**Governors State University**

**[Insert College here]**

**[Insert Division/Department here]**

**Title of Research Study:** [insert title of research study here]

**Principal Investigator:** [insert name of principal investigator/faculty sponsor]

**Key Information:**

The following is a short summary of this study to help you decide whether to participate or not. More detailed information is listed later on in this consent form. [For the section below, include them in a bulleted format].

* Your consent to participate in this study is being sought through a description of activities in this form. Participation in this study is voluntary and you can choose not to participate or withdraw at any time without any penalty.
* The purpose of this study is [insert brief purpose of the study].
* You will be asked to [insert brief statement of the procedures including everything that participants will be asked to do].
* We expect that your participation in this study will take [insert expected duration of the study, and if applicable, the number of times the participant will be asked to participate].
* The risks of participating are [summarize nature of risks]. The benefits of the study [insert nature of benefits, if any. If no direct benefits to participants, state this here].
* [If there are alternatives for participants other than participating, briefly indicate/summarize them here]

**Why am I being asked to participate in this research study?**

We are asking you to participate in this research study because [fill in the reason/eligibility for recruiting these participants].

**What should I know about participating in a research study?**

* Someone will explain the research study to you. [Remove for online consent or any consent that is not in-person]
* Whether or not you participate is up to you. You can choose not to participate.
* You can agree to participate and then later change your mind.
* Your decision will not be held against you or result in penalty.
* You can ask all of the questions that you want before you decide.

**What happens if I agree to participate in the research study?**

[Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:

* A description of the research activities and procedures preferably in chronological order. If practical, prepare a time-line chart or table to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The length and duration of study visits, activities, and procedures
* With whom the participant will interact
* When and where the research will be done
* List experimental procedures and identify them as such
* How often study activities and procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard or customary practice (i.e., if the study takes place in the classroom describe what is the customary educational activity and what is part of the research. If the study involves any type of clinical care (e.g. mental health care), describe what is standard care and what is part of the research
* When applicable, describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.
* When applicable indicate whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of the bio specimen if one is collected]
* [If participants are randomized to comparison groups include the following:] The group you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what intervention you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being assigned to any given group. [For double-blinded research add] Neither you nor the study team will know which group or intervention you are in. [For single blinded research add] You will not be told which group or intervention you are getting, however your study team will know.

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

[Include if there are benefits to participation. Otherwise, delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First, describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Compensation for participation is not a benefit.]

[Include for research involving prisoners only]Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

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

[If anticipated risks are minimal or less, state: “the risks of participating in this study are no greater than those someone would experience in day-to-day life”, and briefly describe any of the minimal risks below.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* Physical risks
* Psychological/emotional risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks
* Group or community harms

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

Participation in research is voluntary. You can decide to participate or not to participate.

[Include if there are alternatives other than participating. Otherwise, delete.]Instead of being in this research study, your choices may include**:** [List alternatives procedures/options. For example, for student participant pools, describe alternatives for course credit.]

[If applicable, explain how frequently participants may be contacted by the research team for keeping participants involved or to remind of appointments.]

## What happens if I say “Yes”, but I change my mind later?

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

[Include if there are potential consequences of withdrawing from the research study. Otherwise, delete] If you decide to leave the research study \_\_\_\_\_\_\_[Describe the consequences.] If you decide to leave the research study, contact the investigator so that the investigator can \_\_\_\_\_\_ [Describe the procedures for orderly termination by the participant, if any.]

[Describe what will happen to data collected to the point of withdrawal.]

## What happens to the information collected for the research?

[Describe how data will be collected and stored. Specifically, address the confidentiality of data (anonymous or deidentified?), what information will be kept, where, for how long, and who will have access to it.]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:]

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]

[It is strongly recommended that you include a section in your consent, to inform participants that you may share de-identified data you collect from them outside of the study team. Certain sponsors now require researchers to make available their de-identified data files to the research community, as do a growing number of journals in a variety of disciplines. This will enable you to share deidentified data.]

[You must include the following statements if the research is a clinical trial. Otherwise delete.] A description of this clinical trial (include NCT#) will be available at 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.

[You must include the following statements if the research is being conducted under a Certificate of Confidentiality. Otherwise, delete.]

