**RESEARCH SUBJECT CONSENT FORM**

**Title:** StudyTitle

**Protocol No.:** Temple protocol number (If the sponsor requires showing their protocol number, include it as a separate line)

**Sponsor/Funder:** Sponsor or funder name (delete if not sponsored)

**Investigator:** Name

TempleAddress

 City, State, Zip Code

 Country

**Email:** Investigator’s email address

**Daytime Phone Number:** Phone Number

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| Instructions for Research Consent Summary Section**If your research is federally funded or is conducted in New York, Virginia, and/or Maryland and the consent document is longer than 4 pages, an initial summary is required.****Otherwise, delete the Research Consent Summary Section.**This summary must be easy to understand and not longer than 3 pages or one-third of the length of the Detailed Research Consent section (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. This summary should highlight **the information that a prospective subject is most likely to care about: e.g., why it's being done, what the participant will do, the potential risks and benefits, and compensation (if applicable).** Detailed information should be saved for the Detailed Consent section of the consent form.For example, in a cancer trial, the summary would emphasize the potential side effects of the treatment, like feeling sick or losing hair. It would also explain how the study might help in developing new treatments. The full list of potential risks and benefits should be included in the main body of the consent form for more detailed information. |

**RESEARCH CONSENT SUMMARY**

(Delete this section (all text up until the Detailed Research Consent section), unless necessary as per above instructions)

This section summarizes a research study you're invited to joins We want you to have the key information upfront to decide if participating is right for you. More details are provided later.

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| **KEY INFORMATION**(Information provided in this section should be concise and easy to understand. Details can be further explained and repeated if needed later in the form) * **Purpose:** The purpose of the study is to (Briefly explain the overall goal and purpose of the study).
* **Procedures**: If you choose to participate, you will be asked to (Briefly describe the main activities, like surveys, interviews, or tasks).
* **Duration:** This will take about (Briefly describe the total time commitment as well as the number of visits).
* **Risks**: The potential risks or discomfort from this research are (Briefly mention reasonably foreseen risks or discomforts).
* **Benefits:** The potential benefits to you from this research are (Briefly describe it or state there are no direct benefits from participation).
* **Options:** Instead of joining this research, you can (List alternative options in simple language. If there are no other options, this can be removed).
* **Payment:** If you decide to join this research, you can be paid up to $XX (Briefly explain any payment, the form of payment, and when it will be provided. If none, this can be removed).

Joining this research is your choice. If you have any questions before making your decision, please feel free to ask. You can change your mind at any time. |

**DETAILED RESEARCH CONSENT**

Organize the details in a clear and comprehensive manner. This will help subjects better understand the reasons why they may or may not want to participate. Avoid simply listing out facts without context or explanation. Instead, aim to present the information in a way that is easy to read and understand.

This is an invitation to take part in a research study. People who join this research are called research subjects or participants.

If a child (or adult lacking capacity to consent) is involved in a research study, and their legally authorized representative or parent is giving specific consent for their participation, and they themselves are not participating in any research activities or surveys, or if they are signing a separate consent form outlining their role and responsibilities in the research, then the following paragraph should be included.

This consent form uses the word "you" to refer to the person directly involved in the study (the research subject). However, if you are a parent or legal guardian giving permission for someone else (e.g., a child or adult unable to provide consent) to join, then "you" refers to the research subject.

**This research has key things you should know:**

* **Someone will explain this research to you. This consent form should match that explanation.**
* **If you don’t understand something, ask questions.**
* **You're in control.** It's totally up to you if you want to join and volunteer to be in this study.
* **There is no penalty for saying no.** Declining, now or later, will not negatively affect you in any way.
* **Can you change your mind later?** Yes, you can always say no, even after saying yes.
* Do not hesitate to ask all your questions before deciding.

**Why are we doing this research?**

This research will help us learn more about \_\_\_\_. Explain the overall goal and purpose of the study. You can use simple pictures or diagrams to explain things.

