UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT FORM

ALL INSTRUCTIONAL RED/BLUE TEXT SHOULD BE REMOVED OR REPLACED WITH STUDY SPECIFIC INFORMATION (including headers and footers)– PRIOR TO SUBMISSION TO THE IRB.

THIS FORM SHOULD BE USED IF YOU ARE CONDUCTING SOCIAL & BEHAVIORAL RESEARCH, SUCH AS SURVEYS, INTERVIEWS, FOCUS GROUPS, BEHAVIORAL INTERVENTIONS, AND ETHNOGRAPHIC OBSERVATIONS.

***IF YOU ARE AFFILIATED WITH PENN MEDICINE OR PENN DENTAL, PLEASE USE THE BIOMEDICAL TEMPLATE, which includes necessary language for HIPAA and other authorizations related to use of PHI, collection of specimens, drugs, biologics, and medical devices.* If you are from Penn Medicine / Penn Dental and you are conducting social & behavioral research that DOES *NOT* involve patients as participants, medical interventions, nor use of a drug or medical device, you may use this template.**
IF YOU ARE AFFILIATED WITH PENN NURSING or another school and are doing research with Penn Medicine patients, you should utilize the biomedical template.

It is strongly recommended research teams start with the Penn template to draft consent forms, rather than starting with consent forms from previously approved research studies. This is to ensure that all current institutional template language is included.

PLEASE NOTE THAT CONSENT FORMS SHOULD BE WRITTEN IN LAYPERSON'S TERMS. PLEASE AVOID USE OF JARGON AND EXPLAIN ANY TERMS THAT MAY BE UNFAMILIAR TO INDIVIDUALS OUTSIDE OF AN ACADEMIC SETTING OR YOUR FIELD.

Protocol Title:	Insert Title of Research Study or Acronym
Principal Investigator:	Insert Name of the Principal Investigator (or Faculty Mentor for Students) Address Insert Phone Numbers
Emergency Contact:	Insert Emergency Contact Insert Phone Number/Pager, etc.
Sponsor	Remove if N/A

Research Study Summary for Potential Participants

*Informed consent must begin with "a concise and focused presentation of the **key information that is most likely to assist a prospective participant,** or legally authorized representative, **in understanding** the reasons **why one might or might not want to participate in the research.** Researchers are encouraged to utilize the IRB developed "**Concise Summary Guidance**".*

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to <INSERT GENERAL OVERVIEW OF THE PURPOSE AND, IF APPLICABLE, WHY POTENTIAL PARTICIPANTS ARE ELIGIBLE>.

If you agree to join the study, you will be asked to complete the following research procedures: <PROVIDE LIST OF STUDY PROCEDURES>.

Your participation will last for <INSERT OVERALL DURATION AND ANY STATEMENT NEEDED ABOUT ONGOING FOLLOW-UP OR ACCESS TO DATA>.

<INSERT STATEMENT OF POTENTIAL FOR BENEFIT, IF ANY>. The most common risks of participation are <INSERT LIST OF MOST COMMONLY EXPECTED OR MOST IMPACTFUL RISKS>.

<INSERT INFORMATION ABOUT ALTERNATIVES TO PARTICIPATION AND OTHER IMPACTFUL INFORMATION BASED ON THE RESEARCH BEING PROPOSED. YOU MAY ALSO UTILIZE THIS SUGGESTED LANGAUGE BELOW TO REMIND POTENTIAL PARTICIPANTS THAT THIS IS A SUMMARY ONLY AND THE MAIN ICF HAS A LOT MORE DETAIL NOT DISCUSSED HERE>

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

- *The participant is being invited to participate in a research study and why they are being asked to volunteer.*
- *The participant will get a copy of the consent form*
- *The participant will be asked to provide consent via signature, verbal agreement, check box, etc.; PLEASE NOTE that signed consent must be obtained for research that presents greater than minimal risk of harm to participants*
- *IF the research is being performed by a participant's employer, doctor, therapist, or anyone else in a position of authority, please ensure that the participant is aware*

that they do not have to enroll in the study and their decision to participate will not affect their relationship with their [employer, doctor, therapist, etc.]

You are being asked to take part in a research study because [why they are being asked to volunteer]. Your participation is voluntary which means you can choose whether or not to participate.

If you do not understand what you are reading, do not [sign it, provide your electronic consent, provide your verbal consent]. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to [sign this form, verbally agree to participate, check a box, etc.]. A copy will of the form will be given to you so that you can find contact information and answers to questions about the study. You may ask to have this form read to you.

