**Jefferson Office of Human Research**

**Verbal Consent with Optional Use of Disclosure of PHI OHR-8H**

**Version Date – FOR OHR USE: 1/20/20**

**Department**:

**Principal Investigator**:

**Study Title**:

**Lay Title:**

To complete this consent form, 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. When creating the consent, fill in all the yellow prompts. The only prompt that can be left blank is the blank line for the name of the interviewer.

**Please use simple words and short sentences when adding study specific information to this consent form.**

Any questionnaires and other subject materials should be included in the IRB submission.

Note: In order to use the OHR-8H, non-exempt studies must meet federal criteria for waiver of written consent (See OHR Policy IC 706) and should be submitted with OHR-3 or OHR-5, depending on whether identifiers are being collected.

Hello, my name is \_\_\_\_\_\_\_\_\_\_. I’m from Jefferson’s Department/Division of Insert Dept./Div.

I am contacting you because Explain how the subjects names are obtained.

We are conducting a research study that consists of asking you questions about Insert what the questions are about. Describe any other study procedures. This will take about Insert duration to complete. About X people will take part in this research at Jefferson and about X in the whole study.

The purpose of this research is Explain the purpose of the study using conversational language. This section is typically 1 paragraph and should make sense to any reader.

The alternative to being in this study is to not take part. Your participation is voluntary. 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 or loss of benefits that you would normally get.

Describe the possible benefits. -OR- You may not personally benefit from taking part in this research, but other people may be helped by what is learned.

A risk of taking part in this study is that you may not feel comfortable answering some of the questions. If any question makes you feel uncomfortable, you do not have to answer the question.

The other possible risk is a loss of the confidentiality of your information. Describe how confidentiality will be maintained. Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

Insert any other risk.

There will be no cost to you for taking part in this study. Describe the payment schedule and/or reimbursement OR. You will not be paid for taking part in this study. If this research or the information or specimens you provide result in commercial profit, you will not receive any money.

Complete if applicable. Jefferson is being paid by Insert Entity to conduct this study.

Include if the study is longer than 1 encounter. New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete.

Include section below if you are collecting PHI

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. I will explain why your information is being collected, what information will be collected, and who will have access to it. By agreeing, 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:

* The information from the questionnaire
* List any information that will be collected. Examples: Information from your medical records, Demographic information such as name, gender, birth date, ethnicity (required if research is federally-funded), 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

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.

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.

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Do you agree to participate in this research study as it has been described to you?

If you have any questions about this research, you can contact:

Name: Insert Phone Number: Insert email: Insert

If you need to contact someone other than the study personnel about a concern or your rights as a research subject, please call the Jefferson IRB at: 215-503-0203, 215-503-8966, or 215-955-4239. Modify for your location if needed

**Investigator writes name of participant and signs to verify verbal response of subject:**

Name of research participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

🗆 YES, the participant consented 🗆 NO, the participant did NOT consent

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Name of Investigator Signature of Investigator Date

Following the verbal consent procedure, the research subject must be provided with a separate letter or information card that clearly identifies a contact person within the department. If the researcher does not already have the subject’s address, then this information must be collected during the phone interview. The letter or information card must be part of the first written communications to the subject. The letter or information card must include the following:

1. Contact person name and title
2. Department/Division address
3. Department/Division telephone and facsimile numbers
4. If you need to contact someone other than the study personnel about a concern or your rights as a research subject, please call the Jefferson IRB at: 215-503-0203, 215-503-8966, or 215-955-4239. Modify for your location if needed