Only if you believe the overall N for the study could impact subjects’ decision to participate, include the following: To get the best picture, we'll need about [number] volunteers to join in this research.

## How long will the research take?

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?**

It's important to let subjects know what to expect when participating in research. This includes explaining all the procedures or information collected because they are taking part in the research. However, Do NOT describe procedures that would be done regardless of their participation (e.g., regular check-ups).

If applicable, you should also provide information about:

* The location where the research will be conducted.
* A timeline of the tests, procedures, surveys, etc. that will be done (including screening procedures). You can also use tables or charts to help explain the schedule.
* A description of each test or procedure in simple terms.
* A description of each group or arm involved in the research and, if there is a random assignment, explain this process along with the probability of being assigned to each group. For example:

You will have a(n) [number] out of [number] chance (or [XX]%) of being placed in each group. Unfortunately, you won't be able to choose which group you're in.

If applicable: In this study, neither you nor the researchers will know which group you're in until the very end. This is called a "double-blind" study and helps prevent any bias in the results. Your study doctor will be able to find out in case of an emergency.

* List any approved drugs, devices, tests, or procedures being used in a new way as experimental.
* If blood will be taken, explain how often and how much in English and metric units.
* Provide an overview of the types of questions asked in surveys, interviews, or diaries and explain what they involve, how frequently they need to be completed, and for how long.
* If the research involves investigational drugs or devices, list any options for the subject to get the drug/device after the research ends and who will pay for it.
* Describe any future research plans (extension study, follow-up study, analysis of specimens) and whether a separate consent form will be required for subjects to sign.
* Indicate whether the study treatment will be available at the end of the study.

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

If it's applicable, explain that the subject will be informed of any clinically important research findings and if so, what the conditions for that will be.

If the study will or might involve whole genome sequencing (always include for biobanks or biorepositories):

This study may involve whole genome sequencing, this means we will be looking closely at your DNA code. This process involves figuring out the order of the building blocks (nucleotides) that make up your genes.

If the study may use biospecimens (even if identifiers are removed) for commercial profit (i.e., either by the investigators or if samples are to be shared outside the institution) include:

Your tissue/blood/biospecimen may be used for commercial profit. You are not expected to share in this commercial profit.

**What is your responsibility if you join the research?**

If you decide to join in this research, you will be expected to: Describe the responsibilities as a subject.

* Describe any warnings or precautions that the subject needs to be aware of
* Describe the requirements to follow all instructions given by the study team and inform them about any new medications or medical issues that may arise.

**Are there any risks?**

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 (e.g., soreness from blood draws or medical side effects):

Blood Draw: Risks associated with drawing blood from your arm include momentary discomfort, bruising, and/or soreness at the site. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely (If applicable).

Psychological risks (e.g., embarrassment, sadness, stress, anxiousness, guilt, etc.)

Privacy risks (e.g., disclosure of private information)

Confidentiality risk (it is nearly impossible not to have some risk of loss of confidentiality)

Loss of Confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality means having your personal information collected for this research seen or used by someone who is not on the study team or was not supposed to see or know about your information. The study team plans to protect your confidentiality to limit this risk to the best that they can.

Legal risks (e.g., legal prosecution or being reported for child abuse)

Social risks (e.g., social ostracizing or discrimination)

Economic risks (e.g., 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 you money to be in this study?**

It is important to inform that there may be additional costs involved. These costs should be clearly outlined in any contract or agreement with the sponsor.

There might be some additional out-of-pocket expenses for you to take part in this research, such as:

* Parking fees
* Travel expenses to come to the research site
* Co-pays for any medications or procedures involved in the study

In some cases, some of the research procedures might be billed to health insurance. If you don’t have health insurance, you will need to pay for these costs yourself. If applicable, include:

* Sometimes, insurance does not cover services that are usually paid for because they are performed as part of a research study.
* We recommend checking with your insurance provider to understand what will and won't be covered and what your out-of-pocket costs might be.

