**TEMPLATE CONSENT FORM**

Updated 4/02/2021

**Instructions for Research Team:**

This template document is for non-medical, social/behavioral/educational research studies. When using 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.

**Readability**: Think of your audience when writing a consent form. If you are addressing the general public, the reading level should be about 8th grade. To do this:

* Use words familiar to a non-medical, non-technical, non-academic reader
* Keep words to 3 syllables or less
* Write short, simple sentences— one thought per sentence
* Keep paragraphs short— just one idea per paragraph
* Use 2nd person: Refer to the participants as “you” or “your.” Avoid using the word “participant.”

**Presentation**: Clearly present all the information the participant (or their legally authorized representative) needs in order to make a reasonable and informed decision concerning voluntary participation.

**Concise Summary**: This is only required if your completed consent is more than 4 pages long. Include a concise and focused summary at the beginning of the consent form that presents the key information that will help participants understand why they would or would 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.

**Required Elements**: Unless otherwise noted, all fields contained in this form are **required.** However, the wording and order of information can be adjusted to fit your needs or preferences. You may add additional sections to this form as necessary. For a list of required elements, see our [Checklist for Informed Consent](https://www.etsu.edu/irb/documents/checklist_for_informed_consent.pdf).

**Format**: You may edit the format of this document to suit your needs, but you must include a 1” margin at the bottom of each page. This will allow room for the IRB to stamp the final, approved document.

**Header & Footer**: Include the name of the Principal Investigator and the title of the project (Select View, then Header and Footer to edit the header or footer of this template) in the header. Include a version date and a page number in the footer.

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 who or what to include for each field.

If at any time during this process you have any questions, please do not hesitate to contact the IRB at 423.439.6053 or IRB@etsu.edu.

**Title of Research Study**: INSERT STUDY TITLE

**Principal Investigator**: INSERT NAME AND CONTACT INFORMATION FOR PRINCIPAL INVESTIGATOR

**Organization of Principal Investigator:** East Tennessee State University

**CONSENT FORM**

This document provides information about being a participant in a research study. Please read this carefully. This will help you decide if you would like to volunteer to join this study.

**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:
* Benefits:
* Risks:

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

**STUDY DETAILS**

* **What is this study about?** The purpose of this study is to 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.]

* **How much of my time will it take?** 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.]

* **What are you asking me to do?** If you decide to volunteer for this study, you will be asked to INSERT PROCEDURES

[Describe the procedures to be used, including invasive or non-invasive techniques, restrictions on normal activities, 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.]

* **Are there any alternative procedures or treatments?** Yes. If you do not want to be in this study, you may choose to **INSERT** ALTERNATIVE TREATMENTS/PROCEDURES – ***If there are no alternative procedures, you can remove this section.*** [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, so state.]
* **Are there any benefits for me?** Yes, the possible benefits are [INSERT POSSIBLE BENEFITS] **OR** There are no direct benefits for you. Possible benefits for others include [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.]
* **Are there any possible risks or discomforts?** Yes, there is the risk of [INSERT POSSIBLE RISKS/DISCOMFORTS and what you are doing to alleviate them] ***OR*** There are no expected risks for participating in this research.

[State any known risks or inconveniences that could be expected as well as risks/discomforts which are not yet known. 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, the consent process must include a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable.]

* **Will I be identified? How are you keeping my information safe?** We will make every effort to keep your study records confidential. The results of this study may be published and/or presented at meetings. You will not be named as a participant. 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. They will not be revealed unless required by law, or as described in this form.

[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.”]

[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.]

* **Will any of my data be used in the future?** [If you are using identifiable data, you must include this paragraph and include one of the following statements.] All information that can identify you will be removed from the data. This data will then be stored for possible use in future research studies. We will not ask for additional consent for those studies.
* **Do I have to pay for anything?** There are possible financial costs if you choose to be in this research. The costs include [INSERT POSSIBLE FINANCIAL COSTS HERE] **OR** There is no cost to you if you decide to be part of this study.

[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.]

* **Will I be paid for participating?** INSERT COMPENSATION ***OR*** You will not be paid for joining this study.

[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.]*

* **Do I have to join this study?** No. This study is voluntary. You get to decide if you want to be part of this study. ***You may decide you do not want to participate.*** If you join this study and then change your mind, you can quit at any time. Deciding not to join the study or quitting will not affect any benefits you would normally receive. You may quit by calling INSERT NAME OF PRINCIPAL INVESTIGATOR, at INSERT PRINCIPAL INVESTIGATOR’S PHONE NUMBER. We will let you know if any of the results of this study are expected to reasonably change your mind about participating. [Only use the pervious sentence if it applies to your study.]

[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, the consent process must disclose that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.]

[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.]

* **Will there be any results I need to know about?** [If yourstudy 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]
* **Who should I contact for questions?** If you have any questions or research-related 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 statements 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 have read and understand this consent form. I also confirm that I had the opportunity to have it explained to me verbally. I confirm that I was able to ask questions and that all my questions have been answered. By signing below, I confirm that I am 18 years or older and I freely and voluntarily choose to take part in this research study. [**Remove 18 years or older if you are using this as an assent form for a minor**. Also, this is a good place to add any other inclusion required to be part of this 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.***