**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, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

**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. (There is often the intent to collect data over a period of years. Ensure that the duration of study participation reflects the duration of all data collection.)

The information that we collect for the registry will be stored and used indefinitely.

## What are the study procedures?

Information (data) will be collected from your medical records. The information will include your diagnosis, treatments, and medications (include any other data points).

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

### Risks associated with completing questionnaires:

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 Food and Drug Administration or the 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.).

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

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?**

Use the following language verbatim:

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 Service.

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 |  |

Signature block for research that may or will involve children as subjects and may also include adult subjects that have capacity to consent

|  |
| --- |
| Your signature documents your permission for you or the individual named below to take part in this research. |
|  |  |  |
| Signature of adult subject capable of consent, child subject’s parent, or individual authorized under state or local law to consent to the child subject’s general medical care  |  | Date |
|  |  |  |
| Printed name of adult subject capable of consent, child subject’s parent, or individual authorized to consent to the child subject’s general medical care |  |  |
|  |  |  |
| Printed name of subject(not required if subject personally provided consent) |  |  |

Always add:

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

If the person obtaining assent will document assent on the consent form, add:

|  |
| --- |
| * I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.

OR* The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |
|  |  |  |
| Signature of person obtaining assent |  | Date |
|  |
|  |
| Printed name of person obtaining assent |

If documentation of assent is by having the child sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of assenting subject |  | Date |