**Will this research benefit you?**

If there are possible direct benefits for the subject:

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

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

This study is not expected to directly benefit you. However, the research might contribute to scientific knowledge, or benefit others or future generations by understanding (describe study topic).

(Include for research involving prisoners. Otherwise, delete) Taking part in this research will not affect your housing or correctional program assignments. It will also not improve your chance of parole or release.

**Are there other choices instead of being in this research?**

If there are other options:

If you do not want to take part in the study, there are other options such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(describe whether or not there are any alternative procedures or courses of treatment the participant could take in order to receive the same level of benefit).

If there are no other options (beyond not participating), delete this section.

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

This research will collect some private information about you. We will only share your information with people who need it for this research and should take steps to protect your privacy. However, we cannot promise complete secrecy.

It is important to know that by agreeing to join this research, your identifiable information (include if a clinical trial of a drug or device including your medical record) 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)
* (If applicable, mention any disclosures required by law for specific tests, like communicable diseases)

Include the following sentence because Legal Counsel has determined that pretty much all Temple employees are mandated reporters: Although this is not the purpose of this research, we are required by law to report instances of child abuse and/or neglect to the relevant university and law enforcement agencies.

If the research may collect information that is considered sexual misconduct on campus or an otherwise university-affiliated event or location, include: If you report that you are the victim or perpetrator of sexual misconduct, we are required to report this to the Temple University Title IX Coordinator.

Include if applicable to the research: We may have to break confidentiality if the researchers believe you pose an immediate danger to yourself (e.g., suicidal thoughts) or someone else.

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

Include the following sentence if the research will be conducted by online data collection:

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications (e.g., MTruk, Prolific, or Qualtrics) used in this study have their Terms of Service and Privacy policies (list the third-party privacy policies).

For FDA-regulated or federally-funded clinical trials, add the flowing 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 it. The IRB does not require this information when not required by the federal government, even if the study will be listed.) A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Include one of the following two blurbs, depending on whichever is accurate.

We may use or share de-identified data (i.e., data that does not contain your identifiers) or samples (only include “or samples” if applicable to the study) from this for future research studies. We may share de-identified data or samples with other researchers for future research without asking for your separate consent.

OR

We will not share any information or samples (only include “or samples” if applicable to the study) collected for this research, even if de-identified.

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.)

Prisoners (if applicable, otherwise. delete): If you are a prisoner, your medical records may also be shared with law enforcement or the criminal justice system, but only when necessary and permitted by law.

***What does it mean that this research has a Certificate of Confidentiality?***

(Include this section if your study is funded by the NIH or you have/will request a Certificate of Confidentiality from the NIH)

Your study information is protected by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means the researchers cannot use or give out information, documents, or samples that may identify you in any action or suit unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

The Certificate does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes, if applicable, putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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

If you have any questions, concerns, or complaints about the research or you think this research has hurt you or made you sick, 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.

**Can you be removed from this research without your permission?**

You can be removed from the research without your permission. Here are some reasons why this might happen:

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 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
* You are unable to comply with your research assignments

We will tell you if the research team becomes aware of new information that we believe could affect your decision to stay in the study.

**What happens if you change your mind and leave the study?**

If you decide to leave this study, tell the research team so that they can follow steps to end your part in the study in a safe way: Describe the steps for orderly termination by the subject.

There might be risks if you leave the study early. The research team can explain these risks to you. Include if there are potential adverse consequences to a subject who withdraws:

[Include for FDA-regulated research. Otherwise, delete.] If you stop being in this research, already collected data may not be removed from the research records. You will be asked if the researchers can continue to look at your regular medical records. [Note: The consent document cannot give the subject the option of having data removed.]If you say yes, this information will be handled like the other research data. [Note: If a subject leaves the study without consenting to follow clinical outcomes associated with the study, the researchers can’t look at the subject’s medical record or other confidential records. However, the researchers 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 the reasons for leaving the study and whether they will be asked for permission to continue collecting data through follow-up interaction or collection of private identifiable information. For example, a subject might want to stop participating in the experimental procedures due to side effects, but might agree to continue with follow-up check-ins and data collection.]

