**IRB Waiver of HIPAA Authorization**

**University of Wyoming**

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| Waiver of HIPAA Authorization | | |
| Purpose of this form:   1. Assist the University of Wyoming IRB in making and documenting the determinations required to grant or deny a Waiver of HIPAA Authorization for research purposes, based on federal law. 2. If waiver is granted, this completed form serves as written permission from the IRB to the researcher to access, use, or disclose Protected Health Information (PHI) without subject authorization. 3. The researcher provides this form to the covered entity maintaining the PHI as documentation that the UW IRB has granted a Waiver of HIPAA Authorization. | | |
| Researcher name: | Date of IRB approval: | |
| IRB application title: | | |
| Review type: ⁭ Full IRB Review ⁭ Expedited Review | | |
| Does the IRB approve the request for a Waiver of HIPAA Authorization? ⁭ Yes ⁭ No | | |
| Purpose of Waiver of HIPAA Authorization (check all that apply):   1. Waiver is granted only for prescreening records containing PHI. When prescreening is complete, researcher must obtain HIPAA Authorization from eligible subjects for any other access of PHI. 2. Waiver is granted for complete access, use, and creation of records containing PHI, but only as described in the IRB approved application. | | ⁭  ⁭ |
| Signature of IRB Administrator: | | |
| Printed Name: | | |

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| OHRP Regulatory Justification for Waiver (45 C.F.R. 164.512(i)(2)(iii)) | |
| All of the following criteria must be satisfied to grant a Waiver of HIPAA Authorization:   1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: 2. An adequate plan to protect the identifiers from improper use and disclosure; 3. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and 4. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted. 5. The research could not practicably be conducted without the waiver or alteration. 6. The research could not practicably be conducted without access to and use of the PHI. | YES NO  ⁭ ⁭  ⁭ ⁭  ⁭ ⁭ |