**Informed Consent Guidance**

**Instructions:** This document provides guidance and language necessary to create an informed consent document. This guidance incorporates the regulatory requirements for informed consent. The format may be modified or expanded as indicated to better meet the needs of the research design and/or participant population.

**The key information section is a regulatory requirement**. There are basic elements of informed consent. For some simple research studies, some of the basic elements of informed consent are satisfied by the information included in the key information section. Therefore, the information need not be reiterated in the body of the consent. In other cases, the key information section will not sufficiently detail all aspects of the study that a participant needs to consider and much more information will need to be provided in the body of the consent form.

# How to use this document:

* Regular **black text** and formatting, including bolding, are template and should not be removed unless otherwise noted.
* The [**blue-bracketed**] text identifies required elements of informed consent. The blue text also
* includes considerations as you develop your version of the document. Some considerations may not be applicable to your research. Enter customized information within the brackets.
* The [**red-bracketed**] text are content that are regulatory requirements to be included when
* applicable to the research.
* **Green text** provides examples or sample phrasing for the blue or red-bracketed text.
* **Remove all instructions, all colored text and italics prior to finalizing your consent document. Should you not follow the instructions for the consent document, it will be returned to you as incomplete.**

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| **Color Code Key** |
| **Black** | **Blue** | **Red** | **Green** |
| **Standard Template Text** | **Required Element of Informed Consent** | **Required Element, when applicable** | **Suggested Language/ Phrasing** |

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| --- |
| Consent for Research Participation |
| **Title** | Study Title |
| **Sponsor** | Name of Study Sponsor (If there is not sponsor, delete this line) |
| **Researcher(s)** | (Name), (Institution)(Name), (Institution) |
| **Researchers Contact Information** | (Phone), (Email) |

You are being asked to participate in a research study. The box below highlights key information for you to consider when deciding if you want to participate. More detailed information is provided below the box. Please ask the researcher(s) any questions about the study before you make your decision. If you volunteer, you will be one of about \_\_\_\_\_ people to do so.

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| **Key Information for You to Consider** |
| **Voluntary Consent:**  You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefit to which you are otherwise entitled if you choose not to participate or discontinue participation. **Purpose:** The purpose of this research is (Provide a brief description of why the research is being conducted, no more than 2-3 sentences).**Duration:** It is expected that your participation will last (Expected Duration)Procedures and Activities: You will be asked to (**BRIEFLY** highlight key research activities/procedures).**Risk:** Some of the foreseeable risk or discomforts of your participation include (Describe the most important risk. Consider those most probable and/or highest magnitudes of harm)Benefits: Some of the benefits that may be expected include (State the direct benefits; if no direct benefit to the subject state no direct benefits but the researcher hope to learn/gain)Alternatives: As an alternative to participation you could, (Note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, “Participation is voluntary, and the only alternative is to not participate”) |

# Who is conducting this research?

# (Lead Investigator, LI) of the University of Memphis, Department of (List Department) is in charge of the study. (If the LI is a student, add the following sentence) His/her faculty advisor is (Advisor). There may be other research team members assisting during the study.

# (State whether any member of the research team has a significant financial interest, and/or a conflict of interest related to the research)

# Why is this research being done?

# (NOTE: If the full purpose is described in the “Key Information Summary” above, this section may be deleted)

# The purpose is (Describe purpose of the study in simple terms) You are being invited to participate because (State the main reason or list the all inclusion/exclusion criteria that may make the individual eligible to participate.)

# How long will I be in this research?

# (NOTE: If the full duration is described in the “Key Information Summary” above, this section may be deleted)

# The research will be conducted at (State general facility). It should take about (State the total time of participation Consider the duration of participation, frequency and provide relevant information in hours, day, 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) of your time.

# What happens if I agree to participate in this Research?

# If you agree you will be asked to (Describe, using simple terms, what the participant can expect while participating)

# Using plain language accurately describe what participation in the research entails. Below are details typically included depending on the nature of the research

# For most research studies

# What the participants will do and what will happen during the research

# What information about the participant will be obtained, including for secondary sources

# Where this research will be done

# Provide a time-line description of the activities, test and/or procedure that will be done, including any screening procedure. You can use tables or charts is they are helpful

# Detail if there will be audio or video recording or photograph

# For research involving survey, questionnaires, and or interviews:

# Inform participants that they can skip any question that makes them uncomfortable and they can stop any time

# It may be appropriate to provide examples of the questions being asked. When asking sensitive information sample questions must be provided

# Other things to consider including

# If your study involves deception, give as much information as possible

# If more than one group, describe each group

# If the research involves random assignments, describe this and the probability of assignment to each group. For example

# You will be put into a study group by chance (Like a coin toss/like drawing straws). You have a \_\_\_ out of \_\_\_ chance of being placed in each group. You cannot pick your study group.