[*Include only if applicable (i.e., if the participant's doctor, employer, therapist, etc. is involved in the study)*]

Your [doctor, employer, therapist, etc.] may be an investigator in this research study. You do not have to participate in any research study offered by your [doctor, employer, therapist, etc.]. If you choose not to participate, there will be in loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family or friends [*if applicable*, or family doctor]. Your decision to participate will not affect your status as a/an [patient, employee, etc.].

[*Additional suggested language for when the participant is a minor or decisionally impaired adult:*]

This consent form is written from the point of view of a research participant. If you are the parent or legal guardian of a minor or a legally authorized representative and will be providing consent on that person's behalf, the words "you" and "your" should be read as "your child" or "the research participant."

What is the purpose of the study?

The purpose of the study is to learn more about

- *Fill in the space with a simple, accurate explanation of the purpose and what specific phenomena or condition(s) are under study.*
- *STUDENTS: If the study is being conducted for a thesis or dissertation, it should be mentioned in here.*

How long will I be in the study?

- *Expected duration of a participant's involvement with the study including expected duration of tasks including questionnaires, MTurk HITs etc.*

- *Expected total duration of study.*
- *(optional) Total number of participants in study *note: if this information is included add "How many other people will be in the study" to the title of this section.*
- *(optional) Include number of participants at Penn if this is a multi-site study *note: if this information is included add "How many other people will be in the study" to the title of this section.*

What am I being asked to do?

- *Provide a full list of research tasks, procedures, methods, and/or interventions using layperson's terms. If applicable, consider including the number of times each procedure/method will occur and where they will occur. Bulleting and subheadings can be useful tools for organization of information that will aid with comprehension.*
- *If there is any screening process to qualify for the study, please include this information in the consent language. This includes any "**attention checks**" within surveys.*
- *If **deception or incomplete disclosure** about any element of the research is occurring, the consent language must include statement informing the participant of the deception or incomplete disclosure.*
- *If the study includes randomization, cross-over design, or blinding, please describe the circumstances and procedures using lay terminology.*
- *[Optional] Consider complementing text with a simple table, chart, picture, or other additional materials as appropriate if it will aid comprehension. Separate handouts require IRB approval.*

What are possible risks or discomforts?

- *If personally identifiable information is collected, note that breach of confidentiality is a risk of participation.*
- *Include any known risks, discomforts, or inconveniences related to the study design, methods, or instruments. When know, please structure them in terms of likelihood/severity.*
- *If the study involves randomization, discuss the risks of randomization (e.g., receiving less effective treatment).*
- *This section may also be detailed in chart format and additional material inserted here or given as a handout. Any such materials require IRB approval.*

What if new information becomes available about the study?

- *Include when relevant to the research design or for research that is greater than minimal risk*

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind

about being in the study. We will notify you as soon as possible if such information becomes available.

How will I benefit from the study?

- *Do not include overly promissory statements*
- *Compensation is not a benefit. Please do not discuss compensation here.*
- *If direct participant benefits are NOT anticipated, then use the following standard clause:*

You are not expected to get any benefit from being in this research study.

- *If direct participant benefits can be reasonably anticipated as a result of participation, then describe these possible benefits and conclude with the following standard clause:*

You may not get any benefit from being in this research study.

- *[OPTIONAL] Describe anticipated benefits to society*

What other choices do I have if I do not participate?

- *Alternatives to entering the study including, when appropriate, supportive care with no additional disease-directed therapy.*
- *[If relevant] A statement that they may discuss alternatives with their [therapist, social worker, personal physician, etc.].*

Will I be paid for being in this study?

- *If there is no compensation for participation in this study, state that here.*
- *If there is compensation, describe any monetary compensation if participants are being reimbursed for their time and/or travel.*
- *Include a breakdown of pro-rated and total compensation (i.e., clarify if paid after each method/procedure/data collection episode or upon completion of the study, etc.). Also detail whether there are any bonuses. If there is a screening process, state whether participants will be compensated for the time it takes to complete this.*
- ***For MTurk Research**: Please provide an estimate of how long it will take for the researcher to approve their HIT (i.e. – how long it takes for the participant to receive payment).*
- *When using Greenphire ClinCard the following is required in the consent form as well as the HSERA Compensation section and, if applicable, Full Protocol payment section:*
  - *That "Greenphire ClinCard" will be used as a payment option as well as the compensation schedule*

- *Whether social security number will be collected for Clin Card purposes (If you have obtained a waiver for collecting social security number, this should be specified in HSERA and, if applicable, the Full Protocol, but NOT the consent form.)*

[If participants will receive monetary compensation for their participation by check or an amount of $100 or more, include the following language]
Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

- *Note anything that may not be covered by the study, such as transportation costs to study sites, use of cellular data or Wi-Fi, etc.*

What happens if I am injured from being in the study?

