

# Informed Consent Template for Federally-Sponsored Research

Use if your research is **Federally-sponsored** AND participants are **adults**.

## Avoid Common Problems with Consent Forms. **Read these tips!**

### 1. Customize this template to reflect the specifics of your study and participant population.

- Text in **[brackets]** represents study-specific information that must be added.
- A **backslash (e.g., will/will not)** requires a selection depending on study-specific procedures.
- **Black text** is required for all studies; keep language and formatting unless instructed otherwise.
- **Blue text** identifies consent elements and information required for ALL studies. The **blue text** also provides instructions/guidance that researchers should consider. Some instructions/guidance may not apply to your research.
- **Red text** identifies consent elements or information required only when applicable to your study.
- **Green text** shows sample language.

Color Code Key			
Black	Blue	Red	Green
Required Template Text	<i>Required Element of Informed Consent</i>	<i>Required Element when applicable</i>	Example/Suggested Language

### 2. When writing your consent documents, always:

- Use **plain language**. Don't cut and paste from your protocol, grant, etc. Use common, everyday language. For example, use "you don't have to be in this study if you don't want to" instead of "your participation in this study is voluntary."
- Aim for an 8<sup>th</sup> grade reading level (junior high) or lower, especially when recruiting from the community (i.e., general population) or anyone likely to be unfamiliar with the study topic.
- Use active voice "we will ask you" instead of passive voice "you will be asked."
- Use short, simple and direct sentences, and limit paragraphs to one main idea.
- Use lists, tables, charts, pictures or diagrams to simplify complex information.

### 3. **Key Information Summary:** The 2018 revised Common Rule requires consent documents begin with a **concise and focused presentation of key information likely assist potential participants in understanding why one might or might not want to participate**.

- Key information may vary study-to-study. Key information appropriate for observation studies will likely be different from that needed for clinical trials.
- This summary should be brief, but address why and why not one may choose to participate.
- Limit the summary to the most important information (i.e., don't list every foreseeable risk; list the most severe or frequently occurring risks). Information in the summary need not be repeated in the main body of the consent document. The main body need only include information not already in the summary. If **all** information related to an element is in the summary, delete that section from the main body.

### 4. **Before submitting consent documents to the IRB:**

- Delete this cover page and remove all instructional text, brackets, etc. The finished document should reflect what you will give to the participant.
- Use a file name(s) that clearly identify each consent document (e.g. online consent, parental permission, adult consent, teacher consent, screening consent, etc.).
- **Submit consent documents in MS Word** whenever possible. The iMedRIS comparison tool for different document versions does not work with PDFs.
- **PROOFREAD** for understandability to participants and consistency with the IRB application.

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## Consent for Research Participation

**Research Study Title:** [Title]

**Researcher(s):** [Principal Investigator Name], [Institution] University of Tennessee, Knoxville  
[Faculty Advisor Name if PI is a student], [Institution] University of Tennessee,  
Knoxville

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### Key Information for You to Consider

The information in this box is a short summary to help you decide if you want to be in this research study. More detailed information is listed later in this form. Please ask questions if there is anything you do not understand. Please take your time. You should not feel rushed or pressured to make a decision.

- **Voluntary Participation.** You should only participate if you completely understand the study and want to volunteer. You do not have to be in this study.
- **Purpose.** The purpose of this research study is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
- **Research Procedures and Activities.** If you decide to be in the study, we will ask you to [briefly highlight the key research activities/procedures].
- **Duration.** If you agree to be in the study, your participation will last for XXXX and will involve XXXX study visits.
- **Benefits.** [Provide a brief description of any direct benefits or, if no direct benefit is expected, state that. Then state any possible benefits to others, science, society (e.g., but the researchers hope to learn about xyz)].
- **Risks.** Some risks of being in the study include [describe the most important risks. Consider the most probable risks, those with the highest magnitude of harm or likely to occur most frequently].
- [If applicable, include] **Alternatives.** Instead of being in the study, you can [identify alternatives that might be advantageous to prospective participants. See additional instructions on page 4. ].
- [If applicable, include] **Costs.** If you participate in the study, you will need to pay for [include appropriate study-specific language].

