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Addendum 7: HIPAA Authorization Form and Template

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| **Principal Investigator:** |  |
| **Study Title:** |  |

## What is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA) is a complex regulation that affects many researchers at the TUN. HIPAA is designed to protect the use and disclosure of individually identifiable health information (also defined as Protected Health Information or PHI). PHI is defined as any of the 18 HIPAA recognized identifiers (see below) **in combination with** health information.

HIPAA recognized identifiers:

1. Names;
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images;
18. Any other unique identifying number, characteristic, or code.

It is important that you understand that you could face criminal and/or civil liabilities for non-compliance with HIPAA. Fill out both sections below, making sure that the two sections do not contradict each other, and that the HIPAA authorization does not contradict your consent form.

**Fill out this form to get IRB approval for the proposed data collection or to request a waiver of HIPAA protections. Below this portion is the template for HIPAA authorization that you should customize, submit for IRB review, and give to potential research subjects.**

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## SECTION 1: Type and Source of Protected Health Information

1. HIPAA recognized identifiers for PHI:

[ ]  Names

[ ]  All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes

[ ]  All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death

[ ]  Telephone numbers

[ ]  Fax numbers

[ ]  Electronic mail addresses

[ ]  Social Security numbers

[ ]  Medical Records numbers

[ ]  Health plan beneficiary numbers

[ ]  Account Numbers

[ ]  Certificate or license numbers

[ ]  Vehicle identifiers and serial numbers, including license plate numbers

[ ]  Device identifiers and/or serial numbers

[ ]  Web Universal Resource Locators (URLs)

[ ]  Internet Protocol (IP) address numbers

[ ]  Biometric identifiers including finger and voice prints

[ ]  Full face photographic images and any comparable images

[ ]  Health plan beneficiary number

[ ]  Any other unique identifying number, characteristic, or code

[ ]  Other, specify

1. Name of entity providing PHI:

1. Describe how the PHI will be used and how access to PHI will further the research aims.

**SECTION II: Consent/Authorization**

*Select options 1, 2, or 3 as appropriate.*

1. [ ]  Written consent/authorization will be obtained (please attach authorization document)
2. [ ]  PHI will be accessed for activities preparatory to research. The following representations are true about my study:
3. The use or disclosure of the PHI being sought is solely for the purposes of designing the study or for assessing the feasibility of conducting the study, **and**
4. The PHI will not be removed from the covered entity

Describe how the PHI will be used in preparation for research

1. [ ]  I am requesting a waiver of authorization for access to medical records. Waivers of consent and authorization are governed by HIPAA, the “Common Rule” (45 CFR 46) and the Nevada State Health Care Information Act. Respond to each of the following and explain how your study is designed to address each of these concerns.
2. The access of PHI without authorization/consent present no more than minimal risk to the subjects and their privacy because:

**Explain:**

1. The waiver will not adversely affect the rights and welfare of the subject because:

**Explain:**

1. The research could not practicably be conducted without the waiver because:

**Explain:**

1. Access and use of the PHI is necessary to conduct this research because:

**Explain:**

1. The risks to the subjects and their privacy are reasonable in relation to the anticipated benefits of this research because:

**Explain:**

1. I have taken the following steps to protect the privacy and confidentiality of the data and to protect identifiers from improper use or disclosure:

**Explain:**

1. I plan to destroy identifiers at the earliest opportunity, no later than:

**Explain:**

1. I will not destroy the identifiers for the following scientific or health-related reasons:

**Explain:**

**SECTION III: Data Security and Data Use**

1. Describe data security measures in place to protect PHI. Include security related to electronic security (password protection, virus software, etc.), physical security measures (locks, surveillance etc.) and data handling techniques (coded data, identifier destruction date, etc), as applicable.

1. Attach any data use agreements, or business associate agreements related to the access and use of the PHI described in this Human Subject Application and Appendices.

[ ]  By checking this box, I am providing assurance that the information is essential to the research and access to the information will be limited to the greatest extent possible, allowable under the Privacy Regulations.

**Template for HIPAA authorization to be reviewed and signed by research subjects.**

Delete or customize all text that appears in red.

AUTHORIZATION TO CREATE, ACCESS, USE, AND SHARE (DISCLOSE) HEALTH INFORMATION FOR RESEARCH

|  |  |
| --- | --- |
| **Principal Investigator:** |  |
| **Study Title:** |  |

By law, researchers must protect the privacy of health information about you. In this form the word “you” means both the person who takes part in the research and the person who gives permission for another person to be in the research. Researchers may use, create, or share your health information for research **only if you let them**. This form describes what researchers will do with your information. Please read it carefully. If you agree with it, please sign your name at the bottom. You will get a copy of this form after you have signed it.

If you sign this form, information will be shared with the people who conduct the research. In this form, all these people together are called “researchers.” Their names will appear on the research consent form that you sign.

The researchers will use the health information only for the purposes named in this form.

**1.** **What “health information” includes**

* All information about you that is collected during the research study. This might include the results of tests or exams that become part of the study records; diaries and questionnaires that you might be asked to fill out as part of the study and other records from the study.
* All health information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures and your medical history.

**2. What the researchers may do with health information**

The researchers may use and create health information about you for the study. They may also share your health information with certain people and groups. These may include:

* The sponsor of the study **THE SPONSOR OR PI**, and its representatives
* Government agencies **(including the FDA if this is a study subject to FDA oversight)**, review boards, and others who watch over the safety, effectiveness, and conduct of the research. Other researchers when a review board approves the sharing of the health information.
* Your health insurer if they are paying for care provided as part of the research study.
* Others, if the law requires.

**3. Removing your name from health information**

The researchers may remove your name (and other information that could identify you) from your health information.No one would know the information was yours.

 If your name is removed, the information may be used, created, and shared by the researchers and sponsor as the law allows. (This includes other research purposes.) This form would no longer limit the way the researchers use, create, and share the information.

1. **How the researchers protect health information**

The researchers [and sponsor] will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.

**5. After the researchers learn health information**

The limits in this form come from a federal law called the Health Insurance Portability and Accountability Act. This law applies to your doctors and other health care providers. Once the researchers get your health information, this law may no longer apply. But other privacy protections will still apply.

**6. Storing your health information**

Your health information may be added to a database or data repository. This permission will end when the database or data repository is destroyed.

**7. Please note**

You do not have to sign this permission (“authorization”) form. If you do not, you may not be allowed to join the study. You may change your mind and take back your permission at any time. To take back your permission, write to: **SPONSOR OR PI CONTACT**

If you do this, you may no longer be allowed to be in the study. The researchers will keep any information in the study record they already collected.

Your authorization will expire when the goals of the study have been met

**[*Insert the text ABOVE only if applicable. For example, a double-blinded randomized trial. Otherwise delete the template language]***

During the study, you will not be allowed to see your health information that the researchers may place in your medical record. After the study is finished, you may see this information.

**8. Your signature**

If I have not already received a copy of the Privacy Notice, I may request one. If I have any questions or concerns about my privacy rights, I should contact the TUN IRB at 702-777-8687.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

I agree to the use, creation, and sharing of my health information for purposes of this research study

Signature of research subject or subject’s legal representative \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Printed name of research subject or subject’s If applicable, representative’s relationship

legal representative to subject