Participant's Name: _____
Participant's Medical Record Number: _____

Consent Form and Consent Process Requirements

(2018 Regulations additions in red)

This coversheet is for information purposes only for the investigator and study team. It should be removed before submitting the consent to the IRB.

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's LAR
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR
4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension

   Note: The consent form template has been revised to include a 'key information' template. The remainder of the consent document is to provide additional information and detail concerning the study.

6. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate
7. No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
8. Investigators are responsible for ensuring the consent and consent process (to include documentation of consent) follow the requirements outlined in the IRB Policy: Informed Consent.

Augusta University

Biomedical Research informed Consent Document

(Title of the Research Project)

Principal Investigator: *name, credentials, institutional affiliation*	**Principal Investigator telephone number (available 24/7 and for emergencies):**
Sub Investigator(s): *name, credentials, institutional affiliation Listing Sub-Investigators is optional*	**Faculty Advisor:** *name, credentials, institutional affiliation*
Sponsor: *name*	**Other Study Contact Numbers,** *if applicable*

Key Information Section

The initial summary cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter. Defer the greater detail to the body of the consent form following the initial summary

Organize the consent information in sufficient detail relating to the research in a way that facilitates the prospective subject's or legally authorized representative's understanding of the reasons.

You may be eligible to take part in this research study. Taking part in this study is completely voluntary.

This form contains information that will help you decide whether to take part. All of this information is important, but here are some key important points to keep in mind:

- It is completely up to you whether you take part in this study.
  - Even if you decide to join the study, you are free to leave at any time if you change your mind.

- This is research; medical scientists do research to learn about diseases or conditions and how to treat them.
    - Research is different from regular medical care, which has already been tested in research.
- If your research involves storage, future use, and/or sharing of specimens and/or data, briefly summarize here.
- Provide a summary of the following:
    - Purpose of the study.
    - Expected duration of the study.
    - Reasonable, foreseeable risks/discomforts.
    - Reasonable, expectable benefits, if applicable.
    - Alternative procedures.
- Optional study components
    - If your research includes optional sub-study, briefly summarize here.
    - If your research involves optional broad consent to storage, future use, and/or sharing of specimens and/or data, briefly summarize here.

Required for Parental Consent or including a Legally Authorized Representative

If you are a legally authorized representative, or parent, permission from you is required. If the research involves a child, their assent (agreement) may also be required. When we say "you" in this consent form, it means the research subject; "we" means the staff involved with this study.

You are being asked to take part in this research study about ***(name of condition/study – keep to as few words as possible)*** (*choose the applicable language 1 and/or 2)*

1) because you have ***[name of condition/diagnosis] OR***

2) as a normal/healthy volunteer

The purpose of this document is to:

- Explain your rights and responsibilities
- Explain the purpose of the study
- Describe what will happen if you decide to take part in this study
- Explain the potential risks and benefits of taking part in the study

Participation in research studies is voluntary. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please

ask them to explain any words or information that you do not clearly understand. You are encouraged to talk with your family and friends before you decide to take part in this study.

Please tell the study staff if you are taking part in another study.

Why is this study being done?
The purpose of this study is to……. *Briefly describe the purpose of the study (1-2 sentences)*

There will be up to *(indicate #)* participants enrolled *at (indicate name(s) of local sites)* with a total of *(indicate total enrollment #)* at all sites.

Required Language for all clinical trials to include, but not limited to, FDA-regulated research:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

How long will I be in this study?
Your active participation in this study is expected to take *[indicate approximate time period].* You can choose not to be in the study or stop participating at any time without penalty or loss of any rights or benefits you are entitled to. Please talk to the study staff first before you stop participating in the study.

What will happen to me in the study?

- *Describe the procedures involved in the study. Include information regarding the study drug, device, samples, questionnaires, follow-up, etc… (whatever is applicable to your study).*

- *When describing what is involved in the study, consider laying out a timeline. For example, on Day 1, you will have an EKG and two tablespoons of blood will be drawn from your arm by needle stick for blood tests. On Day 2, you will receive the study drug intravenously (into your vein) for two hours (and so forth). You can also create a timeline using visits. For example, on Visit 1, you will receive study drug to take daily until Visit 2.*

What tests and/or extra tests will I have if I take part in this study?

Use of this table is optional, but preferred to ensure participant understanding. If you choose not to use the table, the information contained in the table must still be addressed in this section, if applicable. Include information as to whether clinically relevant research results, including individual research results, will be provided to subjects and if so, under what conditions.