# If the research involves blinding, include language describing a single (subject only) or double (subject and research team) blind, as appropriate. For Example

# During the research, you (or you and the researchers) will not know which group you are in. In case of an emergency, the research can find out.

# Describe any follow-up and/or planned future research activities/procedure (e.g., recontact to review quotes, follow-up questions, extension study, follow-up study, analysis of specimens). Include the following when applicable

# We will tell you about any new information that may affect your willingness to continue participating in the research

# For research involving interventions, drugs, devices, biospecimen collection and/or biomedical components:

# If blood will be drawn, indicate how often and the amount using the most appropriate unit of measurement, use lay examples for reference (e.g., teaspoons or tablespoons)

# Identify all experimental procedures

# Identify all drugs, devices, and tests performed that are approved for marketed use.

# Identify all unapproved drugs, devices, test and procedures unapproved for marketed use.

# For studies conducted under an IND, IDE or abbreviated IDE (State: Name of the product or device) is investigational. This means that it is not approved by the Food and Drug Administration (FDA)

# Identify all approved drugs, devices, test and procedures being used in a novel fashion as experimental

# Describe any relevant information about the test article and the control (If used).

# For research on investigational drugs or devices, list any options for the participant to get the drug/device after the research, and who will pay for this.

# If this is a treatment study, indicate whether the study treatment will be available at the end of the study

# Explain whether clinically relevant research results, including individual research results, will be disclosed to the subjects and if so under what conditions

# For research involving biospecimens, the following statement needs to be included “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).

# What happens to the information collected for this research?

# Information (and/or specimens) collected for this research will be used to (Describe how information will be published and disseminated and whether identifiable information would be included such as name.)

#  For Example:

* Your name will not be used in any… (published reports, conference presentation, etc.)
* We may publish/present the results or this research. However, we will keep your name and other identifying information confidential -OR-
* With your permission, your name will be used in... (conferences, published reports, etc.)

# Discuss whether the information and/or specimens collected for this research will be shared and under what circumstance (Data Sharing Agreement, used for future research, data deposited in a formal repository, etc.)

# If research involves the collection of identifiable private information or identifiable biospecimens, one of the following statement must be included

* **Identifiers might be removed for identifiable private information or identifiable biospecimens. This information or biospecimen(s) could be used for future research or distributed to another investigator for future research without obtaining additional consent -OR-**
* **Information or biospecimen(s) collected as part of the research, even if identifiers are removed, will not be used or distributed for future research Studies**

# For clinical trials, the following statement must be included:

# U.S. Law requires that a description of this clinical trial be available on the website. The website will not include information that can identify you. The website will only include a summary of this study.

# CLINICAL TRIAL: A research Study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

# How will my privacy and data confidentiality be protected?

# We promise to protect your privacy and security of your personal information as best we can. Although you need to know about some limits to this promise. Measures we will take include:

* Discuss steps that you will take to protect participant privacy (e.g., conduct research in a private setting and/or other space considerations, security parameters of online survey platforms
* Discuss any known limits to protecting privacy (e.g., group participation and knowing who other participants are research setting)
* Discuss steps that you will take to protect confidentiality (e.g., where will data be stored, who will have access to the data, how long will data be stored, will data be transferred and data coding
* Discuss any known limits to protecting confidentiality (e.g., Limits of data security and storage, data collection in groups setting, Data User Agreements, etc.)

# Individuals and organization that monitor this research may be permitted access to inspect the research records. This monitoring may include access to your private information and (include any other records). These individual and organization include (Edits List below as appropriate for your research

# Institutional Review Board

* Government regulatory agencies
* The Food and Drug Administration (FDA) \* If FDA Regulated\*
* The study sponsors
* People who work with the study sponsor
* Any other individual(s)/entities

# For studies in which mandatory reporting is a requirement, the following state must be included:

# Research team members are required to report the following if a team member suspects child abuse or neglect, or suicidal thoughts. TN Laws may require this suspicion be reported. In such case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

# For Studies that have been issued a Certificate of Confidentiality (COC)

#  NIH has specific criteria for disclosure to participants. Studies that involve collection or use of identifiable, sensitive information may have a Certificate of Confidentiality though NIH either because:

# A COC was automatically issued with the terms and conditions of the award (Only studies funded on or after December 2016) -OR-

# The research team has applied for and obtained a COC for NIH

# NIH expects researchers to tell participants about the protections afforded by the COC. NIH provides the sample language below which should be adapted to the study participants and subject matter of the research

# This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the research does not disclose or use information, documents, or biospecimens that may identify you in a federal, state, or local legal or court hearing. There are exceptions such as to report child abuse, intent to harm self or others or communicable diseases

# If applicable include the following language:

# The certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by (THE AGENCY), which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that this Certificate does not prevent you from releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person, you must provide written permission to allow the researcher(s) to release it.

