Wyoming Department of Health
Institutional Review Board HIPAA Compliance

1. Indicate your sources of Protected Health Information (PHI):

- Interview or written instrument used with participants ☐
- Hospital /Medical records ☐
- Physician/Clinic records ☐
- Mental Health records ☐
- Billing records ☐
- Lab, Pathology and/or Radiology results ☐
- Biological samples obtained from subjects for clinical purposes ☐
- Data previously collected for research purposes ☐
- Other (describe)

2. Identify all WDH affiliated individuals who will be requesting authorization to access the participant's PHI:

Name (First, Middle, Last)/Degree	**Division or Affiliation**	**Role in Project**

3. Identify all Non-WDH affiliated individuals/institutions to which PHI may be disclosed (e.g., study sponsors, consultants, contractors, publications, future collaborators, etc.

Name of Individual/Institution	**Business Associate Agreement**
	☐Attached ☐Pending ☐In Contract ☐N/A
	☐Attached ☐Pending ☐ In Contract ☐ N/A
	☐ Attached ☐Pending ☐ In Contract ☐N/A
	☐Attached ☐Pending ☐In Contract ☐N/A

If PHI is disclosed to Individuals or Institutions outside of WDH, a "Business Associate Agreement" is required. If disclosed information is coded, a BAA is not required.

4. Indicate when PHI will no longer be used or disclosed (please select one):

- Specific date _____
- Closure of the study ☐
- Destruction of the database/registry ☐
- Years after closure of the study ☐
- No expiration date (only available for databases/registries) ☐
- Specimen processing is complete ☐
- Completion of data collection ☐
- Other _____

5. Indicate if individual authorization to use or disclose PHI is required, or if a request for waiver of authorization to access PHI is requested:

☐ **Individual Authorization from Study Participant**
(individual authorization is incorporated in the IRB consent form template)

☐ **Waiver of Authorization requested**
(if "Yes", complete the "Request for Waiver of Consent and/or Authorization"

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 their private health information that was permitted without the individual's authorization.

Definitions and Conditions

Protected Health Information (PHI): is individually identifiable health information that is or has been collected or maintained by WDH or an agent acting under contract or on behalf of WDH, including information that is collected for research purposes only, and **can be linked** back to the individual participant. Once this has occurred, use or disclosure of such information must follow federal privacy guidelines.

Business Associate Agreement: Sets forth the terms and conditions pursuant to which the Covered Entity (WDH) will allow the use and disclosure of a limited data set to the data recipient.
Individual Authorization: The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself.

Waiver of Authorization: The following three criteria must be satisfied in order to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   a. an adequate plan to protect the identifiers from improper use and disclosure;
   b. 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,
   c. adequate written assurances 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 for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

IRB #: (assigned by the WDH IRB) _____

Study Title_____

Date of submission of this form_____

Principal Investigator_____

Principal Investigator Signature_____