

**OKLAHOMA STATE UNIVERSITY
CENTER FOR HEALTH SCIENCES**

**AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF
PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES
ADDENDUM TO RESEARCH CONSENT FORM**

[This is a template HIPAA Research Authorization form. It must be customized by the investigator to be consistent with the use and disclosure of protected health information (PHI) pursuant to the requirements of the specific research/study in which it will be used. All italicized information in this document constitutes instructions to the investigator and should be deleted from the final investigator-customized form that will be provided to the research patient/participants. Pursuant to the HIPAA Privacy Rule requirements, the use of this form is required by Oklahoma State University Center for Health Sciences (“OSU-CHS”) if the investigator’s research study will involve the use or disclosure of previously or newly created (pursuant to orders for tests and treatments) protected health information at/within/by an OSU-CHS-affiliated hospital or clinic. This form may be used as a stand-alone document as an addendum to the Common Rule required informed consent document or the elements herein may be combined with the informed consent document. The OSU-CHS IRB is responsible for reviewing the research study/protocol documentation to ensure the proper use of this required HIPAA information in the investigator’s IRB submission. A separate form must be used for research involving psychotherapy notes. (Notes taken by a psychotherapist during sessions and retained separate and apart from the medical record.)]

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

PRINCIPAL INVESTIGATOR: _____

PRINCIPAL INVESTIGATOR’S ADDRESS: _____

PRINCIPAL INVESTIGATOR’S TELEPHONE NUMBER: _____

OTHER INVESTIGATORS: _____

[If you use this document as a stand-alone form (you do not combine it with the Common Rule-required informed consent), then you must leave in the question and answer instruction that immediately follows. If you combine this HIPAA authorization with the study informed consent, then this Q&A section may be eliminated]

Why is my additional consent being requested?

You have given or will give your consent to participate in the above-named research study. The purpose of this additional form is to provide you with specific information regarding the use and disclosure of your protected health information, that is information about your health care that has a way that you can be identified with it, for the purpose of this research study. While much of this information was provided to you in the consent form, recently enacted laws, focused on the privacy of medical information, require that this information be addressed in a certain manner. Through the use of this additional form, we are seeking your authorization for the use

and disclosure of your medical information for the purpose of this research study as required in these recently enacted laws.

How will my protected health information be used in this research study?

[Include the following paragraph if the research study involves the collection of the participants' current (retrospective record review) or future (for research record repositories) protected health information]

This research study will involve the recording of current and/or future protected health information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning *[specify the nature of the data that will be recorded]*. This information will be used for the purpose of *[specify the purpose of the research use of the current and/or future protected health information]*.

[Include the following paragraph if the research study will involve the generation of information (e.g., diagnostic information, laboratory information, treatment or adverse event information) that will appear or be placed in the participants' hospital's/clinic's medical records]

As a result of your participation in this research study, additional information may be placed in your medical records held at *[specify the name of the applicable institution or physician's office]*. The nature of the additional information to be recorded in your medical record as a result of the research study includes *[specify in general terms the type research data which may or will be recorded in the participant's medical record]*.

Who will have access to my medical information related to this research study?

In addition to the investigators listed on the first page of this authorization form and their research staff, the following individuals may have access to your protected health information related to your participation in this research study:

[Include the following paragraph routinely]

Authorized representatives of the Institutional Review Board that reviewed and approved the performance of this study may review your protected health information for the purpose of monitoring the appropriate conduct of this research study.

[Include the following paragraph if an external sponsor of the research study will have access to the participants protected health information for study monitoring or data analysis purposes]

Authorized representatives of the sponsor of this research study, *[specify name of sponsor and/or contract research organization]*, will review and/or obtain your protected health information for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. *[Include the following sentence in this paragraph if applicable - "Authorized representatives of the study sponsor may also be present during your participation in certain research procedures."]* While the study sponsor understands the importance of maintaining the confidentiality of your protected health information, OSU-CHS can not guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive

funding from the sponsor to perform the research procedures and to provide the sponsor with protected health information related to your participation in the study.

[Include the following if the research study involves an evaluation of any substance or item (e.g., drug, device, biological, etc.) regulated by the U.S. Food and Drug Administration]

Authorized representatives of the U.S. Food and Drug Administration (FDA) may review and/or obtain your protected health information for the purpose of monitoring the accuracy of the research data. While the FDA understands the importance of maintaining the confidentiality of your protected health information, OSU-CHS can not guarantee the confidentiality of this information after it has been obtained by the FDA.

[Include the following if the research study (or any aspect of the research study) will involve the utilization of hospital or health care services (e.g., laboratory tests, diagnostic procedures); hospital or health provider care of the patient-participant; or hospital or health provider billing activities]

Staff of your hospital, the OSU-CHS clinics or other affiliated health care providers will have access to your protected health information as needed for the purpose of (1) following treatment orders made by the investigators for health care services (e.g., laboratory tests, diagnostic procedures) related to your participation in the research study; (2) billing for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

[Include the following if applicable]

Other individuals who will have access to your protected health information include *[Identify any other individuals who may or will have access to the participant's protected health information and the purpose of such access.]*

[Include the following routinely]

In unusual cases, the investigators may be required to release your protected research information in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies as required by Oklahoma law.

Although the researchers may report their findings about this research study in scientific journals or meetings, you will not be identified in their reports or articles.

The researchers, OSU-CHS, and other health care providers affiliated with OSU-CHS will try to keep all information about your participation in this research study confidential, but absolute confidentiality cannot be guaranteed.

May I see my medical information resulting from participation in this research study?

