

Authorization for Use and Disclosure of Protected Health Information for Research Purposes

State and federal medical privacy laws protect the use and release of your personally identifiable health information (“Protected Health Information”). By signing this document, you authorize the Principal Investigator and research team to access, use and/or release your Protected Health Information for the following research study:

Title of Research Protocol: _____

Name of Principal Investigator: _____

This research study is described in full in the associated informed consent document.

The health information that we may use or disclose for this research includes your research record and [may be updated to be more specific] complete health care records. This may include, for example, medical history, results of examinations, treatment and outcomes, results of lab tests, or other information contained within your health, billing and/or other records at the:

[specify, for example:

- University Eye Institute
- The Ocular Surface Institute
- University Health Center
- UH Athletics
- Other covered component/entity. If unsure if a covered entity, please contact the IRB.]

Special permission is required to release drug, alcohol, and substance abuse records, HIV/AIDS-related information, genetic information and mental health information. These kinds of records will not be used or disclosed in this study unless a separate section is included below and you specifically allow us to do so by initialing the applicable box(es).

In addition to the UH research team, your Protected Health Information may be used by and/or disclosed to [include all that apply, as well as any other potential disclosures]:

- Researchers from other entities in the U.S. or other countries who are collaborating with the University of Houston to conduct the research [name other entities]
- Members and staff of the UH Institutional Review Board (IRB)
- The sponsor of the research [name of the funding agency]
- The approved data and safety monitoring or coordinating committee for this study
- The approved data coordinating center for this study; and/or

- Others with oversight of the study or who are required by law to review the quality and safety of the research, such as the U.S. Food and Drug Administration [this statement must remain, but only include FDA language if study is under FDA oversight] and/or the Health and Human Services Office of Human Research Protections.

In addition to the purpose of the research described in the consent form, your Protected Health Information may be used to:

- Improve the design of future studies;
- Share with business partners of the sponsor;
- File applications with U.S. or foreign government agencies to get approval for new drugs or health care products; or
- As authorized by federal/state medical privacy laws or as otherwise required or authorized by federal or state law.

Please note that:

- The research team will use and protect your information as described in this Authorization; however, once your health information is released by the University of Houston, it may not be protected by the privacy laws and might be shared with others. A member of the research team will be happy to respond to any of your questions regarding this.
- Signing this authorization is voluntary. You are not required to agree to the use or disclosure of your Protected Health Information. Signing this authorization is not a condition for treatment (other than treatment related to this research study), payment, or enrollment or eligibility for health plan benefits. However, if you do not sign the document, you cannot participate in this research study and you may not receive research-related treatment.
- The University of Houston will not condition routine clinical treatment, payment, or enrollment or eligibility for benefits based on whether or not you sign this Authorization.
- You may change your mind and revoke (take back) this Authorization at any time. Before doing so, you may want to ask someone on the research team if canceling will affect your research-related medical treatment. If you cancel your permission, you may no longer participate in the research study. Also, if you cancel, your Protected Health Information that has already been collected, used, and/or disclosed in reliance upon this authorization may continue to be used, and to the extent it has already been disclosed may be subject to redisclosure. In addition, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study to the extent authorized/required by law.

Optional research activity [Delete if not applicable] If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

Specific Authorizations: [Please initial below] [Include applicable lines only]

_____ I agree to the release of my drug, alcohol, and substance abuse records.

_____ I agree to the release of my HIV/AIDS-related information, including HIV/Aids test results.

_____ I agree to the release of my genetic information (including genetic test results).

_____ I agree to the release of my mental health information (except psychotherapy notes).

This Authorization does not have an expiration date. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this authorization, please contact the research team to tell them of this decision. They will give you an address so that you can inform the investigator in writing.

You must also notify the Director of the UH Office of Research Policies, Compliance, and Committees to revoke the authorization.

Director, Office of Research Policies, Compliance, and Committees
University of Houston Division of Research
4302 University Drive, Suite 316
Houston, TX 77204-2015

Signing this form indicates that you have read and/or understand the information in this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed authorization.

Signature of Participant
(or Participant's Personal Representative)

Date

Printed Name of Participant
(or Participant's Personal Representative)

If applicable, a description of the Personal Representative's authority to sign for the Participant