### Why am I being asked to be in this research study?

We are asking you to be in this research study because [explain why this person is eligible to participate].

### What is this research study about?

The purpose of the research study is [describe the purpose of the research in simple terms].

## Who is conducting this research study?

The research team and/or the University of Tennessee, Knoxville is receiving [*funding, equipment (e.g., fitness trackers, hearing aids), etc.*] from [*insert sponsor's name*].

Include this section **ONLY** if one or both of the following paragraphs are applicable to the study.

- If the study is **collaborative with one or more institutions/external researchers**, include:

This study is being conducted by researchers at the University of Tennessee, Knoxville and researchers at [*list other institution(s)*].

- If a research team member or University has a **significant financial conflict of interest** or **other type of conflict of interest** (e.g., researcher is participants' instructor, supervisor, health care provider, other service provider, etc.), include:

We are giving you the information below so you can decide if this relationship will affect your decision to be in this study:

- *Insert any required or suggested language from the management plan approved by the UT Research Conflict of Interest Committee, if one exists; or*
- *Describe the conflict and the actions taken to reduce its effect on, and/or minimize risks of, the study.*

## How long will I be in the research study?

*State the total time of participation. Consider the duration of participation and frequency (if multiple study visits/data collection times). Provide relevant information in hours, days, weeks, months, years, or until a certain event. Include the number of times the participant will be involved in research activities, how long each activity or session will take, etc.*

If you agree to be in the study, your participation will last for 1 hour.

If you agree to be in the study, your participation will last for 18 months and will involve 4 study visits, 6 online surveys and 2 phone calls. (*Note: the online surveys and phone calls are included because they are data collection times separate from the study visits.*)

## What will happen if I say "Yes, I want to be in this research study"?

If you agree to be in this study, we will ask you to [*describe the research*].

- *State when, where, and what procedures/tests/activities will occur including their frequency.*
- *When the study includes multiple research procedures/activities, list/describe them in chronological order so participants know what to expect.*
- *If study procedures will occur over multiple study visits and/or at multiple locations, clearly describe what procedures will occur at each visit.*

- Distinguish between normal practice and research procedures if your study involves both (classroom/education research, clinical studies, etc.).
- Tell participants if any procedures and/or equipment/devices used in the study are **experimental**. An experimental procedure is one that is untested or unproven for its intended purpose – typically a manipulation, intervention, treatment, test, some usability studies, etc.

### What happens if I say “No, I do not want to be in this research study”?

Being in this study is up to you. You can say no now or leave the study later. *[Include the statement below that is applicable to your study. Modifications to the language may be necessary based on your participant population and their relationship with UT or other facility/institution associated with the research.]*

- **[If your target population is students at UT or other educational institutions associated with the research, include:]** Either way, your decision won't affect your grades, your relationship with your instructors, or standing with the *[include name of facility/institution (UT, University, school, etc.)]*.
- **[If your target population includes individuals who may receive services or care from UT or other facilities/ institutions associated with the research, include:]** Either way, your decision won't affect your relationship with *[include name of facility/institution]* or the *[services/health care/benefits]* *[you and/or your family]* receive.
- **[If your target population is employees at UT or other facilities/institutions associated with the research, include:]** Either way, your decision won't affect your employment at *[include name of facility/institution (UT, University, community center, etc.)]*
- **[For all other studies, include:]** Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

### **If your study offers course credit or extra credit, include:**

Instead of participating in the study, possible options available to you include *[see below]*.

- describe the non-research alternative(s)\* **or** explain how participants can learn more about non-research alternative(s) (course syllabus, course instructor, etc.), and
- if applicable, include: participation in another research study to receive credit.

\* All courses offering research participation as a means of earning credit **must** offer a non-research alternative for earning credit to participants. The non-research alternative must offer the same amount of credit and be comparable in the time and effort required to complete it.

### **If your study involves any therapeutic interventions (social/behavioral or biomedical), include:**

Instead of participating in the study, possible options available to you include *[inform participants of any known alternatives or any range of alternative options available to them (treatments, therapies, other standard of care options, etc.), or include a statement that they can consult their health care provider for possible alternatives]*.