# Language such as the following should be included if a researcher intends to disclose information covered by the Certificate, such as potential child abuse or intent to hurt self or other in response to specific federal, state, or local laws:

# This Certificate of Confidentiality cannot be used to prevent disclosure as required by law of (List what will be reported, such as child abuse and neglect or harm to others)

# Language such as the following should be included if research intends to disclose information covered by a Certificate, with the consent of the research participants:

# The Certificate of Confidentiality will not be used to prevent disclosure for any purpose. You understand you have consented to in this informed consent document (restate what will be disclosed.)

# What are the risks if I participate in this research?

# (NOTE: If all risks are disclosed in the “Key Information Summary” above and/or limited to breach of privacy and/or Confidentiality, delete this section)

# The risk or discomforts of participating in this research included (Detail any known risk or harm that the participant may experience in simple language. Any risk listed in the protocol must be addressed in the consent)

# Common Categories

* Physical risk
* Psychological risk (e.g., embarrassment, fear, guilt, etc.)
* Privacy risk (e.g., disclosure of private information
* Social risk (e.g., social ostracizing or discrimination

# For some simple minimal risk studies, a brief statement similar to the following to address the scope of risk

# You may experience stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

# Additional aspect of risk to include when applicable:

# Side effects of any comparator drugs

# Risk Associated with washout, withhold treatment, or randomization of treatment

# When the risk profile is not well known

# When there may be unknown risk associated with participation, include the following

# In addition, taking part in this research may have risks that are not known or unforeseeable

# If the Study involves pregnant women or women of child-bearing potential

# If there are known risk to an embryo or fetus associated with participation include:

# Taking part in this research may hurt a pregnancy or fetus in the following way (Describe)

# If the study may involve risk to an embryo or fetus when risk profile in pregnancy is not well known include the following:

# Taking part in this may hurt a pregnancy or a fetus in unknown ways. These may be minor or so severe as to cause death

# What are the benefits of participating in this research?

# (NOTE: If all benefits are disclosed in the “Key Information Summary” above delete this section)

# You may or may not benefit from participating in this research.

# Choose the applicable language to include:

* If there are no expected benefits to the subject by possible benefits to scientific knowledge:
	+ Participating has no known direct benefits to you. We do believe that this study will help (Describe anticipated benefit of research)
* If there are no expected benefits to the subject but possible benefits to other
	+ Participating has no known direct benefit to you. Possible benefits to others include (Describe)
* If there are possible benefits to the subject detail any known direct benefits that the participant, my experience from participating in the study
	+ Although not guaranteed, possible benefits to you include (describe the direct benefit, if benefits from taking part in the research may not continue after this study has ended) Possible benefits to others include (Describe)

# What other choices do I have beside participating in this research?

# (NOTE: If all alternatives are disclosed in the “Key Information Summary” above delete this section)

# If you do not want to take part in the study, there other choices such as (Describe other procedures the subject could participate in to receive the same level of benefit) -OR-

# If you do not want to be in the study, there are no other choices except not to take part in the study

# ADD THE FOLLOWING FOR STUDENT VOLUNTEERS: As a student, if you decide not to take part in this study your choice will not affect your academic status or grade in your class

# What if I want to stop participating in this research?

# It is up to you to decide whether you want to volunteer for this study. It is also ok to decide to end your participation at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decided to withdraw your participation. Your decision about participating will not affect your relationship with the researcher(s) or the University of Memphis. (When applicable, discuss the process for participants to withdraw once the study has begun)

# Will it cost me money to take part in this research?

# Select one of the following statement and complete as indicated:

# There are no costs associated with participation in this research study -OR-

# Taking part in this research may lead to additional cost to you, such as (Describe any cost). For example, you may have to pay for the cost of getting to the study site.

# What if I am injured due to participating in this research?

# (This section MUST be included for any study that is greater than minimal risk or when the study involves the possibility of injury. Delete if not applicable)

# If you believe you need immediate medical attention if you get sick during the study, you should seek immediate medical attention, then call (LI or medical supervisor name) at (\_\_\_) \_\_\_\_\_\_\_\_\_\_. (For greater than minimal risk research, add information for one or combination of the following as a contact for subjects to use in case of illness or injury during his/her participation:

# A dedicated phone number (cell phone)

# A dedicated pager number

# Other reliable 24-hour contact options at your discretion and or

# As deemed necessary, in addition to one or more of the above, Referral to 911 of an emergency

# The University of Memphis does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you got hurt or sick while taking part in this study. Also, the University of Memphis will not pay for any wages you may lose if you are harmed by this study.

