**Consent to Draw Blood for Research**

We are asking you to participate in a research study. This form is designed to give you information about this study. We will describe this study to you and answer any of your questions.

**Project Title:** Click here to enter project title.

**Principal Investigator:** Click here to enter PI name.

**What the study is about:** Click here to enter text.

**What we will ask you to do:** Click here to enter text. Describe the procedures in simple language, so that the participants can follow them in a logical manner. Describe the amount of blood, location, how often, and any other information that they might need to make an informed decision to participate in the study.

**Risks and discomforts**

A blood draw may lead to lightheadedness or fainting. It may also cause bruising, prolonged bleeding, and infection at the site where the blood was drawn. In order to minimize these risks, we will swab the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising.

To protect against infection, we will also provide instructions on how to care for the wound and watch it for signs of infection. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests as the researchers are not using this test to make a diagnosis.

**Benefits**

Click here to enter text. “There is no direct benefit to you by participating in this study. However, your participation will allow us to further understand….”

**Cost of participating**

There will be no cost to you from participation in the research, with the exception of transportation to and from the laboratories.

**Payment for participation**

Click here to enter text. List the payment and if there are any conditions that participants need to meet (including completing the entire study or any staggered payments) to receive the payment.

**Use of Samples/DNA for Future Studies**

*Include this section if you plan to use the remaining blood sample for future use. You can choose between the two options for a description.*

***Option 1- longer, more detailed description***

The blood samples obtained for the research will be used to answer specific research questions. Like most research studies, this study is expected to answer some scientific questions but is also expected to raise new questions and new ideas. We therefore ask you to consider allowing the research team to keep and use your specimens (i.e. blood samples) for future research that is not specifically defined in this protocol. As you consider this, please keep the following in mind:

* Use of the specimens will be limited to Click here to enter PI name and the immediate research team.
* Future research involving collected tissue or cells may or may not be directly related to the current research aims.
* The specimens will be coded prior to being stored in freezers and will be used in experiments by code only. Identifying information that links a participant’s personal information to his or her coded samples will remain protected and locked in filing cabinets or on password protected computers only accessible by Click here to enter PI name and the study coordinators. Laboratory staff responsible for analyzing samples will not have access to the identifying information—only the codes.
* You will not be contacted in the future for additional consent to use your samples.
* The specimens will be stored long-term with no specific end date for usage.
* There are no direct benefits to you as a participant in the collection, storage, and future research use of specimens.
* One risk of allowing storage and future research use of specimens would be a breach of confidentiality. However, as with all information gathered during this study, every effort will be made to maintain the confidentiality of your specimens to the extent permitted by law.
* If you do not agree to allow your samples to be kept and used for future research, after the testing for this research protocol is complete, any samples remaining will be destroyed and not kept for future use.
* Research results from use of samples will be analyzed as a group and published in scientific journals and/or presented at scientific meetings as grouped results—not individually identifiable results. No research results will be placed in your medical records.
* If you wish to withdraw from the study, any samples collected prior to withdrawal will be used to the extent possible, to help meet the research aims of this protocol. Whether those samples will be kept and used for future use (beyond this protocol) will depend on your selection below.
* Your samples will not be used for commercial purposes.

***Option 2: Shorter description***

The blood samples that we collect during the study will be stored for potential use in future studies. These samples might be very useful in helping to address future research questions that may arise following the completion of this study. At the time of storage, the specimen will be identified only by catalogue numbers and any link to your personal information will be removed. The Principal Investigator will oversee the storage of these specimens for up to 15 years and will regulate access to these samples by other researchers. Because your personal information will no longer be linked to the stored specimen, it will not be possible for a participant to have future access to the biological samples.

**Do you give us permission to use your blood or tissue for future research?**

*Include this if you plan to use the materials for future research*

Please indicate if you agree to let us use your tissue or cell samples for future research. You do not have to give permission to use your tissue or cell samples for future research to participate in other parts of this study. Please ask questions if you do not understand why we are asking for your permission to use your samples for future research.

I agree to allow use of my tissue or cell samples for future research. *Please check Yes or No.*

Yes – Please sign:

No

**If you are injured as a result of your research participation**

It is highly unlikely that injury will result from participation in this research. However, in the event that any study-related activities result in an injury, treatment will be made available including first aid and referral for emergency care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. Emergency medical care is not available on-site. No reimbursement, compensation, or free medical care is offered by Cornell University. If you think that you have suffered an injury related to your participation in this study, contact Click here to enter PI name.

If there is a need for immediate medical attention, seek evaluation by your primary care provider or the emergency room.

**Privacy/Confidentiality**

Click here to enter text. Sample language: In the records for this research you will be assigned a subject number only. Access to your samples and any identifying information in the study records will be limited to the PI and staff members involved with the coordination of this research. We may also need to collect some identifying information for administrative purposes (i.e., Cornell parking services, and/or an unexpected finding report); but this will not be linked to the research records. In the unlikely event of an emergency, we will also need to provide your information to medical and/or emergency personnel. The contents of your records will not be disclosed to any party other than a University or government agency if required by law. All research records will be kept in a locked file cabinet and a password protected computer database. Please note that email communication may not be private or secure. Though all precautions are taken to protect your privacy, information sent through e-mail could be read by a third party.

**Data sharing**

Click here to enter text. *(Some journals and sponsors require that de-identified raw data be made available in some manner to reviewers or others who may benefit from sharing of the data. If you believe that this is an expected practice in your field, we strongly recommend adding this language, to ensure that you have consent to share data in this manner.)*

De-identified data from this study may be shared with the research community at large 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, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Taking part is voluntary**

Taking part in this procedure is completely voluntary. If you decide not to take part or not to complete the procedure, it will not affect your current or future relationship with Cornell

University. If you decide to take part in the procedure, you are free to withdraw at any time.

**Termination of research by investigator, physician, or funding sponsor(s)**

The investigators, clinicians, or funding sponsor(s) may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, for example, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study or terminate the research for various other administrative and medical reasons. They can do this without your consent.

**If you have questions**

The main researcher conducting this study is Click here to enter PI name.Please ask any questions you have now. If you have questions later, you may contact Click here to enter PI name and contact information. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at (607) 255-5138 or access their website at http://www.irb.cornell.edu. You may also report your concerns or complaints anonymously through Ethicspoint online at www.hotline.cornell.edu or by calling toll free at 1-(866) 293-3077. Ethicspoint is an independent organization that serves as a liaison between the University and the person bringing the complaint so that anonymity can be ensured.

You will be given a copy of this form to keep for your records.

**Statement of Consent**

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

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Your Signature Date

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Your Name (printed)

Signature of person obtaining consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*This consent form will be kept by the researcher for at least five years beyond the end of the study.*