## Note to Investigators: Orange italicized text is provided for guidance. Remove all orange, italicized help text and any instructional text prior to submitting this document. This form should be used to develop an informed consent document for adults. You must use language that will be understood by your target population. You may delete sections that are not applicable to your study. If your research involves at-risk or more than minimal risk procedures, biomedical procedures (e.g., MRI, biopsies, etc.), certain funding agencies, or is a clinical trial, please use HRP-502 – TEMPLATE – Consent Document as there are important sections that must be included.

## INFORMED CONSENT DOCUMENT

**(NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.)**

## Title of research study[[1]](#endnote-1): *Insert title of research study here with protocol number, if applicable*

## Investigator: *Insert name of principal investigator*

## KEY INFORMATION

## The following table is a short summary of this study to help you decide whether or not you would like to participate in this research study. More detailed information is listed later on in this form.

|  |  |
| --- | --- |
| **General Information** | *Sample language: You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in this consent form.* |
| **Purpose** | *Sample language: The purpose of the study is to \_\_\_\_\_\_\_\_\_.* |
| **Duration & Visits** | *Sample language: There will be a total of \_\_\_\_\_ visits, each lasting \_\_\_\_\_ minutes/hours. Your total time commitment for the entire study will be \_\_\_\_\_\_\_\_\_ minutes/hours.* |
| **Overview of Procedures** | *Sample language: You will be asked to \_\_\_\_\_\_\_\_. This involves \_\_\_\_\_\_\_\_. (Investigators should describe the main study procedures in language that will be understood by their target audience. If using abbreviations, be sure to define them at first use.)* |
| **Risks** | *Sample language: The risks associated with this research are \_\_\_\_\_\_.*  |
| **Benefits** | *Sample language: There are no direct benefits to you for participating in this study. The benefit to researchers is to \_\_\_\_\_\_\_. (Briefly describe benefits, keeping in mind that compensation is not considered a benefit.)* |
| **Alternatives** | *Sample language: The alternative is not to participate in this study. -or- Briefly describe alternatives.* |
| **Right to Withdraw from the Study** | *Your decision to be in this study is voluntary. If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.* |

## DETAILED INFORMATION

## The following is more detailed information about this study.

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

You are invited to participate in a research study to *(state purpose and objectives).* The study is being conducted by *(your name, title)*, under the direction of *(advisor, title)* in the Auburn University Department of *(name)*. You were selected as a possible participant because you are *(insert inclusion criteria and/or describe the target population)*.

## How many people will be studied?

We expect about *(#)* people locally will be in this research study out of *(#)* people in the entire study nationally (or internationally).

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part in the research study is up to you. You may wish to talk to your family and friends about participating in the study.
3. You can choose not to take part in the study.
4. You can agree to take part in the study and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide whether you would like to take part in the study or not.

## Why is this research being done?

Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.

What will be involved if I participate?

If you decide to participate in this research study, you will be asked to (include a high-level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.). Specifically, as a research participant, you will be asked to:

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

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* All devices that will be used
* The length and duration of visits and procedures
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* How often procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care
* When applicable indicate that the subject will be contacted for future research.

If you will be taking photographs or audio/video recording participants, the following information must be included (otherwise delete):

* Purpose of recording/photographs and what the photographs/recordings will be used for
* Where the recordings/photographs will be stored, and the security of that storage
* How long recordings or photographs will be kept
* When the recordings or photographs will be destroyed (i.e., month/date/year)
* Whether or not the photographs or recordings will be de-identified and what the de-identification process is

Example language to include if using audio recording: Interviews may be recorded using audio recording devices to assist with accuracy of your responses. You have the right to refuse the audio recording. Please initial one of the following options:

 \_\_\_\_\_ YES, I consent to audio recording.

 \_\_\_\_\_ NO, I do NOT consent to audio recording.

Example language to include if using video recording: Interviews may be recorded using video devices to assist with the accuracy of your responses. You have the right to refuse the video recording. Please initial one of the following options: \_\_\_\_\_ YES, I consent to video recording.

 \_\_\_\_\_ NO, I do NOT consent to video recording.

Example language to include if taking photographs: Photographs of participants may be taken to preserve an image related to the research. You have the right to refuse to allow photographs to be taken. Please initial one of the following options:

 \_\_\_\_\_ YES, I consent to having photographs taken.

 \_\_\_\_\_ NO, I do NOT consent to photographs being taken.