## What happens if I say “Yes” but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

If you decide to stop before the study is completed, [*include the following information as applicable to the study*].

- *Provide instructions on how to withdraw (e.g., contact the PI, other study-related contact).*
- *Describe what will happen with any information already collected for the research.*
- *If at some point during the research participant data cannot be withdrawn, such as after data are de-identified and code key destroyed or after an anonymous survey is submitted, inform participants of that information.*

## Are there any possible risks to me?

***If the study collects identifiable information*** (including audio and video recordings), the following risk language is recommended:

It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. These procedures are described later in this form.

***If there are other risks*** related to the research:

Possible risks include [*list and describe any reasonable foreseeable risks, discomforts, and inconveniences and what will be done to minimize those risks*].

- *Risks can be physical, psychological, social, financial, or otherwise.*
- *Describe how these risks will be minimized. For confidentiality risks, a statement referring participants to confidentiality procedures described later in this form is acceptable.*

***If there are no known risks:***

We don't know of any risks to you from being in the study.

## Are there any benefits to being in this research study?

***If there are no anticipated benefits to participants:***

We do not expect you to benefit from being in this study. Your participation may help us to learn more about [*insert details*]. We hope the knowledge gained from this study will benefit others in the future.

**OR**

***If the research presents the possibility of benefits to participants,***

There is a possibility that you may benefit from being in the study, but there is no guarantee that will happen. Possible benefits include [*describe possible benefits to participants*]. Even if you don't benefit from being in the study, your participation may help us to learn more about [*insert details*]. We hope the knowledge gained from this study will benefit others in the future.

**\*NOTE:** *Compensation/payment/credit are not considered a benefits of research participation.*

## Who can see or use the information collected for this research study?

***If identifiers will be collected during the study, consider the following:***

- Describe how the study information (i.e., data) and research records (e.g., consent documents, payment records, scheduling logs, etc.) will be kept confidential (e.g., storage, maintenance, transfer/transmission, etc.) by the research team
- Describe the individuals and groups who may have access to study information.
- Describe any circumstances that would limit confidentiality.
- Describe how information will be published and disseminated and whether identifiable information would be included.

We will protect the confidentiality of your information by [\[describe\]](#).

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there may be times when others need to see the information we collect about you. These include:

- People at the University of Tennessee, Knoxville [\[if collaborative or multi-site study, include institution name\(s\)\]](#) who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- [\[agency/sponsor name\(s\)\]](#), who is the study sponsor [\[paying/providing equipment, etc.\]](#) for this research.
- [\[If your study is regulated by the FDA, include:\]](#) The U.S. Food and Drug Administration may inspect the study's research records to make sure research is conducted properly.
- [\[If applicable, include:\]](#) Information about your study participation may be included in your medical record.
- [\[If study involves the delivery of treatment or other health care for which participants might be billed, include:\]](#) Your medical insurance provider or other organizations that may need the information in order to pay your health care costs or other costs related to your participation in the study.
- [\[If applicable, list any other organizations or class of persons to whom the participant's information might be disclosed: e.g., others who will conduct data analysis, data coordinating center, outside laboratories that will analyze specimens/data.\]](#)

***If a topic below applies to your study, contact the IRB (865-974-7697 [utkirb@utk.edu](mailto:utkirb@utk.edu)).***

- *If particularly sensitive data will be collected and remain identifiable, the IRB may require a Certificate of Confidentiality be obtained.*
- *If your study will be registered with [ClinicalTrials.gov](http://ClinicalTrials.gov).*



## What will happen to my information after this study is over?

**Future use by the research team**, select one of the following paragraphs:

We will/will not keep your information to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the study

**OR**

We will/will not keep your information to use for [future research or other purpose]. Your name and other information that can directly identify you will be deleted from your research data collected as part of the study.

**Future use by the others**, select one of the following paragraphs:

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.]

**OR**

We will not share your research data with other researchers.

## Will I be paid for being in this research study?

**Include this section if participants will be given any compensation** (payments, course or extra credit, gift card, involves a drawing, reimbursements, gifts, etc.).

**If no compensation will be offered**, either delete this section from the consent document or include a statement such as, "You will not be paid for being in this study,".

