

New York College of Health Professions

Authorization for Use and Disclosure of Protected Health Information in Research

Section I. Research Information

Sponsor, if applicable: _____

Title of the Study: _____

Study Number: _____

NYCHP IRB Protocol Number:

Name of Principal Investigator: _____

Participant's Name: _____

General Information

In order for you to participate in this study, you must authorize the researchers to access and/or obtain and/or use some of your personal health information. Medical treatment will not be conditioned on signing this authorization, unless the treatment is related to the research study described above.

This form describes what health information about you will be collected during this study and who may use, disclose and receive your health information.

signing this form, you agree that designated health information may be used and disclosed during this study. We will only collect information that is needed for the study. Your health information will only be used and given out as explained in this Authorization form or as permitted by law.

[Participant access to health information. Check one of the following, as applicable.]

- [For blind studies] Due to the nature of this study, signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

OR

- [For other studies] You have the right to inspect or copy your protected health information to be used or disclosed as permitted under federal law (or state law to the extent the state law provides greater access rights).

Please read the information carefully. Please feel free to ask questions about this Authorization, New York College of Health Professions's ("NYCHP's") Notice of Privacy Practices, or the study before signing this form.

Section II. Uses and Disclosures Covered By This Authorization

[Check as applicable: Modify the list as needed.]

A. I hereby authorize:

- New York College of Health Professions, Health Care Center(s)
- New York College of Health Professions, Clinic Pharmacy(s)
- New York College of Health Professions, Sport Psychology Program
- New York College of Health Professions, Center for Assessment and Intervention

to use or disclose the following protected health information ("PHI"):

- Medical and mental health treatment and related information, including, but not limited to: personal and family medical history, information from laboratory and diagnostic tests, psychological tests, blood and urine tests, x-rays, physical exams and other tests or medical procedures performed as part of this research study.
 - Protected Health Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
 - Protected Health Information in medical records located either in your health care provider's office at NYCHP and/or at other health care facilities where you have received treatment.
 - Medical billing records;
 - [List any additional information that may be obtained from participants that is not listed above.]**
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B. Who may use, share and receive your health information as part of this study

During the study, the investigators and other authorized individuals involved in the study at New York College of Health Professions will see your health information and may give out your health information to the persons or entities listed in section C. These individuals include the research investigator and the research staff, the human research

oversight board (Institutional Review Board or IRB) and its staff, legal counsel, research office, compliance office, administrators of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly.

C. Additional Individuals and Entities who may use, share and receive your protected health information.

Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:

- Governmental entities that have the right to see or review your health information
- The Office for Human Research Protections (OHRP)
- The Food and Drug Administration (FDA)
- The National Institutes of Health (NIH)

If any study procedures are billed to your iNYCHPrer, then your healthcare insurer (including Medicare and Medicaid) and their intermediaries (companies contracted to process claims) may also have access to your medical and billing records related to the study.

The following researchers, companies and/or organization(s) outside of New York College of Health Professions may also use, share and receive your health information in connection with this study:

[Insert the appropriate names of non-NYCHP co-investigator(s) and other research sites and organizations that will use and share information, as applicable or delete]

- Health care facilities, research site(s), researchers, health care providers, or study monitors involved in this study.
- Private laboratories and other persons and organizations that analyze your health information in connection with this study.
- The Research Sponsor and companies owned or connected with the Sponsor. **[Insert name(s) of sponsor(s) and the names of the sponsors subsidiaries participating in the research].**
- Independent data and safety monitoring boards and others who monitor the conduct of the study.
- Contract Research Organization (CRO) or Coordinating Center, if applicable.

Others:_____.

D. Purpose of the use and disclosure of health information

The reason we are asking for your permission to use and disclose your protected health information is, for example, to allow the College, regulatory agencies and study sponsors to assess and/or assure compliance with the study protocol, to evaluate the effectiveness of the study, and/or to provide protection to you as a research study participant. The disclosure and use of your information will continue after your participation in the study has ended. There is no expiration date for the use of your health care and billing records from the study. Any information about you disclosed to the individuals/entities identified above may be re-disclosed by them; however, such re-disclosure is not under the protections of this Authorization and may no longer be protected by state or federal law.

The Sponsor and its agents may disclose your health information to each other and use it for the purposes of monitoring the study, future research, the development of scientific databases and the development of new products. The Sponsor and its agents may also disclose your health information to the FDA and other regulatory agencies as necessary to report information regarding the safety and effectiveness of any study product or device that is the subject of this Study.

Even if the terms of the consent say otherwise, this Authorization does not expire, unless you revoke your Authorization in writing.

* * * * *

I have read the above information provided and I am providing my authorization for the use and disclosure of health information as described above.

I understand that I have the right to revoke this authorization, in writing, at any time without penalty or loss of benefits to which I am otherwise entitled, or without jeopardizing my medical care unrelated to the study provided by my health care provider by sending written notification to:

[Insert name/address of Principal Investigator]

I understand that I may also revoke this authorization through the procedure described in NYCHP's Notice of Privacy Practices. I understand that a revocation is not effective to the extent that those listed on this form including but not limited to the covered entity, researcher, research sponsor or affiliated companies has relied on the authorization for the use or disclosure of the protected health information.

I hereby acknowledge that I have read and understand the preceding Authorization form. All of my questions about this Authorization form have been answered to my satisfaction. By signing below, I permit **[Insert name of Principal Investigator]** and the others listed on this form to use and share my health information for this study. I will be given a copy of this signed form.

Signature of Participant or Personal Representative

Date

Name of Participant or Personal Representative

Participant Date of Birth

Description of Personal Representative's Authority