Normal clinical care procedures	**Research procedures done only because of study**	**Optional research tests/procedures**

What are the risks of being in this study?

Please note: The risk section should only contain the risks associated with study procedures. Risks of standard care procedures should not be included in the consent form unless the study is researching the risks associated with standard of care procedures. Please consider all risks including psychological, confidentiality, financial, etc.

As a result of your participation in this study, you may have the following side effects and/or discomforts from ***(List Study Drug/Device Name/Procedure)***

More likely ***(list more common side effect below using bullets)***

-

Less Likely ***(list less common side effect below using bullets)***

-

Rare, but serious ***(list below using bullets)***

-

Please see the glossary of approved language for risks associated with: Drugs, Devices, and Procedures, Those of Reproductive Potential, Risks of Radiation, Risks of Drawing Blood, Drug and Food Interactions, Risks of Washout, Confidentiality risks for minimal risk studies

You should discuss these with the study doctor and your regular health care provider if you choose to do so.

There may be more risks that are not known or not expected.

The study staff will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Required language, if applicable, regarding whether clinically relevant results, including individual research results, will be disclosed to subjects:

Choose either Paragraph A or Paragraph B

Paragraph A:

Results of the research, which may be relevant to your clinical care will not be shared with you.

Paragraph B:

Results of the research, which may be relevant to your clinical care will be shared with you under the following conditions:

{LIST CONDITIONS}

Will I benefit from this study?
Choose either Paragraph A or Paragraph B.

Paragraph A:
The possible benefits of this study are: *Insert all benefits to the participant.*

Required language for Phase I Protocols: The likelihood of you benefitting from this study is low.

Paragraph B: (Required if there is no direct benefit to the participant): This study is not designed to benefit you directly. The study results may benefit others in the future.

What are my other choices if I do not take part in this study?
Required if applicable for studies in which an alternative is available:

You are not required to take part in this study. Some other options for you are *(Use a bulleted list for alternatives and always include their option to not participate in this study.)* The study staff will discuss these other options with you.

Who will see my study information?

Study team members, the sponsor of the study, and their representatives will be able to see your study information. Your records may also be reviewed in order to meet federal or state regulations. Reviewers may include the Augusta University Institutional Review Board (the committee who oversees safety of volunteers in research studies), institutional officials, and outside agencies, such as the Food and Drug Administration (FDA).

How will you keep my study information confidential?

Study records that identify you will be kept confidential except as required by law. You will not be identified in study records or publications disclosed outside Augusta University.

Please note:

- *If there are any exceptions, modify the above-sentence to provide details.*
- *If the study involves access, use, and/or disclosure of protected health information (PHI) please ensure the HIPAA Authorization template (page 8-9) is formatted and is included in this consent document.*

What will happen to my identifiable private information/biospecimens once collected? (Required if there is study involves the collection of identifiable private information or biospecimens):

Choose one of the following:

Paragraph A:

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected as a part of this research. After such removal, the information or biospecimens could be used for future research studies or be distributed to another investigator for future research studies without getting additional informed consent from you or your legally authorized representative.

Paragraph B:

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

Required sentence if the research may involve whole genome sequencing:
The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

Sentence for studies using biospecimens that may be used for commercial profit: Your biospecimen (tissue, blood, etc.) may be used for commercial profit (even if identifiers are removed).

Choose the applicable sentence, A or B:

Sentence A:

You will share in this commercial profit.

Sentence B:

You will not share in this commercial profit.

What are my costs (what will it cost me) for taking part in the study?

Choose either Paragraph A if there is no expense to the participant for the study. Choose paragraph B if the participant or their insurance company is paying for clinical care, and the sponsor is paying for all research related expenses involved. Choose paragraph C if the participant or their insurance company is paying for participant clinical care and research expenses. Choose paragraph D if the participant or their insurance company is paying for some of the clinical care and/or research expenses, and the research sponsor is paying for some of the clinical care and research related expenses.

Paragraph A

It will not cost you anything to take part in the study other than basic expenses like transportation.

Paragraph B:

If you agree to participate in this study, you and/or your insurance will not be billed for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. You will be responsible for all co-pays, deductibles and denied claims.

You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you.

Paragraph C:

If you agree to participate in this study, you and/or your insurance will be billed for the tests and treatments that are standard clinical care as well as those being done only for research. You are responsible for paying for the usual care you would normally receive for the treatment of your illness. You will be responsible for all co-pays, deductibles and denied claims.

You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you.

