

**OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES**

**APPLICATION FOR IRB WAIVER
OF HIPAA PRIVACY AUTHORIZATION**

[This is a template Application for Waiver of HIPAA Privacy Authorization form. I must be customized by the investigator to be consistent with the requirements for a waiver of authorization to use or disclosed Protected Health Information (“PHI”) in connection with Research. All italicized information in this document constitutes instructions to the investigator and should be deleted from the investigation customized from that will be submitted to the OSU-CHS IRB. In order for the IRB to grant a waiver of the HIPAA Privacy Authorization requirement, the IRB must be satisfied that the project involves no more than minimal risk to the privacy of individual participants and meets all of the criteria listed below. Do not submit this form if de-identified data will be used. Do not submit this form if a limited data set will be used. (See definitions of de-identified data and a limited data set on page 3.)]

TITLE: _____
[Specify the name of the research study as it appears on the IRB protocol application]

PRINCIPAL INVESTIGATOR: _____

PRINCIPAL INVESTIGATOR ADDRESS: _____

PRINCIPAL INVESTIGATOR TELEPHONE: _____

OTHER INVESTIGATORS: _____

[The Principal Investigator must fully describe all information requested below and must initial all blanks as requested before Sections B, C, F & G, to certify intention to comply with specific HIPAA requirements].

A. The following protected health information (“PHI”) will be created, collected, used, or disclosed as a result of the patient/participant’s participation or to determine the participant/patient’s eligibility to participate in this research study. *[Check all that apply]*.

___ Complete past medical history to determine eligibility criteria listed in the informed consent form.

___ Information about HIV/AIDS diagnosis or possible diagnosis of the patient/participant.

___ Information about hepatitis infection.

___ Information about sexually transmitted diseases.

- ___ Information about communicable diseases that must be reported to Public Health Authorities.
- ___ Records of physical examinations.
- ___ Laboratory, x-rays, MRI and other test results.
- ___ Diaries and questionnaires.
- ___ Records about study medications or drugs.
- ___ Records about study devices.
- ___ Information related to diagnosis and treatment of a mental health condition.
- ___ Other medical information such as: _____

B. I certify that the project has an adequate plan to protect participant identifiers from improper use and disclosure as described below. *[Examples of elements that should be included in an adequate plan are noted below: **Put an “X” by all that apply and add any other privacy protections in your plan.**]*

- ___ Only authorized persons will be granted access
- ___ Only authorized persons may enter and view study data
- ___ Passwords and system IDs will not be shared
- ___ Physical security of the workstations/files will be maintained
- ___ Adequate back-up plan is in effect
- ___ Staff are trained on the data entry system and importance of security procedures
- ___ Workstations with the database will not be left unattended.
- ___ Additional protections:

C. I certify that the project has an adequate plan to destroy the participant identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or is otherwise required by law. **[Please explain when/if the participant identifiers will be stored or retained. If all participant identifiers will be destroyed, describe the plan for destruction.]** _____

D. **Explain** why the research could not practicably be conducted without the waiver.

E. **Explain** why the research could not practicably be conducted without access to and use of the data/specimens.

Definitions of HIPAA Terms

De-identified Data: Under HIPAA, “de-identified data” includes data that has had **all of the following identifiers removed**. This de-identified data is not considered to be Protected Health Information (PHI):

- Names
- Geographic subdivisions smaller than a state except first three digits of the zip code;
- All elements of dates (except year) for individuals under 90 years old; all elements of dates (including year) for those over 90 years old;
- Telephone numbers;
- Fax numbers;
- E-mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet protocol address numbers;
- Biometric identifiers, including voice and finger prints;
- Full face photographic images and any comparable images;
- Any other unique, identifying number characteristic, or code, with some exceptions.

Expert Certification of De-identified Data:

Under HIPAA, information that an expert certifies has very small risk (alone or in combination with other available information) of identifying the participant is deemed to be “de-identified data.”

Limited Data Set: A limited data set is **information that is stripped of the direct identifiers** (above) of the participant or of relatives, employers or household members of the participant *except*

- Town, city, state and 5-digit zip code;
- All elements of dates for dates directly related to the individual, including birth date, admission date, discharge date, and date of death.

Data Use Agreement: A researcher must sign a Data Use Agreement, prior to using a limited data set, assuring appropriate use of the PHI and that the researcher will not re-identify the information or contact the individuals.

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IRB RECORD OF APPROVAL OF REQUESTED WAIVER

**APPROVAL RECORD
FOR IRB USE ONLY**

IRB Protocol No.: _____

Reviewed by: Convened IRB

IRB Chair or Vice Chair pursuant to expedited procedures

1. The use or disclosure of protected health information involves:

MINIMAL RISK to individual privacy

MORE THAN MINIMAL RISK to individual privacy

2. There IS

IS NOT

an adequate plan to protect identifiers from improper use/disclosure.

3. There IS

IS NOT

an adequate plan to destroy identifiers at the earliest opportunity.

4. There ARE

ARE NOT

adequate written assurances that information will not be reused/redisclosed.

5. The research COULD NOT

COULD

practicably be conducted without the waiver or alteration.

6. The research COULD NOT

COULD

practicably be conducted without the protected health information.

The request for waiver or alteration of authorization is:

- Not Approved**
- Approved as a Waiver (the first box must be checked for all elements above)**
- Approved as an Alteration (*description of nature of alteration required*):**

Signature of IRB Chair or Vice Chair

Date

Print Name