Wyoming Department of Health Institutional Review Board

Request for Waiver of Consent, Authorization, and/or Documentation of Consent

Please check the appropriate category and answer the corresponding questions.

☐ **Request for Waiver of Documentation of Informed Consent.**
The IRB may waive the requirement to obtain a signed informed consent document for some or all of the participants if the study meets one of the following conditions:

1. The only record linking the participant to the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Under this condition, use of oral consent is appropriate. Each participant must be read an informed consent statement witnessed and signed by two study team members. The IRB must review and approve the oral consent document.

Does this study involve procedures that would be minimal risk except for the linking of the consent document to private information? ☐ Yes ☐ No

If "Yes", describe the potential harm to the subject that could result from a breach of confidentiality?

2. The research is minimal risk and involves no procedures for which written consent is normally required outside of the research context.

Does this study involve procedures that, outside of the research context, would require written consent? ☐ Yes ☐ No

If "Yes", waiver of documentation is not appropriate.

3. The research is minimal risk and involves **either**; a) no collection of protected health information, or b) no collection of individual identifiers which could link PHI to an individual participant.

Does this study involve collection of protected health information? ☐ Yes ☐ No

If collecting PHI, does this study involve collection of individual identifiers or specific demographic information which could link PHI to an individual participant? ☐ Yes ☐ No

If "Yes" to both questions above, waiver of documentation is not appropriate.

☐ ***Request for Waiver of Authorization.**
Note: Authorization only applies when protected health information (PHI) will be created, used, or disclosed in the course of the research.

The IRB may approve a waiver or alteration in the Authorization procedure provided that the following conditions are met:

1. Explain why the research could not practicably be conducted without access to the protected health information.

2. Describe how the privacy risks to individuals whose protected health information is to be used are reasonable in relation to the anticipated benefits (if any) and the importance of the knowledge expected from the research.

3. Describe the plan to protect the identifiers from improper use and disclosure.

4. Describe the 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.

5. Verify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research.

Please be aware, if a protocol is granted a "Waiver of Consent and/or Authorization" by the WDH, IRB, the PI must be prepared to provide the following information for any PHI disclosed outside WDH should a disclosure occur:

1 *The date of the disclosure;*
2 *The name, title, and contact number of the WDH workforce member making the disclosure;*
3 *The name of the entity or person who received the protected patient information, and, if known, the address of such entity or person;*
4 *A brief description of the protected patient information disclosed; and*
5 *A brief statement of the purpose of the disclosure that reasonably describes the basis for the disclosure.*

This mandate is pursuant to 45 CFR 164.528, which states that an individual has the right to request and receive an accounting from the covered entity (WDH) of all possible disclosures of his/her protected health information that was permitted without the individual's authorization.

IRB #: (assigned by the WDH IRB) _____

Study Title_____

Date of submission of this form_____

Principal Investigator_____

Principal Investigator Signature_____