If you will be using photographs or audio/video recording outside of the purposes of the research, you must have participants complete a photograph/audio recording/video recording release form (HRP-576 - TEMPLATE - Audio, Video, Photo Release) in addition to the above statement. Upload the release form under Local Site Documents 🡪 Other Attachments in Endeavor.

## How long will the research last and what will I need to do?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ (hours/days/months/weeks/years, until a certain event)**.**

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

This section of the consent form should identify the risks of the research. The risks of procedures may be presented in a table form, if preferred. Consider and describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks associated with participating in this study are:

* Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks

Include for in-person research: This study involves in-person research activities that carry an inherent risk for transmission of illnesses including respiratory viruses such as COVID-19, flu, and RSV. Should you feel uncomfortable, you can either ask researchers to wear a mask or elect not to participate in this research project.

Include for research where the sponsor *provides study-related agents/procedures at no cost to ALL subjects. Otherwise delete:* The sponsor will provide the following study-related items/procedures for you at no cost during participation in the study: Describe what is provided.

Include for research that *may result in additional costs for all subjects, otherwise delete:* Taking part in this research study may lead to added costs to you. Describe what these costs are.

*I*nclude for research that will collect/store data and samples for future research, otherwise delete:

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data. In either case, we cannot reduce the risk to zero.

To minimize these risks, we will:

* Outline measures to mitigate each risk listed above

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

This section of the consent form should identify likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits.

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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. (First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.)

Include for a study with no benefits to participation, otherwise delete: There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Describe any benefits to others. Monetary reimbursement for participation is not a benefit.

## *Include for research involving prisoners*: 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.

***Will I receive compensation for participating?***

To thank you for your time you will be offered *(insert compensation).* *If providing partial compensation, outline how compensation will be determined. It may help to provide an example.* Compensation will be paid *(indicate when the participants will be compensated). If the compensation amount is greater than $100, participants will have to register with the Auburn University Vendor Center per Auburn University policies, unless an exception has been granted due to the nature of the study. If an exception has been granted, please be sure to upload documentation of the exception in ‘Local Site Documents’. If there is not an exception, please include language similar to the following:* You will need to register with the Auburn University Vendor Center to be compensated. The Auburn University Vendor Center will require you to complete tax documents which will require you to provide sensitive information such as your social security number and birth date.

Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid, otherwise delete: Military personnel should check with their supervisor before accepting payment for participation in this research.

Include for students: Please note that if you participate in this study as an Auburn University student, the participant payment will be counted as a resource for the purposes of calculating your financial aid eligibility. If your total aid from all sources (federal aid, scholarships, loans, waivers, resources, etc.) exceeds the published Cost of Attendance (estimated costs for you to attend school and pay for living expenses while enrolled), then the participant payment may result in a reduction to the aid, up to the amount of the participant payment.

## 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. Your decision not to participate or to stop participating will not jeopardize your future relations with Auburn University, the Department of *(insert department, school, center, or institute)* or *(insert any other organization or affiliation associated with the research)*. 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 if there are no alternatives other than participating: Your alternative to participating in this research study is to not participate.

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

Delete this section if the research is not an applicable clinical trial.

If you take part in this research, you will be responsible to: Describe any responsibilities of the subject.

## 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. If you choose to withdraw, your data can be withdrawn as long as it is identifiable.

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 the procedures for orderly termination by the subject, if any).

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

Your privacy will be protected.Any information obtained in connection with this study will remain *(anonymous, confidential, etc.)*. Information obtained through your participation may be used (*e.g., to fulfill an educational requirement, published in a professional journal, presented at a professional meeting, etc*.). Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and (*add* to this list other organizations that may have access to the subject’s records).

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.

*Include for NIH-funded studies or those receiving a CoC by request from NIH, as applicable:*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. Disclosures that you consent to in this document, or you make yourself are not protected. The Certificate **cannot be used** to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. 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.

*Other sample language to consider:* We will protect your privacy and the data you provide by keeping your research data and your identifying information *(like your name and email)* separate, linked only by a randomly generated participant code. Only study staff will have access to your research data.

## FUTURE USE OF DATA

*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.*

If identifiers are removed from your identifiable private information or identifiable data that are collected during this research, that information or those data 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 data 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.

Include if a HIPAA authorization is required, otherwise delete: Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

Include for research involving prisoners, otherwise delete: If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

*Include this section if data or specimens will be retained after the study for future research, add/modify the following text to explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.*

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data for *(insert time frame as indicated in the study protocol)*. To get your data, future researchers must *(insert conditions)*.

