**RESEARCH SUBJECT CONSENT FORM**

**Title:** StudyTitle

**Protocol No.:** Temple protocol number

**Investigator:** Name

TempleAddress

 City, State, Zip Code

 Country

**Email:** Investigator’s email address

**Daytime Phone Number:** Phone Number

**RESEARCH CONSENT**

This is an invitation to take part in a research study. We want you to have the key information upfront to decide if participating is right for you.

**Why are we doing this research?**

Explain the overall goal and purpose of the study. For example: "We're studying how exercise affects quality of life in older adults."

## How long will the research take?

You can expect to be involved for roughly \_\_\_\_ (hours/days/weeks/months/years). Remember, you can always stop being in this research at any time.

**What will happen if you join this research?**

We will collect some information from your medical records. If information from medical or other records will be collected for this research, include (broadly) what that information will be.

**Are there any risks?**

Because we collect health information from your medical records, there is a small risk of your privacy. Your information will be kept confidential, and we’ll only use a code number to identify your data. Include the following if a key will be maintained: However, because there will be a link between the code and your identity, we can’t promise complete secrecy.

**Are there any benefits?**

Explain the potential benefits for subjects or others. For example: "You may see a small improvement in your quality of life as a result of exercising more" or “There will be no direct benefit from joining this research. However, you will contribute to understanding better XXX”

**Who will see the information that you give?**

It is important to know that by agreeing to join this research, your identifiable information may be shared with people who are running or overseeing the research, including (only include bullets if they are applicable to this research):

* The sponsor funding the research (only if applicable)
* People working with the sponsor (only if applicable)
* The Office for Human Research Protections (OHRP) (applicable if federally funded)
* The Food and Drug Administration (applicable if evaluating a drug or medical device)
* The Institutional Review Board (IRB) that approved the research
* Individuals from Temple University and Temple University Health System and its affiliates who oversee research
* (List any specific institutions or organizations, like universities or hospitals)

We may publish the results of this research, but we will not include your name or any other information that could identify you.

We may use or share de-identified data (i.e., data that does not contain your identifiers) from this for future research studies. Also, we may share de-identified data with other researchers for future research without asking for your separate consent.

If obtaining HIPAA Authorization include: Federal law provides separate protections for your personal health information. If we need to access your medical or psychological records for this research, you will be asked to sign a separate HIPAA authorization form. This form will explain exactly how your information will be used and protected. (Note: Answering questions about self-reported medical history does not require HIPAA authorization.)

**Who can answer your questions about this research?**

If you have any questions, concerns, or complaints about the research, you can contact the research team at the phone number or email listed on the first page.

This research is overseen by an IRB, an independent committee that reviews research studies. You can contact the IRB at (215) 707-3390 or irb@temple.edu if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.

**Will you be paid?**

Explain any payment and its form (e.g., gift card, cash, etc.). If none, this section can be omitted. Also, say when the payment will be received.

We might ask for your social security number, full name, address, or other identifying information to pay you for being part of this research. Temple University is required to report payments of more than $599.00 to the Internal Revenue Service, even if the payments come from participating in multiple studies at Temple. You will get a tax form called a 1099-MISC if you earn a total of more than $599 from Temple University for the year.

When you sign this, you agree to be in the research study

Signature of adult participant Date

 Printed name of participant

 Signature of person obtaining consent Date

 Printed name of person obtaining consent

**Signature block for studies include children as subjects and may also include adults who can consent**

When you sign this, you agree to be in the research study

Signature of adult participant, child’s parent, or legally authorized representative Date

Printed name of adult participant, child’s parent, or legally authorized representative

Printed name of participant (remove if person provides 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 in a way the person can understand, and they have agreed to be in the study

OR

* The person is unable to assent because their ability to understand or communicate is too limited

 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 participant Date