# Medical costs that result from research related harm cannot be included as regular medical cost. Therefore, the medical costs related to your care and treatment because of research related harm (Add study specific language by selecting the appropriate option).

# Will be your responsibility -OR-

# Will be paid by the sponsor (Only option if industry sponsored and industry trial) (Sponsor Name) has agreed to pay for medical expenses incurred by treating injuries that directly result from participating in the study, with some exceptions. The exceptions are instances such as your failure to follow the sponsor’s directions or the investigator’s failure to follow the sponsor’s direction -OR-

# May be paid by your insurer if you are insured by a health insurance company (You should ask your insurer if you have any questions regarding your insurer’s willingness to pay under these circumstances) -OR-

# May be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid. If you have any questions regarding Medicare/Medicaid coverage you should contact by calling 1-800-Medicare (1-800-633-4227) or Medicaid at1-800-635-2570. A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the cost. The amount of the co-payment/deductible may be substantial.

# You do not give up your legal right by signing this document

# Will I receive any compensation or reward for participating in this research?

# Address whether subjects will be compensated for participation. Sect and include the statement that applies to your research:

# You will not be compensated for taking part in this research

# If you choose to conduct a lottery or raffle, you must completely detail the raffle procedure. What is being raffled, how much, how many (prizes/gift cards) and the participant must be told what their expected chances of winning will be (how many prizes versus number of participants

# For taking part in this research you may be compensated a total of $\_\_\_ (cash/check/gift card)

# Describe compensation schedule (how will payment be prorated in circumstances of incomplete participation or time-based payments). State in terms of amount of compensation

# Describe when and how compensation will be made

# For taking part in this research, you may receive a total of (Describe course credit or other non-monetary compensation to be issued

# Describe compensation schedule (how will payment be prorated in circumstances of incomplete participation or time-based payments). State in terms of amount of compensation

# Describe when and how compensation will be made

# If compensating a total value of $100.01-599.99 state:

# Please be aware compensation for participation in research may be considered taxable income. The University may require tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data

# If compensating a total value of $600 or greater state:

* + **Please be aware, compensation for participation in research may be considered taxable income. The University may require tracking for compensation that is paid to you; this may include your name and contact information. Because you will receive $600 or more in a calendar year, you will be asked to provide additional (e.g., Social Security Number) information for tax reporting purposes. This information is stored confidentially and separate from research data.**

**If the study includes biospecimen(s), when appropriate, include the following statement:**

* Your specimen(s), even if identifiers are removed may be used for commercial profit. You (will or will not) share in the commercial profit

Who can answer my question about this research?

Before you decide to volunteer for this study, please ask any questions that might come to mind. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_ (If the LI is a student you must provide your faculty advisor contact information as well). If you have any questions about your rights as a volunteer in this research, contact the Institutional Review Board staff at the University of Memphis at 901-678-2705 or email irb@memphis.edu. We will give you a signed copy of this consent to take with you.

**STATEMENT OF CONSENT (The statement of consent should not be separated on multiple pages)**

I have had the opportunity to consider the information in this document. I have asked any questions needed for me to decide about my participation. I understand that I can ask additional questions through the study.

By signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been given a copy of this consent document. I understand that if my ability to consent for myself changes, my legal representative or I may be asked to consent again prior to my continued participation

**If you are using audio/video/photography in the research including the following**

As described above, you will be (Audio/video recorded and/or photographed) while performing the activities described above. (Audio/video recorded and/or photographed) will be used for (describe intend use). Initial the space below if you consent to the use of (audio/video recorded and/or photographed) as described

\_\_\_\_ I agree to the use of (audio/video recorded and/or photographed)

**If requesting permission to identify an individual as having participated in the research include the following:**

With your permission, your name will be used in (Describe intent of data usage) about this study. Initial the space below if you consent to the use of your name as described

\_\_\_ I agree to the use of my name

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|  |  |  |  |  |
| **Name of Adult Participant** |  | **Signature of Adult Participant** |  | **Date** |
|  |  |  |  |  |

**Researcher Signature (To be completed at the time of Informed Consent)**

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understand the information described in this consent and freely consent to participate**.**

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| **Name of Research Team Member** |  | **Signature of Research Team Member**  |  | **Date** |