If the study involves storing biological specimens include: If you ask, we can destroy any blood, tissue, or biological specimens that is being stored for this research. However, already de-identified samples cannot be destroyed because we are not able to know which samples are yours.

**Will you get paid for being in this research?** (remove if subjects will not be paid)

If subjects will be reimbursed for travel:

You will be paid up to $\_\_\_\_\_ to cover travel costs and other expenses. [OR]

You will be paid a per diem of up to $\_\_\_\_ to cover travel costs and other expenses. [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:

You can be paid up to $\_\_\_\_ for taking part in the research. [If the payment is in gift cards, this will be specified.]

We will tell you exactly how much you will get paid for each part of the study and when it will be received.

Describe the payment schedule in terms of the amount

Describe when payments will be made

Describe the amount of payment if the subject drops out (e.g., after completing the study, within 2 weeks of completion, etc.)

Be sure to include any extra conditions (e.g., failure to answer attention-checks correctly, duration to complete study tasks, only being able to participate once, etc.) to the payment that are designed to prevent fake participants (e.g., bots)

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.

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

We will use a type of debit card called a ClinCard to pay you. This card is a secure, reloadable MasterCard debit card supported by Greenphire. We will [give/mail] you the card. You will use the same card for the whole study. 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 Greenphire's cardholder agreement.

We will put money on the card as you finish parts of the study. You can use the card online or anywhere that takes MasterCard. You can also withdraw cash from an ATM with the ClinCard.

A company called Greenphire will help us with the payments. They will know your name, address, birthday, and social security number. This information is only for paying you and will not be shared with anyone else. They will not know anything about your health or the study.

**What if something unexpected is found about you that is not related to the research questions?**

(Delete this section if there are no possible incidental findings that could come about due to the research)

Sometimes, research studies can find possible health problems that a study participant may have, even though the study was not intended to look for those health problems. These are called “incidental findings.”

(Include if incidental findings may be communicated to the participant)

(If applicable) This (provide the procedure (e.g., MRI)) is for research, not to check your health. We won't usually look for health problems with it. But if we see something unusual, the finding will be further examined by a (name appropriate clinician (e.g., a radiologist)), and we will tell you and suggest you see your doctor.

(If applicable) The blood, saliva, or tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic, and proteomic (related to your cells’ proteins) studies. The material will have your name, medical record number, or other identifying information associated with it. The results of these tests may indicate a health problem that is not associated with this research. Please indicate if you wish to be contacted in the future regarding any test results that the researchers determine are significant.

(If communicating incidental findings to subjects include :) Please initial here \_\_\_\_\_\_\_\_ if you would like the researchers to contact you about incidental findings that they determine are significant.

(Include if incidental findings will not be communicated to the participant)

(If applicable) We are collecting this information for research purposes only and are not able to provide clinical quality diagnoses. We can't tell you what the results mean for your health. If your doctor wants to compare this information to other tests you've had, they can ask for it if it is still available. [add the below language if applicable]

(If applicable) We might test or store your blood, saliva, or tissue for future studies, including genomic and proteomic tests. We will remove your name and other personal information from these samples. This means we won’t be able to contact you about any new information we find.

The IRB typically does not require subjects to sign a consent document when the research involves no more than minimal risk and does not involve medical records or procedures. However, if you are accessing health records or consenting subjects who cannot consent for themselves, refer to the Main Informed Consent Template to add the applicable signature blocks. For additional guidance, please see HRP-803 INVESTIGATOR GUIDANCE - Documentation of Informed Consent.