Institutional Review Board
315 Administration Bldg.
Memphis, TN 38152-3370
Office: 901.678.2705
Fax: 901.678.2219

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

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: [Title]

Sponsor: [Name of Study Sponsor, if sponsored. If no sponsor, delete this line]

Researcher(s): [Name], [Institution (e.g., University of Memphis)]

[Name], [Institution (e.g., University of Memphis)]

Researcher Contact Info: [Phone]

[Email]

You are being asked to participate in a research study. The box below highlights key information for you to consider when deciding whether or not to you want to participate. More detailed information is provided below the box. Please ask the researcher any questions about the study before you decide whether to participate. If you volunteer to take part in this study, you will be one of about _____ people to do so.

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 benefits 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 [**BREIFLY** highlight the key research activities/procedures].
- Risks. Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
- Benefits. Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
- 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."].

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Who is conducting this research?

(*Lead Investigator, LI*) of University of Memphis Department of (*list department*) is in charge of this study. *(If the LI is a student, add the following sentence:* He/She is being guided in this research by *(Advisor].)* There may be other research team members assisting at different times 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 key inclusion/exclusion criteria that may make the individual eligible to participate]

How long will I be in this research?

[NOTE: If duration is fully detailed in the **key information summary** above, you may remove this section.]

The research will be conducted at (state general facility. e.g. UofM Psychological Services Center, Memphis Schools etc.). It should take about [state the total time of participation. Consider the duration of participation, frequency (if multiple study visits) and 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.] of your time.

What happens if I agree to participate in this research?

If you agree, you will be asked [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 from secondary sources.
- ☐ Where this research will be done.
- ☐ Provide a time-line description of the activities, tests and/or procedures that will be done, including any screening procedures. You can use tables or charts if they are helpful to explain the schedule
- ☐ If there will be photography, audio or videotaping and what will be recorded.

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

- ☐ Inform participants that they can skip any question that makes them uncomfortable and they can stop at any time.
- ☐ It may be appropriate to provide example of the questions being asked. When asking sensitive information, sample questions must be provided.

Others 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 assignment, 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 an _ 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. (The researcher can find out in case of an emergency).

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

We will tell you about any new information that may affect your willingness to continue participation in this 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 a lay example for reference (e.g., teaspoons or tablespoons).
- ☐ Identify any experimental procedures.
- ☐ Identify all drugs, devices, and tests performed that are approved for marketed use.
- ☐ Identify all unapproved drugs, devices, tests, 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, which means that it is not approved by the Food and Drug Administration (FDA).
    - Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental.
    - Describe any relevant information about the test article and the control (if used).

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- 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 subjects, and if so, under what conditions.

☐ For research involving biospecimens, the following statement needs to be included:

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. You may use the suggested language below as applicable].

- Your name will not be used in any [e.g., published reports, conference presentations, etc.] about this study.
- We may publish/present the results of this research. However, we will keep your name and other identifying information confidential – OR -
- With your permission, your name will be used in [e.g., conferences, published reports] about this study.

Discuss whether information and/or specimens collected for this research will be shared and under what circumstances [i.e., data set shared with other researchers, data deposited in a formal repository, etc.].

If research involves the collection of identifiable private information or identifiable biospecimens, one of the following statements must be included, if either statement is applicable or a possibility for this research:

- Identifiers might be removed from identifiable private information or identifiable biospecimens collected in this research and used for future research or distributed to another investigator for future research without obtaining additional consent. – OR -
- Information or biospecimens 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 will be available at clinicaltrials.gov. This Web site will not include information that can identify you. The Web site will only include a summary of the study. You can search this Web site at any time.

Clinical Trial: A research study in which one or more human subjects are prospectively

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assigned to one or more interventions (which may include 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 will take measures to protect your privacy the security of all your personal information. Despite taking steps to protect your privacy, we can never fully guarantee your privacy confidentiality of all study information will be protected. Measures we will take include:

- ☐ Discuss steps that you will take to protect participant privacy, (e.g., conduct research in private setting and/or other space consideration, 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, etc.).
- ☐ Discuss steps that you will take to protect confidentiality (e.g., where will data be stored, who will have access to the data, how will data be transferred, when will data be de-identified, security of storage (online), etc.)
- ☐ Discuss any known limits to protecting confidentiality (e.g., limits of data security and storage, data collected in group settings, user agreements, etc.).

