**Consent of an Adult to Be in a Research Study**

In this form “you” means a person 18 years of age or older who is being asked to volunteer to participate in this study.

**Parents’ or Guardians’ Permission for Your Child to Be in a Research Study**

**Agreement of a Child to Be in a Research Study**

**Age <18**

In this form “you” means the child in the study *and* the parent or guardian.

* If you are the parent or guardian, you are being asked to give permission for your child to be in this study
* If you are the child, you are being asked if you agree to be in this study.

In this form “we” means the researchers and staff involved in this study at Shenandoah University.

**Protocol Title**: Insert Title

**Principal Investigator**: Name, Credentials, and Contact Information

**Key Information**

**Briefly** summarize the following four (4) elements in red below and delete this line.

1. Please read this form carefully. If you want to be in the study, you will need to give consent by signing this form. Your participation in this research is voluntary. You will get a copy of this form.
2. The purposes of the research, expected duration, and procedures to be followed.
3. Reasonably foreseeable risks or discomforts to the prospective subject
4. Benefits to the prospective subject or others that may reasonably be expected from the research
5. Appropriate alternative procedures or treatments that might be advantageous to the prospective subject.

**Purpose of Study:**

Briefly describe the study here, using second person language (i.e. you, your, yours) in lay language and avoiding professional jargon.

(In situations where it is not possible to fully disclose the purpose of a study, the following statement is optional: "Because the validity of the results could be affected if the purpose of the study is fully divulged to me prior to my participation, I understand that the purpose of the study cannot be explained to me at this time. I understand that I will have an opportunity to receive a complete explanation of the study's purpose following my participation in the study.")

**Period of Time Required:**

Your participation in this study will require # of study visits over # period of time. Each visit will last about X minutes/hours *(or use a similar format appropriate for your study) OR* this studywill add *X* minutes over the procedure you are already having.

You can change your mind about participating in this study at any time. Your permission does not end unless you cancel it. To cancel it, please send an email or a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

**Confidentiality:**

Shenandoah University researchers will do everything possible to protect your privacy. Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained.

**Procedures:**

Tell subjects what will be expected of them and what they will be asked to do; what data will be collected and how it will be used; how confidentiality will be maintained, how the subjects (or you) may terminate their participation, etc.

**Discomforts and Risks:**

Risks and side effects related to the *[procedures, drugs, interventions, devices]* include:

**Likely**

*

 **Less Likely**

*

**Rare but serious**

**Alternate Procedures (if any):**

A disclosure of any appropriate alternative procedures that might be advantageous for the subject.

**Potential Benefits:**

We cannot promise that you will be helped by being in this study.

You may benefit from being in this study. Possible benefits include: *(add benefits here).*In addition, information researchers get from this study may help others in the future.

**OR**

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

**Photographic or Voice Recording:**

This study involves the use of voice and/or video recording. Permission to photograph includes any method of producing a visual image including still cameras, movie cameras, or video camera. Voice recordings may include conventional audiotaping or videotaping. All photographs or voice recordings will remain strictly confidential with regard to your name. Any photograph or voice recording may be used for research, classroom teaching, presentation at professional meetings, or publication in professional journals and books unless specified otherwise.

You are free to with draw your consent for photographic or voice recording at any time prior to completion of the recording. After the recording, you may request that any individually recognizable photographic or voice recording not be shared with anyone but the investigator(s).

**Identifiable Biospecimens**

Your personal identifiers might be removed from the identifiable private information or identifiable biospecimens obtained from this research. After removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

**OR**

Your private information or biospecimens collected as part of the research will not be used or distributed for future research studies, even if identifiers are removed.

**Compensation:**

For research involving more than minimal risk, explain any compensation and an explanation of any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**WHEN APPROPRIATE, EDIT THE FOLLOWING SUBSECTIONS OF CONSENT TO FIT YOUR STUDY. Delete these instructions and all non-applicable statements when finished.**

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, 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 that specimen).

**If you have questions about this research study, contact:**

Principal Investigator, Name, Credentials, and Contact Information

You may report a concern about a study, ask questions about a study, ask questions about your rights as a research subject, or report a research-related injury by contacting the Institutional Review Board listed below.

IRB Compliance Coordinator, sucomply@su.edu or

IRB Chair, irbchair@su.edu

**What does your signature mean?**

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this document after you have signed it.

**Consent From Adult
To be completed by participant if 18 years of age or older.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARTICIPANT(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**Person Obtaining Consent**

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PERSON OBTAINING CONSENT(PRINT) |  | \_\_\_\_\_\_\_\_DATE |

**Parental/Guardian Permission**

By signing below you confirm you have the legal authority to sign for this child.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARENT/GUARDIAN(SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PARENT/GUARDIAN(PRINT NAME) |  | \_\_\_\_\_\_\_\_DATE |

*If obtaining assent from a minor, first obtain parental consent. Then, use the Minor Assent Form to obtain assent from a child.*