**TEMPLATE CONSENT DOCUMENT**

Updated 12/18/2024

**Instructions for Research Team:**

This document must be written in commonly used, easily understood language (not above 8th grade reading level is recommended) with all technical terms fully explained in language the participants can be expected to understand, and must clearly present all the information the participant (or legally authorized representative) needs in order to make a reasonable and informed decision concerning voluntary participation.

You may edit the format of this template to suit your needs, but you must include a 1-3/4” margin at the bottom of each page to accommodate the IRB approval stamp. A (version) date must be inserted as a footer on each page shown as month/date/year.

Not all research studies involve protected health information (PHI). However, when a study necessarily involves PHI, specific assurances in the form of a HIPAA Authorization must be obtained in order to request/use/disclose PHI of research participants. **If you anticipate collecting PHI from the participants’ healthcare providers for your study, or if your research includes provision of healthcare and thus creation of PHI, do not use this template**. Use the template provided on the IRB website that includes a HIPAA authorization form in your submission to the IRB.

**All fields contained in this form are needed to meet regulatory requirements** unless otherwise noted, and should be included as appropriate. You may add additional sections to this form as necessary, but you should not delete any statements (other than those bracketed in red or as otherwise instructed).

All fields that require attention appear in RED. For each section that requires attention, please carefully read the additional instructional information that follows that particular field in [bracketed red]. This information may help you determine what to include for each field.

When you use this template for submission to the IRB, you should:

* Fill out all fields appearing in RED and change the text color to black;
* Delete all the instructions that appear in [bracketed red];
* Delete any optional language that appears in RED;
* Delete this instruction page; and
* Ensure appropriate heading and footer appear on each page.

If at any time during this process you have any questions, please do not hesitate to contact the IRB Office. We will be happy to assist you.

Institutional Review Board

Ross Hall Fourth Floor | Box 70565

p: 423.439.6053

**CONSENT FORM**

This Consent Form will explain about being a participant in a research study. It is important that you read this material carefully, and then decide if you wish to voluntarily participate.

**SUMMARY**

**[*THE SUMARY SECTION SHOULD ONLY BE INCLUDED IN CONSENT FORMS THAT ARE MORE THAN 4 PAGES LONG.* The information in this section should be a concise and focused presentation of the key information that will help participants understand why one might or might not want to participate. This should be brief yet provide enough information for the potential participant to decide if he/she would like to look into this study further.]**

Here is a brief summary of this study.

* Purpose:
* Duration:
* Summary of Procedures:
* Risks:
* Benefits:

If you are interested in volunteering for this research study, please read the rest of this document.

**STUDY DETAILS**

1. **Purpose:** The purpose(s) of this research study INSERT SPECIFIC PURPOSE(S)

[State specific purposes of the investigation and a general statement as to its nature, i.e., how it relates to other knowledge and what use may be made of the results obtained. It should be made unmistakably clear whether the study involves an investigational and/or marketed drug or device.]

1. **Duration:** INSERT SPECIFIC DURATION

[State the expected duration of the subject’s participation. For example, if your study includes multiple visits, explain how many visits and how long each will take, and over what time period they will occur. In addition, if the approximate number of participants involved in the study is important to a decision to take part in the research, state the approximate number of participants.]

1. **Procedures:** You will be asked to INSERT PROCEDURES

[Identify any procedures which are experimental. Describe the procedures to be used, including invasive or non-invasive techniques, restrictions on normal activities, possibility of receiving inactive material in a double-blind trial, an identification of any experimental procedures, and specimens to be collected, including frequency and size/amount.]

[If there are anticipated circumstances under which the participant’s participation will be terminated by the investigator without regard to the participant’s consent, the consent process must disclose those anticipated circumstances.]

1. **Alternative Procedures/Treatments:** The alternative procedures or treatments available to you if you decide not to participate in this research study are INSERT ALTERNATIVE TREATMENTS/PROCEDURES

[State any appropriate alternative procedures or course of treatment that might be available or advantageous to the participant. Identify the risks of alternative procedures/treatment. If there are no alternatives, delete this section.]

1. **Possible Risks/Discomforts:** The possible risks and/or discomforts from your participation in this research study include INSERT POSSIBLE RISKS/DISCOMFORTS

[State any known risks, side effects or inconveniences that could be expected as well as risks/discomforts which are not yet known. If applicable, state that the drugs/devices with which you are being treated experimentally are/are not packaged in child resistant containers and should be kept out of reach of children; also, suggest “You should not allow study medication to be taken by anyone but yourself.” If appropriate, list exclusions, e.g., For Females Only: “You should not participate in this study if you are now pregnant or could become pregnant. Should you become pregnant you must notify the study physician immediately.” Alternately, if there are no known or expected risks/discomforts, this must be clearly stated.]