*If the data are coded and can be linked back to the identity of the participant enter the following text:*

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before they are shared with other researchers. Only the study team *(or indicate who has the code key)* will have a code key that can be used to link to your identifying information. The code key will be securely stored.

*If the data cannot be easily linked back to the identity of the participant enter the following text:*

Your name and identifying information will be removed from any data you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data.

*Include when sharing of data will NOT be optional (e.g., where sharing is integral to the purpose of the study):*

Participating in this study means you agree to share your data. You can change your mind later, but researchers might still use your data if they have already been shared. If you do not want your data and samples used for other research studies, you should not participate in this study.

*Include an area for participants to endorse the future use of their data:* It is your choice whether or not to let researchers share your data 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, you should contact the investigator. We will do our best to honor your request and to get back any data 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, we will not be able to get them back. In addition, if the data have already been used for new research, the information from that research may still be used. We will destroy any data we have or are able to get back.

Please initial next to your choice:

 \_\_\_\_\_\_YES, my data **may** be used in other research studies

 \_\_\_\_\_\_NO, my data **may not** be used in other research studies

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

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.

## What else do I need to know?

Include for sponsored research, otherwise delete: This research is being funded by (insert name of sponsor). *If you have conflicts of interest to disclose, please do so here.*

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at insert contact information for the research team. This research has been reviewed and approved by the Auburn University Institutional Review Board (IRB). You may contact the Auburn University IRB at (334) 844-5966 or IRBadmin@auburn.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 subject.
* You want to get information or provide input about this research.

There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used. Omit the signature page if there is no written documentation of consent.

ELECTRONIC, ONLINE, OR VIRTUAL CONSENTING *must include the following statement:* The Auburn University Institutional Review Board has approved this document for use from \_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_. Protocol #\_\_\_\_\_\_\_\_.

Signature Block for Capable Adult

Having read the information provided, you must decide whether or not you wish to participate in this research study. Your signature documents your permission to take part in this research. A copy of this document will be given to you to keep.

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

Signature of subject Date

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Printed name of subject Date

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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).*

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 subject, and that consent was freely given by the subject.

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

Signature of witness to consent process Date

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Printed name of person witnessing consent process Date

Signature Block for Adult Unable to Consent

Having read the information provided, you must decide whether or not you wish for the named subject to participate in this research study. Your signature documents your permission for the named subject to take part in this research. A copy of this document will be given to you to keep.

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Printed name of subject

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Signature of legally authorized representative Date

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Printed name of legally authorized representative

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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 you will document assent of the subject.*

Assent

[ ]  Obtained

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

*Add the following block if a witness will observe the consent process(e.g., short form of consent documentation or illiterate subjects).*

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 subject, and that consent was freely given by the subject.

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

Signature of witness to consent process Date

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Printed name of person witnessing consent process

***Signature Block for Children***

Having read the information provided, you must decide whether or not you wish for the child named below to participate in this research study. Your signature documents your permission for the named child to take part in this research. A copy of this document will be given to you to keep.

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Printed name of child

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Signature of parent or individual legally authorized Date

to consent to the child’s general medical care

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Printed name of parent or individual legally authorized Date
to consent to the child’s general medical care

[ ]  Parent

[ ]  Individual legally authorized to consent to the child’s general medical care (See note below)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.

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Signature of parent Date

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Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

[ ]  The IRB determined that the permission of one parent is sufficient. *Delete if the IRB did not make this determination*

[ ]  Second parent is deceased

[ ]  Second parent is unknown

[ ]  Second parent is incompetent

[ ]  Second parent is not reasonably available

[ ]  Only one parent has legal responsibility for the care and custody of the child

*Add the following block if you will document assent of children.*

Assent

[ ]  Obtained

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

*Add the following block to all consents.*

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

Signature of person obtaining consent and assent Date

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Printed name of person obtaining consent IRB Approval Date

*Add the following block if a witness will observe the consent process (e.g., short form of consent documentation or illiterate subjects).*

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 subject, and that consent was freely given by the subject.

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

Signature of witness to consent process Date

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Printed name of person witnessing consent process

ELECTRONIC, ONLINE, OR VIRTUAL CONSENTING: If using an electronic or virtual consent process, please be sure to include a signature block and a typed name field.

1. This template satisfies AAHRPP elements I.1.G, I.4.A, I-9, II.3.C-II.3.C.1, II.3.E, II.3.F, II.4.B, III.1.F, III.1.G [↑](#endnote-ref-1)