In accordance with the OSU-CHS Notice of Privacy Practices document which you have been provided, or will be provided when you present for services at the OSU Clinic *[Specify the place where the patient will go for tests/treatments pursuant to the study. If this study only involves a retrospective record review (of records held/owned by OSU-CHS), then you must be responsible*

for obtaining a copy of OSU-CHS's Notice of Privacy Practices and providing it to the patient/participant] you are permitted to see the information contained in your medical records and kept by your health care provider unless otherwise specifically stated below.

[Include the following section if you intend to restrict patient/participant access to medical information generated as a result of the patient's/participant's participation in the research study]

Because of the nature of this research study, you or your personal representative will not be given access to your protected health information created as a result of your participation in this research study until the end of the study. *[If the patient/participant will only be restricted as to certain information, describe the restriction and the specific information the patient/participant will be able to access.]* This restriction on your ability to access your protected health information during the course of the study has been specifically authorized by (the OSU-CHS Privacy Officer and) the Institutional Review Board overseeing the research.

May I refuse to authorize the use and disclosure of my protected health information for the purpose of this research study?

Your authorization (permission) to use and disclose your protected health information for the purpose of this research study is completely voluntary. However, if you do not provide your written authorization for the use and disclosure of your protected health information, you will not be allowed to participate or continue to participate in the research study.

Whether or not you provide your authorization for the research use and disclosure of your medical information will have no affect on your current or future medical care at the OSU-CHS-affiliated clinic or hospitals where you receive care or your current or future relationship with a health insurance carrier. Whether or not you provide this authorization will have no affect on your relationship with OSU-CHS.

May I withdraw, at a future date, my authorization for the use of my protected health information for the purpose of this research study?

You may withdraw, at any time, your authorization for the use and disclosure of your protected health information for the purpose of this research study. However, if you withdraw your authorization for the use and disclosure of your protected health information, you will also be withdrawn from further participation in this research study. Any protected health information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes described above *[or specify what other action will be taken with regard to the retention of previously collected protected health information upon patient/participant withdrawal from study participation].*

To formally withdraw your authorization you should notify the principal investigator of this research study. Contact information is listed on the first page of this form. The investigator will ask you to sign a document with the date you asked to withdraw.

Your decision to withdraw your authorization for the research use and disclosure of your medical

information will have no affect on your current or future medical care at the OSU-CHS-affiliated clinic or hospitals or your current or future relationship with a health insurance provider. Your decision to withdraw this authorization will have no affect on your current or future relationship with the OSU-CHS.

For how long will the investigators be permitted to use my protected medical record information?

The investigators may continue to use and disclose your protected health information for the purposes described above for an indefinite period of time.

Voluntary Consent

All of the above has been explained to me and all of my current questions have been answered. Throughout my participation in this research study, I have been encouraged to ask any additional questions I may have about the research use and disclosure of my protected health information. Such future questions will be answered by the investigators listed on the first page of this form.

Any questions I have about my rights associated with the research use and disclosure of my medical information will be answered by *[specify the name and phone number of the person associated with the IRB who is designated to serve as a participant advocate]*

By signing this form, I agree to allow the use and disclosure of my medical information for the purposes described above. **I UNDERSTAND THAT MY MEDICAL RECORDS MAY CONTAIN INFORMATION THAT INDICATES THAT I HAVE A COMMUNICABLE OR VENEREAL DISEASE WHICH MAY INLUDE, BUT IS NOT LIMITED TO, DISEASES SUCH AS HEPATITIS, SYPHILIS, GONORRHEA, OR THE HUMAN IMMUNODEFICIENCY VIRUS, ALSO KNOWN AS ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).** With this knowledge, I give my authorization and consent to the use and disclosure of information as described in this document to the people identified in this form. A copy of this authorization form will be given to me.

Participant's Signature

Date

**ASSENT FORM FOR DEVELOPMENTALLY
DISABLED ADULT**

[If applicable: For adults (age ≥ 18 years old) determined to be decisionally-impaired and thus unable to provide direct consent, incorporate the following standard statements and signature lines]

TITLE OF STUDY: _____

Participant's Name (Print)

The above-named individual is unable to provide direct consent for study participation because,

Therefore, by signing this form, I give permission for the use and disclosure of her/her medical information for the purpose of this research study.

Representative's Name (Print)

Representative's Relationship to Participant

Representative's Signature

Date

[Attach documentation of authority to sign for the participant.]

[If applicable, incorporate the following statements if the potential patient/participant is capable of exercising some judgment concerning the use of her/his medical information for the purpose of the research]

Verification of Explanation

I certify that I have explained the nature and purpose of the research use and disclosure of the above-named individual's medical information in appropriate language. He/she has had an opportunity to discuss this with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to allow the use of his/her medical information for the purpose of this research study.

Investigator's Signature: _____

Date: _____

[If applicable: For research studies wherein the nature of the participant population is such that an individual may not be capable of initially providing direct authorization for the research use of his/her medical information but may recover adequate decision-making capability for direct consent at a later time, also incorporate the following standard statements and signature lines]

Authorization for Continued Research Use of Medical Information

I understand that I am currently participating in a research study. I further understand that authorization for the research use and disclosure of my medical information was initially obtained from my authorized representative as a result of my inability to provide direct authorization at the time that this initial authorization was requested. I have now recovered to the point where it is felt that I am able to provide direct authorization for the continued use and disclosure of my medical information for the purpose of this research study.

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my continued participation in this research study, I am encouraged to ask additional questions I may have about the research use and disclosure of my protected health information. Such future questions will be answered by the investigators listed on the first page of this form. Any questions I have about my rights associated with the research use and disclosure of my medical information will be answered by _____ at _____ *[specify the name and phone number of the person associated with the IRB of record for this study that is so designated to serve as a participant advocate; contact the IRB for this information].*

By signing this form, I agree to allow the continued use and disclosure of my medical information for the purposes described above. A copy of this consent form will be given to me.

Participant's Signature: _____

Date: _____