any unique identifying number, characteristic or code (a rare disease can be considered a unique ID)[ ]  Link to identifier (code) |
| **B. Record/Specimen Use** - Indicate your source(s) of health information |
| [ ]  Physician/clinic records[ ]  Interviews/questionnaires[ ]  Mental health records[ ]  Billing records[ ]  Lab, pathology and/or radiology results[ ]  Biological samples obtained from the subjects[ ]  Hospital/medical records (in- and out-patient)[ ]  Data previously collected for research purposes[ ]  Other; specify:       |
| **C. Request for Waiver or Alteration of Authorization 45 CFR 164.512(i) Ensure that only IRB approved individuals have access to PHI for research purposes.** |
| **Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:**      |
| **Describe investigator’s plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time:**      |
| **Explain why research could not practicably be conducted without the waiver or alteration:**      |
| **Explain why research could not practicably be conducted without access to and use of the protected health information:**      |
| **D. Attestation: Required only when requesting Waiver or Alteration of PHI**  |
| **Principal Investigator**  |
| I assure the IRB that the protected health information which I have detailed in this Waiver of PHI Authorization will not be reused (i.e.: used other than as described in this application) or disclosed to any person not a part of this research study or entity except as required by law, for authorized oversight of this research protocol. I also assure the UA IRB that the information that I provide in this application is accurate and complete, and that the PHI that I request is the minimum amount of identifiable health information necessary for my research protocol.**Attestation of Principal Investigator:** [ ] **Print Name:**       **Date:**       |