**RESEARCH SUBJECT CONSENT FORM**

**Title:** Title

**Protocol No.: TU IRB protocol number**

**Investigator:** Name

**Daytime Phone Number:** Phone Number

**Email:** Email address

**RESEARCH CONSENT**

You are being asked for your consent to take part in a research study. This consent document describes the key information that we believe most people need to decide whether to take part in this research.

**Why am I being invited to participate in this research?**

Include a brief introduction to the research and a statement indicating why the participant is being asked to take part in this research.

# How long will I be in this research?

We expect that your taking part in this research will last \_\_\_\_\_ hours, days, weeks, months, years, or until a certain event.

# What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will be asked to complete (Choose the applicable data collection method:) a(n) interview/focus group/survey/interview and survey.

If the study involves multiple interviews, focus groups, or surveys, describe the number and frequency (e.g., 5 interviews over about 6 months).

Include how long each data collection will take (e.g., each survey will take between 20 and 40 minutes).

Include if the interview, focus group, or survey data will be identifiable and when identifiers will be destroyed.

Include the applicable recording information if the study is using interviews or focus groups: The interview(s) will not be recorded, will be audio-recorded, will be audio- and video-recorded.

In addition to the interview/focus group/survey/interview and survey, information will be collected from your medical records. The information will include your give a general overlay of what will be extracted from their records.

If collecting medical information include the above statement. Additionally, please clearly state the type of information that will be gathered from self-reports and the information that will be collected via medical record.

**What are the risks of this study?**

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable. (Include a statement, if applicable, to discuss any counseling/resources that may be available or any mandatory reporting requirement that must be met because of concerns that are raised.)

Research that uses health information from your medical record can affect your privacy. Your participation in this research will be held strictly confidential and only a code number will be used to identify the stored data. Include the following if a master link will be maintained: However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.

# What happens to the information collected for this research?

Your private information may be shared with individuals and organizations that conduct or watch over this research, including, if applicable:

* The research sponsor
* People who work with the research sponsor
* Government agencies, such as the FDA or Department of Health and Human Services
* The Institutional Review Board (IRB) that reviewed this research
* Temple University
* Temple University Health System and its affiliates
* List others with whom private information will be shared

Clarify the extent to which data will be held confidential (i.e. if identifiers will be maintained, who data will be shared with, how data will be protected, etc.). Include information regarding audio or video recording of participants (i.e. if required for participation, how long recordings will be kept, if transcripts will be sent to participants to ensure fidelity).

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your personal information. These are described in an attached document titled “Authorization to use and disclose your protected health information.” (If accessing medical records, include the previous statement as well as a HIPAA Authorization)

We may de-identify this data and share it with other researchers for research that is currently unknown.

# Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number or email listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (215) 707-3390 or irb@temple.edu if:

1. You have questions, concerns, or complaints that are not being answered by the research team.
2. You have questions about your rights as a research subject.

# Will I be paid for taking part in this research?

If subjects will be paid for participation:

For taking part in this research, you may be paid up to a total of $\_\_\_\_[If the payment is in gift cards, include that fact.]

Federal tax law requires you to report this payment as income to the Internal Revenue Service. You may be asked to tell us your social security number, full name, address, or other identifying information in order to compensate you for your participation. We may request this because we are required to report cumulative payments more than $599.00, to the Internal Revenue.

If subjects will not be paid, either delete this section, or include the following statement:

You will not be paid for taking part in this research.

**Your signature documents your permission for you to take part in this research.**

|  |  |
| --- | --- |
| Signature of person providing consent | Date |
| Printed name of person providing consent |  |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent |  |