**RESEARCH SUBJECT CONSENT FORM**

**Title:** Title

**Protocol No.:** Sponsor’s protocol number

**Sponsor:** Name

**Investigator:** Name

 Address

 City, State, Zip Code

 Country

**Daytime Phone Number:** Phone Number

**24-hour Phone Number:** Phone Number (A 24-hour phone number is required for studies that are more than minimal risk)

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| Instructions for Research Consent Summary**We encourage all research studies whose consent document is longer than 4 pages to include an initial concise summary. (If your research is federally funded or is conducted in New York, Virginia, or Maryland, and is not subject to FDA regulations, and the consent document is longer than 4 pages, an initial summary is required.) The initial summary cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter.**The templated statements in the “RESEARCH CONSENT SUMMARY” below provide a guide to the content of the summary. The content should be adjusted to be appropriate for the specifics of the study. Under each heading, limit the description to the key information that is relevant to why one might or might not want to take part in the research. Defer the greater detail to the body of the consent form following the initial summary For example, with a cancer trial the initial summary should identify the most important risks, like the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them. The initial summary should emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form. |

# RESEARCH CONSENT SUMMARY (See above instructions for if this section is needed)

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

# What should I know about this research?

* Someone will explain this research to you.
* Taking part in this research is voluntary. Whether you take part is up to you.
* If you don’t take part, it won’t be held against you.
* You can take part now and later drop out, and it won’t be held against you
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

# 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.

# Why is this research being done?

The purpose of this research is to \_\_\_\_\_. Explain in no more than a few sentences the main purposes of the research.

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

If you decide to take part in this research study, the general procedures include \_\_\_\_\_. Briefly outline in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part in the research study.

# Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include \_\_\_\_\_. In simple language, explain the risks and discomforts that are most likely to affect someone’s decision about whether to take part in the research study. Identify the most important risks, like the information that a doctor might deliver in the clinical context. Emphasize how those risks are changed by taking part in the study. Include the complete list of reasonably foreseeable risks in the main body of the consent form.

# Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include \_\_\_\_\_. In simple language, explain the reasonably expected benefits to subjects that are most likely to affect someone’s decision about whether to take part in the research study. If there are no benefits, state: It is not expected that you will personally benefit from this research.

Possible benefits to others include \_\_\_\_\_. In simple language, explain the reasonably expected benefits to others that are most likely to affect someone’s decision about whether to take part in the research study.

# What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include \_\_\_\_\_. List the major approved alternative options that are available that may be advantageous to the subject. If this is a study in which there is no disease or condition being treated, you can eliminate this section from the summary, and include it only in the body of the consent. If there are no alternatives, this section can be omitted.

# What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is Describe any additional information that may be important in this specific study, such as large out of pocket expenses, subject responsibilities that many people might consider burdensome (e.g., abstinence from sexual relations, cigarettes, or alcohol, inability to drive a car while taking study medication, need for overnight stays or admittance to a secure facility), unusual issues related to privacy or confidentiality (e.g., situations where the subject’s research participation is likely to be reported in the media), or serious implications for future treatment (e.g., taking the study drug may limit future treatments options.) If there is no other information in this category, this section can be omitted.

**DETAILED RESEARCH CONSENT**

Organize the information in sufficient detail relating to the research in a way that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. Do not merely provide lists of isolated facts.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

When the research involves consent by a legally authorized representative or parent, and this consent is specific to the child (i.e., the parent/guardian is not participating in any research activities, including surveys, or they are signing a separate consent describing their responsibilities/participation), include the next paragraph:

In this consent form “you” generally refers to the research subject. If you are being asked as the legally authorized representative, parent, or guardian to permit the subject to take part in the research, “you” in the rest of this form generally means the research subject.

# What should I know about this research?

* Someone will explain this research to you.
* This form sums up that explanation.
* Taking part in this research is voluntary. Whether you take part is up to you.
* You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
* You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

# Why is this research being done?

The purpose of this research is to explain in simple terms the main purposes of the research. You can use simple illustrations, diagrams or figures if they are helpful in the explanation.

About \_\_\_\_ subjects will 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?

Tell the subject what to expect using simple terms. Include all procedures done because the subject is taking part in this research, including procedures to monitor subjects for safety.

Do NOT describe procedures that will be performed regardless of whether the subject takes part in this research.

When appropriate for your research, include the following items:

Describe where this research will be done

Provide a time-line description of the tests and procedures that will be done, including screening procedures. You can use tables or charts if they are helpful to explain the schedule.

Describe each test/procedure in layman’s terms.

