## INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

## Informed Consent Form Version Date: Insert Date

## Title of Research Study: Insert Title of Research Study

## Principal Investigator (PI) Name: Insert Name of Principal Investigator

## *[If student-led research, include. Otherwise delete]*Faculty Advisor Name: Insert Name of Faculty Advisor

## Thank you for your interest in this research. This form tells you about our research study. A research study is a way for us to learn new things and answer important questions. Please read this form carefully to understand more about the study. We will answer all of your questions. You will be given a copy of this consent form.

[If your study involves a parental permission form, please use this template. Change "you" to "your child" in all relevant places. Also add the signature block for parental permission and remove other signature blocks that are not applicable.]

**KEY INFORMATION**

[Provide a brief overview of the study and highlight the reasons that a person may or may not want to participate in the study. Generally, this section should describe what participants are going to do, the duration of their participation, participation is voluntary, and what the potential benefits and risks are. *The informed consent must be organized and presented in a way that facilitates participant comprehension. It is recommended to write it at an 8th grade reading level.*]

The purpose of this research study is insert purpose. Your participation is voluntary and you may stop participating at any time. Participating in this research involves insert what participants are going to do as part of this research and the duration of their participation (e.g., a ten minute online survey, two 60-minute one-on-one in-person or virtual interviews, etc.). Reasons you may choose to participate in this research include insert benefits. Reasons you may choose not to participate in this research include insert risks. You will or will not benefit directly from your participation in the study.

[Include for sponsored/funded research. Otherwise delete.] This research is being funded by insert name of sponsor.

If you have questions about the research study, please contact insert name & contact information of Principal Investigator (if applicable, also the Primary Contact name & contact information).

**DETAILED INFORMATION**

## Why am I being invited to take part in a research study?

We are inviting you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes participants eligible for the research.]

## What should I know about this research study?

1. Someone will explain this research study to you.
2. Whether or not you participate is up to you. You can choose not to participate.
3. You can agree to participate and later change your mind without penalty or loss of benefits to which you are otherwise entitled.
4. You can take your time to decide and can ask all the questions you want before you decide.

## Why is this research being done?

[Tell the participant the purpose of the research. Explain the background of the research problem in lay language. Explain any potential benefits to others. Keep it simple for comprehension purposes.] The purpose of this research study is insert information here.

If applicable, include the following for collaborating research. Otherwise delete. The Vanderbilt University research team is collaborating with (insert collaborating site names) for this research.

## How long will the research last?

We expect this research to last for \_\_\_\_\_\_\_\_.

How many participants will take part in this research?

We expect that insert enrollment number participants will take part in this research.

What will I be doing as part of this research?

You will be asked to [insert a detailed description of all study procedures and total time commitment for each procedure in lay language and simple terms; if there are multiple procedures, consider listing them in table format or in bullet points for participant comprehension]

Consider the following:

* study procedures and duration of each procedure
* with whom the participants will interact
* where and when the research will be done
* when applicable, indicate that the participant will be contacted for future research
* if blood will be drawn, indicate the amount (mL and teaspoons/tablespoons) and frequency [consider if it is appropriate to use mL and/or teaspoon/tablespoon metrics based on the research context and location]
* when applicable, research devices that will be used (e.g., Fitbit, Smart Watch, MRI, EEG, etc.)
* experimental conditions

[Include for a study involving randomization. Otherwise delete.] Participants will be randomly assigned to a condition group, which is like flipping a coin. You will **OR** will not know which condition group you are assigned to in this research.

* audio and/or video recordings; photographs

[If applicable, include details about the use of audio / video recordings / photographs. Otherwise delete.]

Audio / Video Recordings

The research team will audio / video record the \_\_\_\_\_\_\_\_\_\_\_\_\_ as part of this research for study purposes. To protect the confidentiality of the recordings, they will be securely stored, with access limited to the research team. Recordings will be kept indefinitely OR destroyed \_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g., upon completion of the study).

If recording is optional, include the following statements, otherwise delete: The recording is optional. You are not required to agree to being recorded to participate in this study. Recordings will only be made with your consent. Please select one of the following.

* I consent to the use of my audio / video recording in this research
* I do not consent to the use of my audio / video recording to be used in this research

Only include the following statement if using A/V recordings for other purposes beyond the study: In addition, with your permission, audio / video recordings will be used for (state specific purpose) (e.g., education or training purposes, medical evaluation purposes). Your identifiable OR de-identified (blurred face, modified voice) recordings will be used.