*[Include injury language for research that **poses greater than minimal risks to participants. This section can be deleted for minimal risk research**]*
--- OR ---
[If there is sponsor-specific injury language, add it here. However, for industry-sponsored research, the sponsor must pay for research related injury unless otherwise negotiated with the institution.]

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

- *Define when the overall study is to end.*
- *Explain what events could lead to early study closure.*
- *Note that the participant can elect to leave the study at any time. Discuss the consequences of a participant's decision to withdraw from the research and*

procedures for orderly termination of participation by the participant. This should include who to contact if they want to withdraw, and any requirements related to withdrawal (e.g., end of study visit).

- *Note whether data from participants who withdraw will be kept or destroyed*

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time because:

- The Primary Investigator feels it is necessary for the welfare, rights, or safety of participants. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your [employment, future care, current or future services, etc.].

Could I be withdrawn from the study?

- *Explain situations in which the participant could be withdrawn from the study. Include a statement (as applicable) in the informed consent about instances in which participants may fail to qualify or might be rejected for a task (e.g., failed attention checks).*
- *Explain how they will be informed of their withdrawal.*

You could be removed from the study if

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

- *[In addition to the text above, explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the participant. For example, explain if data will be de-identified or coded, explain if it will be stored under lock and key, etc. Please note; the content of this section will vary according to the research design. There may be cause for more or less protections depending on the nature of the research.*
- *For MTurk Research: If there is any need to collect MTurk worker IDs ensure that the consent language describes this, the reason for their collection, and confidentiality measures in place (e.g., worker IDs will be deleted after being used and not linked to survey data)*

Certificate of Confidentiality

[If your study is funded by the NIH or if you have otherwise obtained a Certificate of Confidentiality (COC) from the NIH, please include the language below. ***Delete this section if your study is NOT NIH funded or you do not have a COC from the NIH.****]*

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence 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.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will information about this study be available to the public?

[If this is a controlled clinical trial that requires registration on clinicaltrials.gov, include the below regulatory statement in full. NIH Definition of a clinical trial: "A research study in which one or more human participants are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or ***behavioral*** *outcomes."]:*

A description of this clinical trial will be available on 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.

What may happen, in the future, to my information collected on this study?

This section is intended to include consent language required by the 2018 common rule about storage of collected data for future secondary research uses. Any collection and storage of biospecimens for future use requires the use of the biomedical consent form template.

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Definitions for Guidance:
Non-Identifiable

- *Anonymous: The data was collected without knowing the identity of the participant. There is no chance of re-identification.*
- *De-identified: The data was collected knowing the identity of the participant, but identifiers were destroyed or are not accessible to the recipient. There is no chance of re-identification.*

Identifiable

- *Coded: The data is assigned a unique random identifier that is separately linked to participant identifiers. Re-identification is possible.*
- *Identified: The data contains participant identifiers (e.g., name, medical record number, etc.)*

Future Use of Data

[To address §46.116(b), include 1 of the 3 following statements about whether there may be future use of data

PLEASE NOTE:** It should be considered whether storage of data for future secondary research uses is optional or a required part of participation. Providing options is particularly important in studies that offer the prospect of direct benefit to avoid undue influence to participate. **Please make clear within this section whether the storage for future secondary research uses is optional or a required element of participation. If optional: ensure the end of the consent form includes an area to indicate the participant's decision.]

1. *"A statement that data will not be stored or distributed for future research studies." Suggested language:*
   Your information will not be stored or shared for future research purposes.

OR

2. *"A statement that data and, if applicable, data will be de-identified, and could be stored and distributed for future research studies without additional informed consent." Please refer to the definitions above. This only applies to anonymous and de-identified data. Please note any plans to store data in repositories, and what the access controls will be. Please note that CODED data (such as stored with a study ID or other unique identifier CANNOT be considered de-identified unless the linking set is destroyed prior to any sharing of data, or the link and all identifiers are deleted from the data disclosed. Suggested language:*
   Your information will be de-identified prior to storage for future use. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within Penn or other research institutions as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study. If you change your mind, we will

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not be able to destroy or withdraw your information that was shared because all identifiers would have already been removed.

OR

3. *A statement that identifiable data will be stored and distributed for future research studies without additional informed consent. Please refer to the definitions above. Please note any plans to store data in repositories, and what the access controls will be. This applies to coded or identified data when that information is stored locally at Penn or elsewhere. Suggested language:*
   Your coded or identifiable information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

   - *[If statement 3 is included, please also include the following additional elements of consent]*
     - *"A statement about which identifiers will be retained and shared with data." If there are circumstances under which a code key may be used to re-link identifying information to data, consider including language to address this. Suggested language:*
       The following identifiers will be retained with your information: *[detail the identifiers that will accompany data during storage and sharing, e.g., the linking ID code, date of birth, etc.].*

     - *"A description of the period of time that the data may be stored, maintained, and used for research purposes." If indefinite, please state this. Suggested language:*
       Your information may be stored and used for future research purposes for an indefinite amount of time [or state alternate timeline].

