**Jefferson Office of Human Research**

**Authorization to Use or Disclose Health Information for Research**

**Version Date – FOR OHR USE: 4/12/19**

**Department**:

**Principal Investigator**:

**Study Title**:

To complete this HIPAA authorization, please modify it as appropriate for your study. Generally, you will modify the yellow highlighted text as appropriate for your study or remove it if it is a note to you, the author. As you work, please remove all highlighting and prompts to the author. If Jefferson plans to recruit subjects from EU countries, contact Jefferson’s General Data Protection (GDPR) Officer for additional required language.

The purpose of this research is explain the purpose of the study using conversational language.

# Privacy and Confidentiality: HIPAA Authorization

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

* Information from your medical records
* Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
* Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
* Information collected about any research related injury
* Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
* List any additional information that will be collected that is not included above. Examples: demographics including race and ethnicity (required if the research is federally funded), labs, imaging results (e.g., x-rays), questionnaires, photos, video, audio and any other information/results collected for this study.

Your personal information will be used by and shared with the following:

Modify the list below as necessary.

* Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
* Research personnel at Rothman
* Institutional Review Boards (ethics committees that review research) including insert reviewing IRB(s)
* Health insurance providers
* Insert Sponsor (sponsor), which is providing money to the researcher to carry out this research
* Research monitors hired by the sponsor to oversee the study and review health care records to ensure study-related information is correct
* Government Agencies like the Food and Drug Administration (FDA)
* An organization such as a contract research organization (CRO) that has been hired to coordinate the study (Specify if known)
* Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
* Groups monitoring the safety of the study such as a data and safety monitoring committee
* Others as required by law
* Add others as necessary

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. If you want to end your permission to collect your information, please inform the investigator in writing. If you do this, no more information will be collected, but the information already collected will still be used. If you end your permission to use your personal information, you will not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

One of the following statements must be included if the research involves the collection of identifiable private information or identifiable biospecimens.

Your private information and specimens, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

OR

Your private information and specimens will not be used or distributed for future research studies, even if the identifiers are removed.

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Make sure you discuss your concerns and have all your questions answered before deciding to take part in this research.

**Contacts**

**If you are having a medical emergency, call 911 or go to an emergency room right away. You should let emergency personnel or providers know that you are taking part in this study.**

Contact Name: Phone Number:

**Signatures**

Make sure the finished signature page fits on one page.

Patient/Subject: By signing this form, you are agreeing that:

* You were given the opportunity to read this form.
* All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
* All your questions have been answered to your satisfaction.
* You were not pressured and you voluntarily agree to take part in this research.

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Your Name Your **Signature**  Date

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Name of Person Obtaining/ Signature of Person Obtaining/ Date

Assisting with Consent Assisting with Consent

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Name of Investigator Signature of Investigator Date

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Name of Minor Signature of Minor Date

*(To be completed if the subject is a minor and this form will be used as the parental consent and the child assent. The child must be capable of understanding this form.)*

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Name of Witness Signature of Witness Date

*(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)*

[ ]  **Copy of Signed and Dated HIPAA Authorization Form Given to the Subject/Parent/LAR**