* I consent to the use of my audio / video recording to be used for (state specific purpose)
* I do not consent to the use of my audio / video recording to be used for (state specific purpose)

Photographs

The research team will obtain photographs as part of this research study. [Explain how the photographs will be used in the research.] To protect the confidentiality of the photographs, they will be securely stored with limited access to the research team. Photographs will be kept indefinitely OR destroyed \_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g., upon completion of the study).

* I consent to the use of my photographs to be used for (state specific purpose)
* I do not consent to the use of my audio / video recording to be used for (state specific purpose)
* [If applicable, state the research study is a behavioral clinical trial and consider the following. Otherwise delete.]
	+ If you plan to register this behavioral clinical trial on the clinicaltrials.gov website, follow clinicaltrials.gov requirements and include the following statement in the consent form:

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 for a behavioral clinical trial that involves randomization. Otherwise delete.]

The treatment **OR** condition you get will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what treatment **OR** condition you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment **OR** condition. [For double-blinded research add. Otherwise delete.] Neither you nor the study team will know which treatment **OR** condition you are getting. [For single blinded research add. Otherwise delete.] You will not be told which treatment **OR** condition you are getting, however the study team will know.

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

If you take part in this research, you will be responsible for: [Describe any responsibilities of the participant.]

## Will being in this study help me in any way?

[First describe any direct benefits to the participant, then any benefits to others/science/society. Compensation/incentives for participation is not a benefit and should not be stated here as a benefit.]

We cannot promise any benefits to you or others from your taking part in this research. You will **OR** will not directly benefit from your participation in the study. Possible benefits to science and society include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

## Is there any way being in this study could be bad for me?

[For research with several risks, consider presenting them in a table form or in bullet points for participant comprehension purposes. e.g., physical, psychological/emotional, privacy, confidentiality, legal, social, economic, reputational, etc.]

Possible risks in this research include the following. explain risks in a simple manner here

[If applicable, include for research that involves pregnant women. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The research may also hurt a pregnancy or fetus in ways that are unknown.

*[If applicable,* include for research where the sponsor *provides study-related procedures at no cost to ALL participants. Otherwise delete.]* The sponsor will provide the following study-related items/procedures for you at no cost during participation in the study (e.g., device, etc.): insert information here

*[*If applicable, include for research that *may result in additional costs for all participants. Otherwise delete.]* Taking part in this research study may lead to the following added costs to you (e.g., transportation costs, etc.): insert information here

*[Include if conducting focus groups. Otherwise delete.]*We cannot guarantee confidentiality in the focus group. Participants in the focus group are requested to keep what is said in the focus group confidential.

## What happens to the information collected for the research? How will my confidentiality be maintained?

All efforts, within reason, will be made to keep your information confidential, but total confidentiality cannot be guaranteed. Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [If applicable, add to this list other organizations that may have access to the participant’s records such as the Food and Drug Administration (FDA) when the research if FDA-regulated, the Department of Health and Human Services (DHHS), when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

To strengthen confidentiality, personally identifiable information will be stored separate from the research data and/or samples OR completely destroyed.

*[Include if data/samples will be collected from participants in another country. Otherwise delete.]*
Your identifiable **or** de-identified data **and/or** samples will be transferred to the United States.

Data Use and Sharing

*[*If applicable, include if sharing data and/or samples with other collaborators. Otherwise delete.] Your data **and/or** samples will be shared with insert name of entities for the purposes of \_\_\_\_\_\_\_\_\_\_ *(e.g., sample analysis, data analysis, etc.)*.

*[*Must include the following statement.] Your de-identified data **and/or** samples collected in this research may be **OR** will not be used and/or shared in future research. *[If the study is sponsored and the sponsor requires data to be shared, include a statement that says this.]*

*[*If applicable, include for research that will collect/store data and samples for future research. Otherwise delete if data and/or samples will not be used in future research.] We will do our best to protect your data **and/or** samples during storage and when they are shared. However, there remains a possibility that someone might access your data **and/or** samples and identify you.

*[If applicable, include if requesting permission from participant to use/share their data and samples for future research. Otherwise delete if data and/or samples will not be used in future research.]*

It is your choice whether or not to let researchers share your data **and/or** samples for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study. If you change your mind and no longer wish to have us store or share your data **and/or** samples, you should contact the investigator. We will do our best to honor your request and to get back any data **and/or** samples that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data **and/or** samples, we will not be able to get them back. In addition, if the data **and/or** samples have already been used for new research, we will not be able to get them back. We will destroy any samples we have or are able to get back. Please initial *[or sign depending on institutional practice]* next to your choice:

* \_\_\_ I DO consent to the use and sharing of my data **and/or** samples in future research
* \_\_\_ I DO NOT consent to the use and sharing of my data **and/or** samples in future research

[If applicable, include. Otherwise delete.] Identifiable data may be used in final reports and results with your permission. OR Only de-identified will be used in final reports and results.