Describe each group or arm

If the research involves random assignment describe this and the probability of assignment to each group, For example:

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have a(n) \_\_\_\_\_ out of \_\_\_\_ chance (XX%) of being placed in each group. You cannot choose your study group.

If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind study design, as appropriate. For example:

During the research, you (or you and the Principal Investigator) will not know which group you are in. (Your study doctor can find out in case of an emergency).

* Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental
* If blood will be drawn, indicate how often and the amount in English units
* Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed
* For research on investigational drugs or devices, list any options for the subject to get the drug/device after the research, and who will pay for this.
* Describe any planned future research (extension study, follow-up study, analysis of specimens). Describe them and whether subjects will be asked to sign a separate consent form.
* Indicate whether the study treatment will be available at the end of the study.

If applicable, explain whether the subject will be told clinically relevant research results, and if so, under what conditions.

Include if the research may involve whole genome sequencing:

The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

# What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Describe the responsibilities of the subject.

Describe any warning or precautions that the subject needs to know

Describe requirements to follow the instructions as provided by the study team and to give them any new information about new medications, new medical issues, etc.

# Could being in this research hurt me?

In simple language and in a simple bullet format (whenever possible), explain the known possible risks and discomforts.

List risks and discomforts in order of most common and most likely to occur, with least likely to occur listed last.

If there are many risks, use a bulleted format. If known, provide the percentage or range of occurrence for the risks.

Describe the duration of the risks and discomforts.

Consider:

Physical risks (for example, medical side effect)

Psychological risks (for example, embarrassment, fear or guilt)

Privacy risks (for example, disclosure of private information)

Confidentiality risk (if identifiable information is being retained, then there is a risk of loss of confidentiality)

Legal risks (for example, legal prosecution or being reported for child abuse)

Social risks (for example, social ostracizing or discrimination)

Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)

# Will it cost me money to take part in this research?

Include for research that may result in additional costs to the subjects. This should match any terms defined in the contract with the sponsor, if applicable:

Taking part in this research may lead to added costs to you, such as: Describe these costs.

Include for research where insurance will be billed. This should match any terms defined in the contract with the sponsor, if applicable:

In some cases, insurance does not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

# Will being in this research benefit me?

If there are possible benefits to the subject:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include \_\_\_\_\_. Describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, describe them. Possible benefits to others include \_\_\_\_\_. Describe any benefits to others.

If there are no expected benefits to the subject but possible benefits to others/ scientific knowledge:

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_. Describe any benefits to others.

# What other choices do I have besides taking part in this research?

If there are alternatives:

Instead of being in this research, your choices may include:

List the major approved alternative options

For student subject pools, describe alternatives for course credit.

If there are no alternatives, delete this section

 [Include for research involving prisoners. Otherwise, delete.] Taking part in this research will not improve your housing or correctional program assignments. Taking part in this research will not improve your chance of parole or release.

# What happens to the information collected for this research?

Your private information include only if applicable and your medical record may be shared with individuals and organizations(if applicable) that conduct or watch over this research, including:

* 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
* When the procedures include communicable disease testing, include any disclosures mandated by state-law.

Include the following sentence if the research will be conducted by mandated reporters: Although this is not the purpose of this research, we are required to report instances of child abuse and/or neglect to the relevant university and law enforcement agencies.

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

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

For controlled drug/device trials (except Phase I drug trials**),** pediatric device surveillance trials, and NIH-funded clinicaltrials add the following language verbatim: (If the research does not require listing on www.clinicaltrials.gov, but will be listed anyway, you may use this language or a variation of this language. The IRB does not require this information when not required by FDA/NIH, even if the study will bested.)

A description of this clinical trial will be available on [www.ClinicalTrials.gov](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.

Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.

[Include if a HIPAA authorization is required. Note, self-reported medical history does not require HIPAA Authorization. HIPAA Authorization is required only if medical/psychological records are being accessed, otherwise delete.] 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.”

[Include for research involving prisoners. Otherwise, delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

***What is a Certificate of Confidentiality?***

[Include this section if the NIH has issued a Certificate of Confidentiality for this research (e.g., any new or ongoing research funded by the NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information).]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality helps protect your identifiable information and biological samples. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[You may use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

# 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 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 are not getting answers from the research team.
3. You cannot reach the research team.
4. You want to talk to someone else about the research.
5. You have questions about your rights as a research subject.

# Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

Describe reasons why the subject may be withdrawn. Include all reasons for withdrawal described in the protocol. For example:

It is in your best interest

You have a side effect that requires stopping the research

You need a treatment not allowed in this research

You become pregnant

The research is canceled by the sponsor

You are unable to take the research medication

You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

# What happens if I agree to be in this research, but I change my mind later?

Include if there are procedures for orderly termination of taking part in the research.