Describe payments to be made including:

- State the amount and method of payment (check, cash, type of gift card, course or extra credit, gift, etc.).
- If course/extra credit offered, describe the method used to determine the amount offered.
- Describe when and how payments will be issued (in-person, U.S. mail, method used to assign credit, etc.) to participants. If the study includes multiple study visits or data collection times, describe the payment schedule including how payment will be prorated should a participant not complete the study.
- If participant information is required to facilitate payment, list the information to be collected.
- If participants will be entered into a drawing describe
  - the odds of winning; and
  - Tennessee gaming law requires that any individual be allowed to participate in the drawing even if that individual does not participate in the research. Accordingly, the consent document must include a statement that anyone age 18 and over may enter the drawing even if they do not participate in the research and provide instructions on how to do so.

- *If the study participants include individuals who cannot consent for themselves (children, decisionally-impaired, etc.), explain if the payment is to the participant or parent/legally authorized representative.*
- *[If participant payments will be processed through the UT's business offices, etc., include:] Business offices at the University of Tennessee, Knoxville may be given your [name, address, Social Security Number, payment amount, etc.] to issue your payment and report tax information.*

### Will it cost me anything to be in this research study?

***Include this section if it is possible that participants will incur costs*** (transportation to and from study visits, parking, etc.) related to their participation in the study.

If you agree to be in this study, you will need to pay for [describe any costs the participant may be required to pay such as transportation, parking, data charges for mobile devices, fees for lost or damaged equipment/devices provided to participants for the conduct of the study].

***If there will be no extra costs to participants, either*** include a statement such as, "It will not cost you anything to be in this study," ***or*** delete this section from the consent document.

### What else do I need to know?

***Include this section if any of the following paragraphs are applicable to the study.***

***Number of research participants.*** Often researchers opt to include this information in consent documents for all their studies. Generally, the IRB only requires this information be disclosed when the sample size is associated with increased risks to participants. For example, a small sample size may increase the likelihood of participant re-identification: About [sample size] people will take part in this study. [Describe why this information is important (e.g., because of the small number of participants in this study, it is possible that someone could identify you based on the information we collected from you).]

***If participants may be withdrawn without their consent, include:***

We may need to stop your participation in the study without your consent if [describe the circumstances under which someone's participation may be ended, such as for your safety, you do not follow study instructions, you no longer meet the study's eligibility requirements, if the study is stopped for any reason, etc.].

***New information affecting participant's willingness to continue, include:***

If we learn about any new information that may change your mind about being in the study, we will tell you. If that happens, you may be asked to sign a new consent form.

***If the research may result in commercialization, include:***

Your research data may be used to create products or to deliver services, including some that may be sold or make money for others. If this happens, there are no plans to provide financial payment to you or your family.



If the study is **greater than minimal risk** and includes the **possibility of a research-related injury** (physical, psychological, social, financial or otherwise), include:

We use procedures to lower the possibility of these risks happening. Even so, you may still experience problems or injury, even when we are careful to avoid them. Please tell the researcher in charge, [PI name and phone number], about any [injuries, side effects, etc.] or other problems that you have during this study.

*If physical injury or psychological injury, describe what help or treatment will be available if the injury occurs during a study visit (first aid will be provided, referral, etc.) and what procedures participants should follow if they become aware of such injury outside of a study visit (seek medical attention from their health care provider, inform the researcher as soon as possible, referral, etc.).*

The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

### Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researchers, [PI name, email, phone (also include the faculty advisor's name and contact information if PI is a student)].

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board  
The University of Tennessee, Knoxville  
1534 White Avenue  
Blount Hall, Room 408  
Knoxville, TN 37996-1529  
Phone: 865-974-7697  
Email: utkirb@utk.edu.

### STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

\_\_\_\_\_  
Name of Adult Participant

\_\_\_\_\_  
Signature of Adult Participant

\_\_\_\_\_  
Date

*The researcher signature section below is not required, but is recommended for research studies involving an in-person consent procedure, especially when consent may be obtained by multiple members of the research team.*

**Researcher Signature** (to be completed at time of informed consent)

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

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Name of Research Team Member

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Signature of Research Team Member

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Date