Authorization to use and disclose personal health information for research at Temple University, Temple University Health System Affiliates, and Temple University Clinical Faculty Practice Plan

Information that will be collected from you and disclosed

During the course of this research study, which is described by title in the attached consent form and study-specific document, certain personal health information will be collected and disclosed to recipients identified in this document. It is important for you to know that your personal health information may identify you by name, address, telephone number, photograph, social security number, health plan number, and date of birth, dates relating to various tests and procedures, or other personally identifiable information. This information may be obtained from your medical records, physical examinations and procedures: (a) to determine if you are eligible to participate in the research study or (b) created as a result of your participation in the research study.

How your information will be used and to whom it will be disclosed

By signing this authorization form, you give Temple University, Temple University Health System affiliates, and Temple University Clinical Faculty Practice Plan, Temple University Institutional Review Board, and the investigator(s) named in the attached study-specific document, permission to use your personal health information and to disclose this information to the following recipients (as applicable): sponsor; sponsor’s agents; governmental entities overseeing research in the United States and abroad, which may include in the United States, the Food and Drug Administration and the Department of Health and Human Services. It is important for you to know that the recipients, and their agents or representatives, will take all reasonable efforts to maintain your personal health information in confidence, and to use appropriate safeguards to prevent further use or disclosure by those not authorized to use or disclose your personal health information. However, once your health information is disclosed to the recipients, then your personal health information may no longer be protected by federal privacy laws and regulations and there is a potential for re-disclosure of this information. However, the laws of the Commonwealth of Pennsylvania or your state of residence may provide further privacy protection.

How you can access your information

You should know that you have the right to see and receive a copy of your personal health information that was collected from you during the research study for as long as this information is maintained by Temple University and the principal investigator. However, while the research study is in progress, you will not be able to access your personal health information in order to preserve the integrity of the research. You will be able to access this information when the study is completed. There may be associated charges for copying these materials.

How to revoke your authorization

You should also know that you can revoke your authorization to disclose your personal health information at any time by sending a written notice to the principal investigator and Temple University at the address listed in the attached study-specific document. Should you decide to revoke your authorization, Temple University and the principal investigator will stop collecting your study-related health information. In addition, Temple University and the principal investigator will stop using and disclosing your personal health information, except to the extent such information was collected prior to your revocation. For instance, Temple University, principal investigator, recipients, and their agents or representatives may use the information obtained before you revoked your authorization in order to preserve the scientific integrity of the research study.

Important notices

You will receive a signed copy of this authorization to acknowledge your approval for Temple University and the principal investigator to the release your personal health information. If you do not sign this authorization or if you revoke this authorization, the principal investigator and Temple University cannot allow you to participate in or to continue to participate in the research study identified in the attached study-specific document.

STUDY-SPECIFIC DOCUMENT

1. RESEARCH STUDY: [INSERT STUDY TITLE]

2. PRINCIPAL INVESTIGATOR: [INSERT PRINCIPAL INVESTIGATOR NAME]

3. EXPIRATION DATE: This Authorization does not expire.

4. FOR HIV, MENTAL HEALTH OR SUBSTANCE ABUSE RECORDS ONLY

(THE PI HAS THE OPTION TO DELETE SECTION #4 IF IT DOES NOT APPLY TO THE STUDY):

HIV: I understand and acknowledge that my HIV records will be used or disclosed as a part of the research. I consent to such use or disclosure for a period of: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Signature of Subject: Date:

Mental Health: I understand and acknowledge that my mental health records will be used or disclosed as a part of the research. I consent to such use or disclosure for a period of: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Signature of Subject: Date:

Substance Abuse: I understand and acknowledge that my substance abuse records will be used or disclosed as a part of the research. I consent to such use or disclosure for a period of: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Signature of Subject: Date:

5. OTHER INFORMATION:

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Signature of Subject Date

Printed Name of Subject

Signature of Personal Representative of the Subject Date

Printed Name of Personal Representative of the Patient and Relationship to Subject

Signature of Person Collecting Authorization Date

Printed Name of Person Collecting Authorization

Instructions for Completing the Study-Specific Document:

*DO NOT INCLUDE THIS PAGE IN THE MATERIALS GIVEN TO SUBJECT*

1. RESEARCH STUDY: Enter the full title of the research protocol including identification number assigned to the protocol

2. PRINCIPAL INVESTIGATOR: Enter the name, department affiliation and address of the PI

4. HIV, Mental Health or Substance Abuse: If the research will involve the use and/or disclosure of any HIV, mental health or substance abuse records, the subject MUST indicate the duration for authorization of release of such information and provide a separate signature and date where indicated.

5. OTHER INFORMATION: If applicable, enter any special elements of PERSONAL HEALTH INFORMATION that will be used, created and/or disclosed, and also indicate whether any samples of blood, urine or tissue will/may be stored for additional laboratory testing/storage for research at a later date.