**INSTRUCTIONS FOR COMPLETING USC’s**

**HIPAA RESEARCH AUTHORIZATION**

**General Instructions**

The HIPAA Privacy Rule generally prohibits health care providers from using or releasing protected health information for research purposes without written authorization from the patient.

The regulations require specific elements for a HIPAA-compliant authorization and this template was developed to comply with those requirements.

This document should be given to the research participant or his/her legal representative during the informed consent process. The participant or representative should sign and date the last page. Please give a copy of the signed authorization to the participant.

The authorization should be kept with the informed consent document.

**Specific Instructions**

1. **Header.** In the header of the document, please insert the name of the Principal Investigator and the IRB Number, if known. You may include the title of the study, unless identifying the name of the study would provide information to the health care provider that the investigator or participant does not want to reveal.
2. **Who May Release Your Health Information**

On page 1, please check the box of name of the health care provider(s) (e.g., physician, hospital, clinic) from whom you are requesting health care information related to the participant. Please check ALL the boxes that apply.

Please check the box labeled, “All heath care providers with health information about me,” if:

* You do not know the names of all the health care providers that might have relevant information; and/or
* If it is possible that the patient may need treatment at a facility not listed (e.g., emergency room treatment)

1. **What Health Information Will be Used:**

Health information requested: On page 2, please check the applicable box to indicate the type of health information you wish to access and use. You must check one of the top two boxes.

1. **Health Information with Special Protections:**

Sensitive health information: State and federal law give additional protections to certain sensitive health information. If the researcher intends to obtain sensitive health information as described below, the researcher or his/her research coordinator obtaining the authorization must obtain specific permission from the participant before they are allowed to use or release that data for the research study. Sensitive health information is:

1. HIV test results;
2. Mental health records; and/or
3. Substance abuse records,

Please have the participant initial those provisions that apply, if any, to your research study. Otherwise, you should leave those spaces blank. If you do not obtain specific permission from the participant to use this information for the research study, you may not access it or release it to third parties.

1. **How Your Health Information Will Be Used**

This section describes how the researchers, staff and research sponsor will use the participant’s health information in connection with the study. It also describes other units and agencies that may have access to the information in the course of their duties.

You may add the name of the sponsor in the blank provided.

1. **Creation of a Research Database**

This section of the authorization applies if the researcher intends to put information collected in the study into a research database for future research purposes. This section only permits a researcher to input information into a database. It is necessary to obtain a separate authorization or waiver of authorization when the researcher wishes to use information from the database for research purposes.

**Please have the participant initial this section if it applies.**

1. **Scope of this Authorization**

This section notifies the participant that the HIPAA privacy protections may not extend to third parties outside of USC but that state law may protect certain types of information.

1. **Right to Deny Access to Health Information**

Under the privacy rule, USC may deny a participant access to his/her health information collected in the research study while the study is in progress. Please see USC HIPAA policy PAT-601, “Access to Protected Health Information,” for further information.

1. **Term of this Authorization**

This section defines the term as 25 years after the end of the expiration or termination of the study. This term incorporates state law requirements for a stated term but also acknowledges that sponsors and others may need to retain data for longer periods of time to meet FDA or other record retention requirements. This term also takes into account changes in the privacy rule that give greater flexibility for use of health information for future specified research purposes.

1. **Refusal to Sign/Right to Revoke**

This section informs the participant that he/she has a right to cancel the authorization. Please fill in the blank with the Principal Investigator’s (1) name; and (2) business address where the revocation should be sent.

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**No Modifications**

This authorization may not be modified except for completing the blanks as described above. Any other modifications of this document must be approved by the Office of Compliance. The respective Institutional Review Board also must be notified of any changes to the document that are approved by the Office of Compliance.