Paragraph D:

If you agree to participate in this study, you and/or your insurance will not be billed for the following tests and treatments that are being done for clinical care or for research:

- A
- B
- C
- Etc.

You or your insurance company are still responsible for paying for research care and/or the usual care you would normally receive for the treatment of your illness (including all co-pays, deductibles and denied claims) listed below:

- A
- B
- C
- Etc
- Any items not listed above as being covered.

You have the right to ask what it will cost you to take part in this study. You have the right to contact your insurance company to discuss the costs of your routine care and whether these will be covered if you participate in this study. You may choose not to be in this study if your insurance does not pay for your routine care. In that case, your doctor will discuss other treatment plans with you.

Will I be paid for participation in this study?
(Choose paragraph A or B)

Paragraph A: (If the participant will not be paid)
You will not be paid for taking part in this study.

Paragraph B: (If the participant will be paid)
You will get $____ for each completed study visit, to compensate you for your time and effort. Your payment will be made via *(list method of payment and use additional language from the Optional Template Language, if needed).* If you do not finish the study, we will compensate you

for the visits you have completed. You will get $____ total, if you complete all study visits. Augusta University is required by law to report any payments we make to the Internal Revenue Service (IRS). To do this, you will need to complete a W-9 form and provide your name, address, date of birth, research study name and social security number.

Payment received as compensation for participation in research is considered taxable income to the research participant. If payment to an individual exceeds $600 in any one calendar year, Augusta University is required to report this information to the Internal Revenue Service (IRS). Research participant payments to a non-employee of AU exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Please see the Optional Template Language regarding:

- *Greenphire ClinCard, (NOTE to study team: use of card is required for studies involving more than one payment for study visits)*
- *Augusta University employee payment*
- *IRS Form 1099 requirement for total compensation from AU if total reimbursement for the calendar year exceeds $600.00*

What happens if I am injured or hurt because I took part in this study? (Optional Language - Required for greater than minimal risk research only)

Choose either Paragraph A (if the participant is responsible for costs associated with injury) or B (if the sponsor is responsible for costs associated with injury)

Paragraph A

If you think that you have suffered a research related injury seek medical care right away and contact the study team as soon as possible at *[insert phone number].* In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company.

No reimbursement, compensation, or free medical care is offered by Augusta University (AU), AU Medical Center, AU Medical Associates, AU Dental Associates, AU Nursing Associates, Inc., AU Health Professions Associates, Inc. collectively designated AU Affiliates, [or any other facility involved with this study]. You do not give up your legal rights by participating in this study.

Paragraph B

If you think that you have suffered a research related injury seek medical care right away and contact the study team as soon as possible at *[insert phone number]*. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed, so long as (1) the injury was not caused by negligence or willful misconduct of the institution and (2) it was not due to the natural progression of a pre-existing condition, cost for such care will be paid by *[insert sponsor's name].*

No reimbursement, compensation, or free medical care is offered by Augusta University (AU), AU Medical Center, AU Medical Associates, AU Dental Associates, AU Nursing Associates, Inc., AU Health Professions Associates, Inc. collectively designated AU Affiliates, [or any other facility involved with this study]. You do not give up your legal rights by participating in this study.

Who can answer my questions about this study?

You can ask questions about this study at any time. Please contact the study staff listed on page 1 of this document if you have questions about:

- Study procedures or treatments
- Reporting an illness, injury or other problem
- Leaving the study before it is finished
- Expressing a concern about the study
- Any other questions you may have about the study

Who can I contact to discuss my rights, problems, concerns, questions, or complaints I have as a study participant?

Contact the Augusta University Institutional Review Board at (706) 721-1483.

Could there be any harm to me if I decide to stop participating in the study before it's finished? Optional Language, only if applicable:

Where applicable, describe the consequences of a research participant's decision to withdraw, and the procedures for orderly termination of participation by the participant. [45 CFR 46.116(a)]

If you decide to stop taking part in the study, the study staff will discuss ways to safely remove you from the study. You should follow the instructions the study staff gives you.

Can I be removed from the study? Optional Language, only if applicable

Indicate the investigator regardless of the research participant's consent may terminate the research participant's participation, and if possible, describe the circumstances under which this might happen. [45 CFR 46.116(a)]

Yes, you may be removed from the study if:

{insert bulleted list of applicable reasons for withdrawal}

Some examples are:

- *The sponsor or study doctor decides to stop the study.*
- *The study doctor stops your taking part in the study for your safety.*
- *You are not eligible to take part in the study.*
- *Your condition changes and you need treatment that is not allowed while you are taking part in the study.*
- *You do not follow the instructions from the study staff.*

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study ***(Required for all studies that will access, use, review, collect, or disclose protected health information)***

If you sign this document, you give permission to Augusta University and AU Affiliates to use or release your health information that identifies you for the study described earlier in this document.

