Campbell University College of Pharmacy & Health Sciences

INSTRUCTIONS: HIPAA RESEARCH AUTHORIZATION SHORT FORM

Instructions for Using the HIPAA Research Authorization Short Form for Interview, Survey, Questionnaire, Qualitative or other Non-Interventional Studies

A valid authorization is required to use and/or disclose ***individually identifiable health information*** that is collected in a research study unless the study qualifies for a waiver of authorization. Waivers are generally reserved for very large epidemiological or records-based studies where face-to-face interaction with subjects is not planned or practical.

For some types of studies that utilize interview, survey, or questionnaire methodologies, Campbell's standard research authorization form may be shortened so that information that is not relevant is eliminated. The following explains each item on the authorization short form and presents some clarifying information.

Individually Identifiable Health Information is information that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. Please note that demographic information is included in the definition of individually identifiable health information (45CFR160.103).

Required Items:

All information before Item 1 is required. Please fill out the information fields such as Title of Study, Name of Investigator, etc.

Authorization Statement: A valid authorization must include a statement adequate to place the individual on notice of the health care provider's ability or inability to condition treatment on the authorization and of the consequences to the individual or a refusal to sign the authorization. This information is provided in the bolded box at the top of the model form and must be included exactly as it is written.

Items 1-4 on the form may be altered. Please follow the guidelines below.

Item 1: A valid authorization must include a description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion and a description of each purpose of the requested use or disclosure. You may address this requirement by describing all *individually identifiable health information* that you will collect and each purpose for the use or disclosure in the consent form, and then refer to this part of the consent form in Item 1 of the authorization form.

Item 2: A valid authorization must include the name or specific identification of the person(s), or class of persons, authorized to make the requested disclosure. This normally will include the investigators listed on the consent form and the IRB.

Item 3: A valid authorization must include the name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure. You may modify this statement as appropriate for your study, but must always include the phrase "federal or other governmental agencies as required for their research oversight and public health reporting in connection with this research study."

Item 4: A valid authorization must include an expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," is sufficient if you intend to destroy the information when you terminate the study. The statement "none," or similar language is sufficient if you intend to keep the information in a database or repository for future research uses. Please note that the expiration date of an authorization and the termination date of a study are two different events. The expiration date relates solely to the ability to use or disclose the subject's information. It must be stated in the authorization form regardless of any statements that may appear in the *Participation* section of the consent form.

Statement 1 and 2 and the signature area are protected.

Statement 1: A valid authorization must place the individual on notice of his/her right to revoke the authorization in writing. Include this statement, exactly as it is written in the model form.

Statement 2: A valid authorization must place the individual on notice of the potential for information that has been disclosed pursuant to the authorization to be subject to redisclosure by the recipient(s) and no longer protected. Include this statement, exactly as it is written in the model form.

Signature: A valid authorization must include the signature of the individual and the date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided. The signature block is provided at the end of the model form.

Optional Item: If needed, the optional item should be inserted after Item 4 and numbered in sequential order.

If you are collecting information that may be placed into the subject's medical record, you must include the following statement:

While this study is still in progress, you may not be allowed to see the health information that the researchers place in your medical record. After the study is finished, you may see any information placed in your record."

Instructions may be deleted.
----------END OF INSTRUCTIONS----------

Campbell University College of Pharmacy & Health Sciences

HIPAA RESEARCH AUTHORIZATION – SHORT FORM
AUTHORIZATION FOR THE CREATION, USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR INSTITUTIONAL REVIEW BOARD APPROVED RESEARCH

Title of Study:

Name of Investigator:

Phone Number:

Sponsor:

IRB Number: IRB00005697

Protocol Approval Date:

Consent Form approval Date:

This form authorizes Campbell University College of Pharmacy & Health Sciences to use and disclose certain protected health information about *[name of research volunteer]* that we will collect and create in this research study.

This authorization is voluntary, and you may refuse to sign this authorization. If you refuse to sign this authorization, your health care and relationship with your health care provider will not be affected, however, you will not be able to enter this research study.

1. The specific health information we will collect from you will be limited to your responses to questions in a questionnaire and/or interview with the investigator. The purposes of our use and disclosure of this health information are described in the **Purpose** section of the research consent form, the survey instructions or information letter.

2. The persons who are authorized to use and/or disclose your health information are all of the investigators who are listed on page one of the Research Consent Form or on the survey instructions or information letter.

3. The persons who are authorized to receive this information are the sponsor of this study (if any) and federal or other governmental agencies as required for their research oversight and public health reporting in connection with this research study.

4. This authorization will expire and we will no longer keep protected health information that we collect from you in this study. ***(Enter a date or "study is completed," "indefinitely," or similar language)***.

Statement 1: You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed at the top of this authorization form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date he/she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with Campbell University College of Pharmacy & Health Sciences.

Statement 2: The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law. However, federal or state law may restrict re-disclosure of HIV/AIDS information; mental health information; genetic information; and drug/alcohol diagnosis, treatment or referral information. Campbell University College of Pharmacy & Health Sciences tries to protect against re-disclosure without your permission by being very careful in releasing your information. If the researchers publish results of the research, they will do so in a way that does not identify you unless you allow this in writing.

You will receive a copy of this authorization form after you sign it.

Printed name of research volunteer:_____

Signature of Volunteer:_____

Date:_____

OR

Printed name of volunteer's Legally Authorized Representative:

_____

Signature of Volunteer's Legally Authorized Representative:

_____

Date:_____

Description of relationship to volunteer:_____