If you decide to leave this research, contact the research team so that the investigator can: Describe the procedures for orderly termination by the subject.

Include if there are potential adverse consequences to a subject who withdraws:

If you decide to leave the research early, there may be risks with this decision. These may include: Describe the adverse consequences.

[Include for FDA-regulated research. Otherwise, delete.] If you stop being in this research, already collected data may not be removed from the research database. You will be asked whether the investigator can collect data from your routine medical care. [Note: The consent document cannot give the subject the option of having data removed.]If you agree, this data will be handled the same as research data. [Note: If a subject withdraws from the interventional portion of a research and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to this research the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review research data related to the subject collected prior to the subject’s withdrawal from this research, and may consult public records, such as those establishing survival status.]

[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

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

If subjects will be reimbursed for travel:

You will be reimbursed up to $\_\_\_\_\_ for travel and incidentals.

[OR]

You will be reimbursed a per diem of up to $\_\_\_\_\_ to offset the costs of travel and incidentals. [This must be in accordance with the www.gsa.gov guidance].

Reimbursements are not considered taxable income and may be made only if a receipt is provided by the subject.

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.]

Your compensation will be broken down as follows:

Describe payment schedule in terms of amount

Describe when payments will be made

Describe the amount of payment if the subject drops out

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. This is because we are required to report payments more than $599.00, to the Internal Revenue Service and you will be sent a Form 1099-MISC if your total payment from Temple University is more than $599.00 for the year.

[Include if Greenphire will be used for payments. Additionally, the ClinCard FAQ sheet should always be provided when a ClinCard is assigned.]

Payments will be made to you using ClinCard, a secure, reloadable MasterCard debit card supported by Greenphire. We will [give/mail] you the card. You will be given one card for the entire time of your participation. You will also get a pamphlet about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study’s payment schedule. You may use this card online or at any store that accepts MasterCard.

Greenphire is a company working with Temple University to manage and process payments. Greenphire will be given your name, address, date of birth, and social security number. They will use this information only as part of the payment system, and it will not be given or sold to any other company. They will not receive any information about your health status or the study in which you are participating.

[Include the following 2 sentences if the research data is being stored in a de-identified manner.]This information will not be associated with the information or data you provide for this research. It will be stored separately from your data, it will not be linked in any way, and your identifying information will be destroyed within 1 year of study completion.

If you do not give us your social security number or other identifying information you may take part in this research if you agree to not be paid.

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.

If the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit, include the following statement: (Modify if subjects will share in commercial profit.)

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

**What if this research has additional findings about me that were not related to the research questions?**[DELETE THIS SECTION IF THERE ARE NO POSSIBLE INCIDENTAL FINDINGS THAT COULD COME ABOUT DUE TO THE RESEARCH]

[Include if incidental findings may be communicated to the participant] This (provide imaging procedure (e.g. MRI)) is done for research purposes rather than for diagnosis. The (provide procedure)will not be routinely examined by health professionals for potential structural and functional clinical abnormalities. However, in the event an abnormality is detected by the investigators or the (administer of the procedure (e.g. MRI technician))*,* the (named procedure) will be further examined by a (name appropriate clinician (e.g. a radiologist)) and the investigator may encourage you to consult your physician. [add below language if applicable]

The blood, saliva, tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic and proteomic studies. The material will have your name, medical record number and other identifying information associated with it. Please indicate if you wish to be contacted in the future regarding any test results that may be obtained.

[Include if incidental findings will not be communicated to the participant] The (named procedure) we collect are for research purposes only and we cannot provide a (name appropriate clinician) clinical interpretation of the results. However, if your healthcare provider would like to use the (type of data e.g. scans) for comparison with another clinical (applicable types of data) that has already been obtained or may be obtained in the future, they may request these (type of data) if they are still available. [add the below language if applicable]

The blood, saliva, tissue that is obtained will be tested and/or stored for future use and potential genomic and proteomic studies. However, the material will be de-identified (will not have your name, medical record number or other identifying information associated with it). Therefore, we will not be able to contact you in the future regarding any test results that may be obtained.

[The IRB typically does not require subjects to sign a consent document when the research involves no more than minimal risk, by waiving/not requiring documentation of consent. However, if you are accessing health records or consenting subjects that cannot consent for themselves, refer to the Main Informed Consent Template to add the applicable signature blocks. For additional guidance, please see HRP-803 - Documentation of Consent.]