The health information Augusta University and AU Affiliates may use or release for this study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or released to the following, as applicable:

- Researchers and their staff;
- The sponsor of the study including its agents such as data storage banks or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurers or payers in order to secure payment for covered treatment;
- Parents/Guardians of children younger than 18 years
- Federal/state agencies and Augusta University and AU Affiliates committees having authority over the study. These may include, but are not limited to:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Food and Drug Administration;
    - National Institutes of Health;
    - Other governmental offices as required by law.

Augusta University and AU Affiliates are required by law to protect your health information. By signing this document, you authorize Augusta University and AU Affiliates to use and/or release your health information for this research.

Once your information has been released outside Augusta University and AU Affiliates, it may no longer be protected by federal laws and regulations and might be disclosed by the persons or institutions receiving the information.

Please note that:

REQUIRED SENTENCE IF THE STUDY INVOLVES TREATMENT:
You cannot receive research-related treatment if you do not sign this Authorization.

Augusta University and AU Affiliates may not withhold treatment whether or not you sign this Authorization.

You may change your mind and take back (revoke) this Authorization at any time. If you revoke this Authorization, Augusta University and AU Affiliates may still use or release health information and any data and/or specimens already obtained about you as necessary for this study. If you revoke this Authorization, you cannot continue to participate in this study. To revoke this Authorization, you must write to the Principal Investigator listed at the top of this document.

You may not be allowed to see or copy the study information described on this Authorization as long as the study is in progress. Feel free to ask the study staff if this applies to this study. When the study is complete, you have a right to request a copy of your personal health information collected for the study.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization does not have an expiration date. If you have questions or concerns about this Authorization or your privacy rights, please

contact the Augusta University and AU Affiliates Privacy Officer at 706-721-0900 or the toll free hotline at 1-800-576-6623

Regulations require that you be given a copy of the Augusta University and AU Affiliates Notice of Privacy Practices describing the practices of Augusta University and AU Affiliates regarding your health

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **I am not giving up my legal rights by signing this form.**

_____
Participant's Name (print)

_____ _____
Participant's Signature Date /Time (00:00)

Additional Signature Blocks, as applicable

PARENTAL STATEMENT OF CONSENT

(The parental statement should be used when enrolling minors and the above Statement of Consent should be removed. Unless otherwise approved by the IRB, the minor must review and sign the applicable Children's Assent Document.)

I have read this form and the information in it was explained to me and my child. My taking part in the study is voluntary. All of my questions were answered. I will receive a copy of this form for my records. I agree to take part in this study. **My child is not giving up their legal rights by my signing this form.**

_____
Child's Name (print)

_____
Parent or Child's Legally Authorized Representative Name (print)

_____ _____
Signature of Parent or Child's Legally Authorized Representative Date /Time (00:00)

LEGALLY AUTHORIZED REPRESENTATIVE STATEMENT

I am the legally authorized representative of the participant and I am acting on behalf of the participant. I am not aware of anything that might create a conflict of interest for me in this role (for example, something that might bring me personal benefit). I am acting solely in the interest of the participant. I consent to the participant being in this study.

If, during the course of the study, the participant regains the ability to make decisions he/she will be informed of the decisions I've made during the time of their incapacity and any effects that may have occurred as a result. The participant will then be asked to read this consent form and decide whether to continue in the study.

_____
Legally Authorized Representative's Name (print)

_____
Legally Authorized Representative's Signature Date /Time (00:00)

_____
Authority of the Legally Authorized Representative or Relationship to Subject

WITNESS STATEMENT
A witness to consent is used on an as-needed basis.

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

_____
Witness Name (print)

_____ _____
Witness's Signature Date /Time (00:00)

INVESTIGATOR STATEMENT (***Required***)
I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. They have voluntarily agreed to participate. I have documented this action in the participant's medical record source documents or research chart source documents, as applicable. A copy of this signed document will be placed in the participant's medical record or research chart, as applicable. A copy of this document will be given to the participant or the participant's legally authorized representative.

_____
Printed name of Investigator obtaining consent

_____ _____
Signature of Investigator obtaining consent Date /Time (00:00)