[Note: State the specific identifiers in the consent statement that you will be including in final reports and results, if including identifiable data (e.g., first and last name)]

* \_\_\_ I DO consent to the use of my identifiable information in final reports and results.
* \_\_\_ I DO NOT consent to the use of my identifiable information in final reports and results.

[If applicable, describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

*[For studies covered by a Certificate of Confidentiality (CoC), researchers are required to include the content from the CoC Informed Consent Addendum on the VU HRPP website.]*

**What compensation will I receive for participating in the study?**
*[If offering compensation/an incentive, describe the compensation that participants will receive. This includes forms of payment such as cash, gift cards or course credit, etc. Indicate if the amount is pro-rated for research visit completion. If using a lottery/raffle as an incentive, describe the total number of payments/items and the odds of receiving the payment/item. Otherwise, state participants will not be compensated.]*

For participating in this research you will receive \_\_\_\_\_\_\_\_\_. **OR** You will not be compensated for participating in this research.

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

[Include for a clinical trial. Otherwise delete.] Instead of being in this research study, the alternative is your usual standard of care.

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

## What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete.] If you decide to leave the research, describe the adverse consequences. If you decide to leave the research, contact the investigator so that the investigator can

* describe procedures for what participant has to do to leave the research
* describe what will happen to data collected to the point of withdrawal
* describe whether participants will be asked to explain the extent of their withdrawal
* describe if the participant has the option to withdraw from one procedure (e.g., research intervention) but can still participant in another procedure (e.g., follow-up procedures)

## Can I be removed from the research without my permission?

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include describe reasons why the subject may be withdrawn, if appropriate.

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## Who do I contact if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, contact the research team at insert contact information for the research team. For student-led research, also insert the Faculty Advisor contact information.

This research has been reviewed and approved by the Vanderbilt University Human Research Protections Program (HRPP). You may contact them at irb@vanderbilt.edu if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research participant.
* You want to get information or provide input about this research.

What happens if I experience an injury or illness from this research? [Include this section only for research involving potential risk for injury or illness. Otherwise delete.] If you need immediate medical attention because of taking part in this research study, seek medical care immediately and notify the principal investigator. This care will be billed to you, your insurance, or another third party. Vanderbilt University has no program to pay for medical care for research-related injury or illness. [describe any compensation available for research related injury, if any.]

## What else do I need to know?

*[Include when applicable.]*Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *[or replace with plans when using identifiable information/samples]* to tell you, or to pay you, or to give any compensation to you or your family.

*[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and for research involving biospecimens.]*Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will **OR** will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

*[Include for research involving biospecimens if whole genome sequencing (WGS) will or might be performed (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). Otherwise delete.]* This research will **OR** might include whole genome sequencing (insert a simple, brief explanation of what WGS is for participant comprehension).

*[When the research involves genetic testing or the collection of genetic information, researchers are required to include the content from the Genetic Information Nondiscrimination Act (GINA) Informed Consent Addendum on the VU HRPP website.]*

*[When the research involves protected health information (PHI) from a HIPAA covered entity, researchers are required to include the content from the Health Insurance Portability and Accountability Act (HIPAA) Informed Consent Addendum on the VU HRPP website.]*

Signature Block for Adult

Your signature documents that you understand the information presented to you, that your questions have been answered by the research team, and confirms your consent to take part in this research.

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Signature of participant Date

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Printed name of participant Date

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Signature of person obtaining consent Date

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Printed name of person obtaining consent

*[Replace the participant signature block with the following if the participant is unable to consent (e.g., diminished capacity to consent, etc.) and you are obtaining permission from the legally authorized representative (LAR). Otherwise delete the LAR signature block.]*

Your signature documents your permission for the named participant to take part in this research.

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Printed name of participant

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Signature of Legally Authorized Representative (LAR) Date

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Printed name of Legally Authorized Representative (LAR)

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Signature of person obtaining consent Date

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Printed name of person obtaining consent

*[Add the following block if a witness will observe the consent process. e.g., short form of consent documentation or illiterate subjects. Otherwise delete the witness signature block.]*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the research participant, and that consent was freely given by the research participant.

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Signature of witness to consent process Date

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Printed name of person witnessing consent process Date

**Signature Block for Parental Permission** *[Remove if not applicable.]*

Your signature documents your permission for the named child to take part in this research.

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Printed name of child

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Signature of parent or child’s legal guardian Date

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*[Remove second signature line if only obtaining permission from one parent/legal guardian]*

Signature of parent or child’s legal guardian Date

***Note:*** *Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to provide permission for the child. Contact legal counsel if any questions arise.*