[Statement must be included here if the risk profile of all research-related interventions is **not** well known **or** If the research involves investigational drugs or devices, the consent process must include a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.]

[Statement must be included here if the research includes pregnant women or women of child bearing potential, the consent process must disclose that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable unless the risk profile of all research interventions or interactions on embryos and fetuses is foreseeable or there is no reasonable expectation that this research causes risks to fetuses or embryos.]

1. **Possible Benefits:** The possible benefits of your participation in this research study are INSERT POSSIBLE BENEFITS

[Describe potential benefits, which might reasonably result from the research. Identify those to be gained by the individual participant as well as those by society in general. If the individual participant will receive NO direct benefit, this must be stated.**]**

1. **Voluntary Participation:** Your participation in this research is voluntary. ***You may choose not to participate.*** If you decide to participate in this research study, you can change your mind and quit at any time. If you choose not to participate, or change your mind and quit, the benefits or treatment to which you are otherwise entitled will not be affected. You may quit by calling INSERT NAME OF PRINCIPAL INVESTIGATOR, at INSERT PRINCIPAL INVESTIGATOR’S PHONE NUMBER. You will be told immediately if any of the results of the study should reasonably be expected to make you change your mind about continuing to participate.

[Statement must be included here if significant new findings during the course of the research which may relate to the participant’s willingness to continue participation are likely.]

[Statement must be included here if there might be adverse consequences (physical, social, economic, legal, or psychological) of a participant’s decision to withdraw from the research. The consent process must disclose those consequences **and** procedures for orderly termination of participation by the participant.

Indicate that for data already collected prior to the participant’s withdrawal, that the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data. Also indicate that specimens

already used cannot be withdrawn, if applicable.]

1. **Compensation for Research Injury:** If you have an injury while you are in this study, you should call the Principal Investigator immediately. East Tennessee State University (ETSU) will pay the cost of emergency first aid for any injury that may happen as a result of you being in this study. ETSU makes no commitment to pay for any other medical treatment. Claims against ETSU or any of its agents or employees may be submitted to the Tennessee Claims Commission. These claims will be settled to the extent allowable as provided under TCA Section 9-8-307. For more information about claims contact ETSU Office of University Counsel.

[Must include the above statement verbatim if greater than minimal risk and/or research-related injury is reasonably foreseeable. Otherwise, delete this section in its entirety.]

1. **Financial Costs:** The possible financial costs to you as a participant in this research study are INSERT POSSIBLE FINANCIAL COSTS

[If there are any additional costs to the participant that may result from participation in the research, the consent process must disclose any additional costs. The research team must clearly explain who (which entity) is responsible for any standard/nonstandard treatment of service.]

[If there are no additional costs to the participant you can delete this section altogether.]

1. **Compensation in the Form of Payments to Participant:** INSERT COMPENSATION

[If compensation in the form of payments to the participants is being provided, state the amount, timing and terms of the payment (e.g. check, cash, gift certificate, etc.) precisely. If no compensation in the form of payments is being provided include a statement here indicating the same.

For studies that anticipate an aggregate payment to a single individual of $600 or more, the following information must be included in the informed consent document signed by the subject:

 Personal information about you, including name, address, and social security number, will be released to the University for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS). ETSU will issue you an IRS Form 1099 listing your payment as reportable income.

For studies that anticipate payment via University check, with aggregate payment to a single individual of $100 or more (but less than $600), the following information must be included in the informed consent:

Personal information about you, including name, address, and social security number, will be released to the University for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS), if necessary.

For studies that anticipate payment via University check, gift cards\*, cash or merchandise, with aggregate payment to a single individual of less than $100, the following information must be included in the informed consent:

Personal information about me, including my name and address, will be released to the University for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS), if necessary.

For studies that anticipate payment by a method other than check, such as gift cards\*, cash or merchandise, with aggregate payment to a single individual of less than $100, then the following information must also be included in the informed consent:

You will be asked to sign or initial a form confirming that you received the (insert gift card or cash or merchandise as appropriate). This form will be released to the University for the purpose of payment record-keeping.

\**See exception in “ETSU Payments to Research Subjects” Policy for electronic gift cards when the study is anonymous/confidential.]*

1. **Biospecimens:** The researchers will collect tissue, blood and biospecimens that are important to this study and to future research. If you join this study, the biospecimens given by you to the investigators for this research will no longer belong to you. The research team and sponsor of this research may study your data, tissue, blood, or other biospecimens collected from you. Any product or idea created by the researchers working on this study will not belong to you. There is no plan for you to receive any commercial profit from the creation, use or sale of such a product or idea. If data, tissue, blood, or other biospecimens are in a form that identifies you, the researchers may use them for future research only with your consent or Institutional Review Board (IRB) approval.

