

INSTRUCTIONS FOR COMPLETING HIPAA RESEARCH AUTHORIZATION FORM

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. A HIPAA authorization must contain specific elements to be valid under the regulations.

The enclosed template authorization was prepared to comply with the HIPAA privacy regulations. The University of Southern California and its respective Institutional Review Boards have approved this document for use. It should be provided to the research subject during the informed consent process. The investigator should obtain the signature of the subject (or his or her personal representative) and the date of signature, as indicated on the last page of the document. The authorization should be appended to the informed consent document.

Specific Instructions

Instructions for completing specific sections of the authorization are in italics in the authorization document. You may delete the instructions in italics in your final version of the document.

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 that the investigator and/or subject does not want revealed to the provider from whom health information is being requested.

Authorization to Obtain and Use Health Information From Provider for Research Study

1. 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 subject. Please check ALL the boxes that apply. The following are some examples:

- IF THE RESEARCHER DOES NOT KNOW THE NAMES OR LOCATIONS OF ALL OF THE PROVIDERS WITH RELEVANT HEALTH INFORMATION, PLEASE CHECK THE BOX LABELED, “All health care providers with health information about me.”

YOU SHOULD CHECK THIS BOX IF IT IS POSSIBLE THAT THE PATIENT MAY NEED TREATMENT OR ADMISSION AT ANOTHER FACILITY NOT OTHERWISE LISTED IN THE AUTHORIZATION (e.g., emergency room treatment) AND YOU WOULD NEED ACCESS TO THOSE HEALTH RECORDS.

- IN MANY CASES, THE RESEARCHER WILL BE OBTAINING HEALTH INFORMATION FROM A USC AFFILIATED HOSPITAL (Norris Cancer Hospital, USC University Hospital, Childrens Hospital Los Angeles, LAC+USC Medical Center). IN THOSE CASES, PLEASE CHECK THE BOX NEXT TO NAME OF THE EACH APPLICABLE HOSPITAL.
- IF THE RESEARCHER IS OBTAINING HEALTH INFORMATION FROM ANY USC PHYSICIAN, PLEASE CHECK THE BOX LABELED, “USC Care Medical Group, Inc. and its affiliated practice plans.”
- IF THE RESEARCHER ALSO IS A CLINICIAN GENERATING CLINICAL INFORMATION IN THE COURSE OF THE RESEARCH, PLEASE CHECK THE BOX LABELED, “The researcher/clinician generating health information through this study.”

- IF THE PROVIDER IS NOT OTHERWISE LISTED, PLEASE CHECK THE BOX LABELED, “Other,” AND GIVE THE NAME AND/OR LOCATION OF THE PROVIDER.

2. On page 2, please check the applicable box to indicate the type of health information you wish to access and use. If the researcher intends to obtain any of the following health information from the provider:

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

the regulations require the researcher to obtain a specific authorization for use and or release of that information. Accordingly, have the subject initial those provisions that apply, if any, to your research study. Otherwise, you should leave those spaces blank. Please refer to USC’s HIPAA policy, CLIN – 203, “Special Privacy Considerations,” for further guidance about use and disclosure of these categories of health information.

Authorization to Use Health Information for a Research Database

This section of the authorization only will apply if the researcher intends to input 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 access or extract information from the database. If this section is not applicable, please remove this section from the document.

Use and Disclosure of Health Information by Pharmaceutical Company Sponsor

State law requires a research sponsor that is a pharmaceutical company to inform the subject if the sponsor intends to use the subject’s health information for reasons beyond the research study and to obtain the subject’s authorization for those uses. However, whereas USC can condition a subject's participation in a study on the subject signing a HIPAA authorization, the sponsor may not condition a subject's participation on his or her agreement for the sponsor to use his/her health information for the purposes that are not related to the study. For these reasons, this section states that the subject is not required to agree to this provision in order to participate in the research study. In addition, if the subject does agree, he or she must separately initial this section where indicated.

This section of the authorization may not be applicable in all cases. THE SPONSOR IS RESPONSIBLE FOR DETERMINING IF IT IS USING HEALTH INFORMATION IN A MANNER THAT TRIGGERS THIS STATE LAW PROVISION. HOWEVER, IF YOU DISAGREE WITH OR HAVE QUESTIONS ABOUT A SPONSOR’S DETERMINATION, PLEASE CONTACT THE OFFICE OF COMPLIANCE FOR CLARIFICATION. If this section is not applicable, please remove this section from the document.

Term of this Authorization

This section should be completed by the research team prior to giving the authorization to subjects. The number of years must be specified to constitute a valid authorization under state law. It is recommended that the term be 20 years or less.

Refusal to sign/Right to Revoke

Please insert the IRB that has jurisdiction over this study. Please elect from one of the following:

- IRB Chair, HSC Institutional Review Board, 2020 Zonal Avenue, Room 425, Los Angeles, CA 90033
- IRB Chair, University Park Institutional Review Board, ADM-300, Los Angeles, CA 90089-4019

No Modifications

This authorization may not be modified except 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.