CONSENT FORM ADDENDUM

AUTHORIZATION (CONSENT) TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION) FOR RESEARCH PURPOSES

(Division, Department, School, or Center Letterhead)

University of Pittsburgh
Institutional Review Board
IRB Number:
Approval Date:
Renewal Date:

TITLE:

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATORS:

SOURCE OF SUPPORT:

Why is my additional consent being requested?

You have previously given your consent to participate in the above-named research study. The purpose of this additional consent form is to provide you with specific knowledge regarding the use and disclosure of your identifiable medical record information for the purpose of this research study. While much of this knowledge was provided to you previously, recently enacted laws focused on the privacy of medical record information require that this knowledge be addressed in certain manner. Through the use of this additional consent form, we are seeking your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study as per the requirements addressed in these recently enacted laws.

What uses of my identifiable medical record information will this research study involve?

[Include if the research study involves the collection of the subjects' current or future identifiable medical record (i.e., hospital, health care provider) information:]

This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other health care provider (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 identifiable medical record information]*.

[Include 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 subjects' medical (i.e., hospital, health care provider) records:]

This research study will result in identifiable information that will be placed into your medical records held at *[specify the name of the applicable hospital or health care provider's office]*. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes *[specify the type research data which may or will be recorded in the subject's medical record]*.

Who will have access to my identifiable medical record information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to your identifiable medical record information related to your participation in this research study:

[Include routinely:]

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical record information for the purpose of monitoring the appropriate conduct of this research study.

[Include if an external sponsor of the research study will have access to the subjects identifiable medical record 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 identifiable medical record 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 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 identifiable medical record information, the UPMC and University of Pittsburgh cannot 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 identifiable medical record information related to your participation in the study.

[Include if research study involves an evaluation of any article (e.g., drug, device, electronic product, food additive) regulated by the U.S. Food and Drug Administration:]

Authorized representatives of the U.S. Food and Drug Administration may review and/or obtain your identifiable medical record information for the purpose of monitoring the accuracy of the research data. While the U.S. Food and Drug Administration understands the importance of maintaining the confidentiality of your identifiable medical record

information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the U.S. Food and Drug Administration.

[Include 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-subject; or hospital or health provider billing activities:]

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable medical record information for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

[Include if applicable:]

[Identify any other individuals who may or will have access to the participant's identifiable medical record information and the purpose of such access.]

[Include routinely:]

In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record 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, as required by Pennsylvania law, the appropriate agencies.

May I have access to my medical record information resulting from participation in this research study?

In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider unless otherwise specifically stated below.

[Include if you intend to restrict patient-subject access to medical record information generated as a result of the patient's-subject's participation in the research study:]

[Specify any restrictions on the patient's-subject's access to medical information generated as a result of research participation. Indicate that such access will be granted at the end of the research study. Note that the UPMC does not generally permit investigators to include restrictions on patient-subject access to medical record information held by the UPMC or affiliated health care providers. The principal investigator must petition the Privacy Officer, UPMC, on a study-specific basis, if s/he wishes to restrict respective patient-subject access to their own medical record information. If the Privacy Officer, UPMC, grants such restrictions, it will be the principal investigator's responsibility to clearly communicate to the involved UPMC

hospital(s) or affiliated health care providers the restrictions that have been granted. This communication must include documentation of the Privacy Officer's permission along with a copy of this signed consent form/authorization.]

May I refuse to provide my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

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

Whether or not you provide your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Whether or not you provide this written authorization (consent) will have no affect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my authorization (consent) for the use of my identifiable medical record information for the purpose of this research study?

You may withdraw, at any time, your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study. However, if you withdraw your authorization (consent) for the use and disclosure of your identifiable medical record information, you will also be withdrawn from further participation in this research study. Any identifiable medical record 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 identifiable medical record information upon subject withdrawal from study participation]*.

To formally withdraw your authorization (consent) you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your authorization (consent) for the research use and disclosure of your medical record information will have no affect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider. Your decision to withdraw this authorization will have no affect on your current or future relationship with the University of Pittsburgh.

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

The investigators may continue to use and disclose your identifiable medical record 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. I understand that, throughout my participation in this research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my identifiable medical record 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 of my medical record information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

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

_____ _____

Participant's Signature Date

[If applicable: For adults (age > 18 years old) determined to be decisionally impaired and thus unable to provide direct authorization for the use of their identifiable medical record information, incorporate the following standard statements and signature lines:]

_____

Participant's Name (Print)

The above-named individual is unable to provide direct authorization for the use and disclosure of his/her identifiable medical record information for the purpose of this research study because:

_____

_____.

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

_____ _____

Representative's Name (Print) Representative's Relationship to Participant

_____ _____

Representative's Signature Date

[If applicable: Incorporate the following statements if the potential patient-subject is capable of exercising some judgement concerning the use of his/her medical record information for the purpose of this research study.]

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 identifiable medical record 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 and disclosure of his/her identifiable medical record information for the purpose of this research study.

_____ _____

Investigator's Signature Date

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

AUTHORIZATION (CONSENT) FOR THE CONTINUED RESEARCH USE OF IDENTIFIABLE MEDICAL RECORD INFORMATION

I understand that I am currently participating in a research study. I further understand that authorization (consent) for the research use and disclosure of my identifiable medical record information was initially obtained from my authorized representative as a result of my inability to provide direct authorization (consent) at the time that this initial authorization (consent) was requested. I have now recovered to the point where it is felt that I am able to provide direct authorization (consent) for the continued use and disclosure of my medical record 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 identifiable medical record 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 identifiable medical record information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

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

_____ _____

Participant's Signature Date

[If applicable: For children (age 0-17 years), incorporate the following standard statements and signature lines:]

_____

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to directly authorize the research use and disclosure of his/her identifiable medical record information. Therefore, by signing this form, I give my authorization (consent) for the use and disclosure of his/her identifiable medical record information for the purpose of this research study.

_____ _____

Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____

Parent's or Guardian's Signature Date