[Note: If the researcher obtains informed consent for research covered by a Certificate of Confidentiality, NIH expects that the researcher will tell participants about the protections afforded by the Certificate and any exceptions to that protection. Sample consent language describing the protections, limitations and exceptions afforded by a Certificate is below. Researchers may adapt the language to the needs of the research participants and to the subject matter of the study. However, the language used **must cover the basic points noted below**:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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.

[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].

**Data Sharing**

Results from this study (without any of your personal information) may be shared with other researchers to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, to the best of our knowledge, no one will be able to identify you from the information we share. Despite these precautions, there is always the remote risk that there could be a breach of confidentiality, but we will do our best to avoid that risk.

## Can I be removed from the research without giving my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise, delete.] The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the participants 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.

## What else do I need to know?

[Include one of the following Mandated or permitted Reporter Language statements only if applicable. In studies in which researchers are probing for or likely to elicit information about child [or elder] abuse or neglect, the State of Illinois requires or permits researchers to report such information to authorities.] If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Or

An exception to our promise of confidentiality is when law or policy permits us in good faith to report evidence of child [or elder] abuse or neglect.

Or

We will not ask you about child [or elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

[Describe any other limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover drug use or other sensitive information (like HIV diagnosis), explain that this information may be disclosed to appropriate authorities.]

[Include for research involving more than minimal risk. Otherwise, delete.]If you need medical care because of taking part in this research study, please seek medical treatment through the investigator or a treatment center of your choice. If you seek treatment from someone other than the investigator, contact the investigator to inform [her/him] about any related injury or illness. Generally, this care will be billed to you, your insurance or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury. [Describe any compensation available for research related injury.]

[For studies taking place in a school, this paragraph must be included:]

Parents please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232 (c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

[Additional note regarding educational data: If your study involves FERPA protected information, you will be required to obtain a written (or electronic) signature. Waiver of documentation is not permitted.]

[Include if participants will be paid. Otherwise, delete.] Compensation: If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount]for your time and effort. [Indicate if the amount is pro-rated for any part of the research. Include if there is partial compensation if a participant chooses to withdraw from the research before the end.] You will be paid \_\_\_\_\_\_ [indicate how payment will occur, i.e., at the end of the session, in two week, etc.;] and you will be paid with \_\_\_\_ [what form: cash, gift card, check sent in the mail, etc.]

[When applicable indicate that the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product.]

[When applicable indicate when and how the participant will be informed of the results of the research.]

[When applicable, include whether assessment, educational or clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.] Most tests done in research studies are only for research and have no clear meaning for [developmental, educational or health care.] If the research with your identifiable information or biospecimens samples gives results that do have meaning for your health, the researchers will/will not contact you to let you know what they have found. [If appropriate:] If the researchers return biomedical 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 laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

## Who can I talk to?

If you have questions, concerns, or complaints talk to the Principal Investigator [Name and contact phone or email] and [You can list another investigator such as a student if appropriate.].

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may contact the IRB Co-Chairs (Darrin Aase and Renee Theiss) at irb@govst.edu if you have questions or concerns regarding your rights as a research participant. You may also contact the Director of Sponsored Programs and Research at 708/235-2846.

Signature for Adult 18 or older

Signing here mean that you are agreeing (consenting) to participate in this research and that you are giving the researchers permission to use the information that they collect from your participation.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

[Add the following if a witness will observe the consent process. e.g., short form of consent documentation or participants unable to read. **A witness signature is required for studies using mental health information or medical records.** Otherwise delete.]

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person witnessing consent process

Signature Block for an Adult 18 or older Unable to Consent

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

[Add the following if you will document assent of the participant.]

Assent:

[ ] Obtained verbally without a signature

[ ] Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

[Add the following if a witness will observe the consent process. e.g., short form of consent documentation, participant is illiterate, participant physically unable to sign. **A witness signature is required for studies using mental health information, or if medical record information is included.**]

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person witnessing consent process

For consent taking place online, utilize the following consent language as applicable:

If you want a copy of this consent for your records, you can print it from the screen.

[If obtaining consent via an electronic signature, please include applicable signature and date fields.]

[If obtaining consent via “I agree/I do not agree” statements (or equivalent), include the following:

If you wish to participate, please click the “I Agree” button and you will be taken to the survey.

If you do not wish to participate in this study, please select “I Disagree” or select X in the corner of your browser.]