     - *"A general description of the types of research that may be conducted with the data". Suggested language:*
       There are no plans to tell you about any of the specific research that will be done. Possible future research may include: [include examples]

     - *"The types of institutions or researchers that might conduct research with the data, including plans to store data in repositories."*
       [NOTE: The below text is required institutional language if there are or may be intentions to share data outside of the institution.] Suggested language:
       We may share your identifiable information with other researchers within Penn or other research institutions, [**if applicable:** as well as pharmaceutical, device, or biotechnology companies].

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- *"A statement regarding whether participants will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research." Suggested language:*
  We [will/will not] follow up with you to tell you about the specific research that will be done. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

- *Specifically related to the future use: "A description of how confidentiality will be maintained during storage/ sharing, reasonably foreseeable risks and benefits of future research use" [including, if applicable, stigmatization related to sharing of sensitive data], "who to contact about future use/storage and research related harms." Suggested language:*
  There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by [detail confidentiality measures, e.g., encryption, access controls, etc.].

  You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by [*insert language relevant to your study/broader design and goals*], and developing new scientific knowledge.

  If you have questions about the storage of your information, or have changed your mind, you can contact [Name or office] at [Phone Number]. If you change your mind, [Note the following: 1) *what will happen to the data when a participant withdraws* (e.g., data will be destroyed), and 2) *any limits to destruction of information* (e.g., if data shared outside the institution were de-identified, it may not be possible for them to be destroyed), *stopping ongoing research, etc.*]

Financial Interest Disclosure

Delete this section if there is no financial conflict of interest to disclose.
If a member of the research team has identified a financial conflict of interest this information may be included in the consent form using one of the template disclosures listed below. These template disclosures are intended to serve as a guide. The template language may be modified to best inform participants of any financial conflicts of interest. For example, "the person leading this study" may be replaced with "Dr. XYZ, a member of the study team." Suggested Language:

Research Team Member Financial Conflict of Interest template language
Disclosure of Money received outside of the study:
This research study is supported by money from *Company XYZ*. In addition, the person leading this research study receives extra money from *Company XYZ* for work that is

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not a part of this study. These activities may include consulting, advisory boards, giving speeches or writing reports. If you would like more information, please ask the researchers or the study coordinator.

Researcher or the University Holds a Patent:
The person leading this research study has invented a new *(drug, treatment, device, etc.)* that is being evaluated through this research. Therefore, the researcher could benefit financially from the results of this research study. If you would like more information, please ask the researchers or the study coordinator.

Researcher Owns Equity
This research study is designed to test a product made by *Company XYZ*. The person running this study has an investment in *Company XYZ*, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study. If you would like more information, please ask the researchers or the study coordinator.

Institutional Financial Conflict of Interest ***template language***
University Owns Equity
This research study is designed to test a product made by *Company XYZ*. The University of Pennsylvania has an investment in *Company XYZ*, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the University of Pennsylvania could gain or lose money depending on the results of this study. If you would like more information, please ask the researchers or the study coordinator.

Other Institutional Financial Conflict of Interest
The University of Pennsylvania has a significant financial interest in the study product *(name)* being evaluated in this study. In the event that the study product proves to be effective, the University of Pennsylvania will likely receive significant financial benefit.

Generic Disclosure
The person leading this medical research study might benefit financially from this study. Specifically, *… (insert description of financial relationship)*. If you would like more information, please ask the researchers or the study coordinator.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other

than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Participant **[print]**	Signature of Participant	Date

If participants are required to provide their legal (government) name, please consider implementing a dual-name consent documentation process so that participants who use a different name (such as some transgender individuals) have the ability to provide it.

_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date

Use the authorization line below when Non-English speaking participants are incidentally encountered and enrolled via a short form process. See IRB SOP IC 703 Consent Documentation, Section 3.2 Obtaining Informed Consent from Non-English Speakers

For use with Non-English Speaking participants / LARs utilizing a short-form process:

_____	_____	_____
Name of Witness (Please Print)	Signature of Witness	Date

_____	_____	_____
Name of Interpreter (Please Print) *(When available)*	Signature of Interpreter	Date

(Optional) Use the authorization line only in studies which are approved by the IRB to use representatives to authorize a participant's inclusion in research. Delete if not applicable.

For participants unable to give authorization, the authorization is given by the following authorized participant representative:

_____	_____	_____
Authorized participant representative **[print]**	Authorized participant representative Signature	Date

Provide a brief description of above person authority to serve as the participant's authorized representative.

_____