**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:** | |