[If genetic research may occur with the specimens, include the following paragraph.] Sometimes data and biospecimens are used for genetic research (about diseases that are passed on in families). Even if your data and biospecimens are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to share any commercial profit from such developments. Because your genetic information is unique to you, there is a small risk that someone

could connect the information back to you.

[For research involving biospecimens, describe 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).]

[This section is required for studies that involve the collection of biospecimens. Otherwise, this section can be deleted in its entirety.]

1. **Confidentiality:** Every attempt will be made to see that your study data and results are kept confidential. The results of this study may be published and/or presented at meetings without naming you as a participant. Your information [and biospecimens] may be de-identified and used for future research studies without your additional informed consent. [**Remove the previous sentence if the study does not collect any identifiable private information or identifiable biospecimens.]** Although your rights and privacy will be maintained, both the research records and signed consent form that identify you may be looked at by others that have the legal right to see that information. This may include the ETSU IRB overseeing this research, other individuals at the University with the responsibility for ensuring we follow the rules related to this research, the federal Office of Human Research Protections (OHRP) that protects participants like you, [ENTITY, the sponsor of this research], and the Principal Investigator and research team. Your records will be kept completely confidential according to current legal requirements and will not be revealed unless required by law, or as described in this form.

[If the study is sponsored, in whole or in part, by the NIH or CDC, the study is automatically issued a Certificate of Confidentiality per terms of the associated award. This informed consent must include CoC language to inform the participant of the parameters of the protection.]

[Mandatory Reporting of Child or Elder Abuse: If there is the possibility that study staff can find elements of abuse during the research procedures (especially studies that involve a home visit), include the following text: “If the study staff finds evidence of child or elder abuse or neglect, we may be required by Tennessee law to report it to local law authorities.”]

1. **Drugs and/or Devices:** Because this study involves test articles regulated by the United States Food and Drug Administration (FDA), the FDA may choose to inspect records which identify you as a participant in this investigation.

[This section is required only if the study involves investigational drugs or devices regulated by the FDA or if data from the study will be submitted to the FDA. Otherwise, this section can be deleted in its entirety.]

1. **Clinical Trial:** A description of this clinical trial will be available on 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.

[This section is required if the study is an applicable clinic trial or federally sponsored clinical trial. Must include the above statement verbatim if a clinical trial; otherwise, this section can be deleted in its entirety.]

1. **Clinically Relevant Research Results:** [If your study may involve clinically relevant results, include one of the following]

We will alert you of any clinically relevant research results, including individual results, under the following conditions: [PI to add conditions here] **OR** Any clinically relevant group or individual research results will not be shared with you or any other participant. [Provide explanation why results are not being shared.]

**Contact for Questions:** If you have any questions about the research or experience any problems at any time, you may call INSERT NAME OF PRINCIPAL INVESTIGATOR, at INSERT PRINCIPAL INVESTIGATOR’S PHONE NUMBER, or INSERT ADDITIONAL PERSON TO CONTACT, at INSERT ADDITIONAL PERSON’S PHONE NUMBER. This research is being overseen by an Institutional Review Board (IRB). An IRB is a group of people who perform independent review of research studies. You may also contact the ETSU IRB at 423-439-6054 or IRB@etsu.edu for any issues, questions or input that you may have about the research or your rights as a research participant.

[Must include the above statement for IRB contact information verbatim. You can add other research team contacts or contacts for individuals/groups independent of the research such as a patient advocate.]

By signing below, I confirm that I am 18 years or older and have read and understand this Consent Form. I confirm that I have had the opportunity to ask questions and that such questions have been answered. By signing below, I confirm that I freely and voluntarily choose to take part in this research study.

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Signature of Participant Date

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Printed Name of Participant

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Signature of LAR Date

If signed by someone on behalf of the Participant, state your relationship to the Participant and a description of your authority to act on the Participant’s behalf: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Above Included only if being signed by LAR]

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Signature of Person Obtaining Consent Date

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Signature of Witness Date

[Signature of a Witness is necessary when the participant or their representative speaks and understands English, but cannot read and write; or when the participant or their representative is visually impaired and such impairment cannot be accommodated with increased font size; or for translated consents where a credentialed Translator is present for the informed consent discussion. The witness must be present for the consent process not just present for the signature. The Translator may serve as the Witness. The witness is attesting that the informed consent process took place and apparently understood by the Participant.]

***You will be provided with a copy of this signed consent form.***