Individuals and organization that monitor this research may be permitted access to and inspect the research records. This may include access to your private information and [include any other records]. These individuals and organizations include: [Edit the list below as appropriate for your research].

- ☐ The Institutional Review Board
- ☐ Government regulatory agencies
- ☐ The Food and Drug Administration (if FDA regulated)
- ☐ The study sponsor (if sponsored)
- ☐ People who work with the study sponsor
- ☐ Any other individuals/entities
- ☐ When the procedures include communicable disease testing, include any disclosures mandated by state-law.

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

Research team members are required to report the following: If a team member suspects child abuse or neglect, TN Law may require this suspicion be reported. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information. Information about elder abuse or domestic violence or the possibility of doing harm to others may also need to be reported to authories.

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

- A Certificate of Confidentiality 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 Certificate of Confidentiality from NIH.

NIH expects researchers tell participants about the protections afforded by the Certificate of Confidentiality. 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 any federal, state, or local, legal or court hearing. There are exceptions such as to report child abuse or communicable diseases.

Additionally include the following language as applicable:

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 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 researchers to release it.

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

The 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 researcher intends to disclose information covered by a Certificate, with the consent of research participants:

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

What are the risks if I participate in this research?

[NOTE: If all risks are disclosed in the key information summary above and/or are limited to

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breach of privacy and/or confidentiality, delete.]

The risks or discomforts of participating in this research include [detail any known risk of harm that the participant may experience in simple language. Any risks listed in the protocol must be addressed in the consent form.

Commonly categories of risks to cover:

- ☐ Physical risks
- ☐ Psychological risks (e.g., embarrassment, fear or guilt)
- ☐ Privacy risks (e.g., disclosure of private information)
- ☐ Social risks (e.g., social ostracizing or discrimination)

For some simple minimal risk studies, a brief statement similar to the following addresses the scope of risk associated with participating:

There may be risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

The following are additional aspects of risks to include if applicable:

- ☐ Side effects of any comparator drugs.
- ☐ Any risks associated with washout, withholding treatment, or randomization of treatment.
- ☐ When the risk profile is not well known, this should be discussed.
- ☐ When there may be unknown risks associated with participation, include the following:

In addition to these risks, taking part in this research may have risks that are unknown or currently unforeseeable.

- ☐ If the study involves pregnant women or women of child-bearing potential:
- ☐ If there are known risks to an embryo or fetus associated with participation, include:

Taking part in this research may hurt a pregnancy or fetus in the following ways: [include the ways that are known].

- ☐ If the study may involve risks to an embryo or fetus or procedures whose risk profile in pregnancy is not well known:

Taking part in this may hurt a pregnancy or 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, you may delete.] 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 but possible benefits to scientific knowledge:

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Participating has no known direct benefits to you. We do think that this study will help [describe anticipated generalized societal benefit of the research].

☐ If there are no expected benefits to the subject but possible benefits to others:

Participating has no known direct benefits to you. Possible benefits to others include [describe any benefits to others].

☐ If there are possible benefits to the subject, detail any known direct benefits that the participant may experience from participating in the study. Include:

Although not guaranteed, possible benefits to you include [describe any direct benefits to the subject. If benefits from taking part may not continue after this research has ended, state these]. Possible benefits to others include [describe any benefits to others].

What other choices do I have besides participation in this research?

[NOTE: If there are no alternatives or these have been fully disclosed in the key information summary above, delete.]

If you do not want to take part in the study, there are other choices such as _____. *(Describe whether or not there are any procedures the subject could participate in to receive the same level of benefit).* Add the following for student volunteers: As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or grade in your classes.

OR

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

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation is voluntary, and you can stop at any time. There is no penalty or loss of benefits to which you are otherwise entitled is you decided to not be involved. Your decision about participating will not affect your relationship with the researchers 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 statements 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 costs to you, such as [*Describe any costs the subject may incur as a result of participating in the study. For example:* You may have to pay for the cost of getting to the study site and a parking fee.)☐

What if I am injured because of participating in this research?

[This section must be included for any study that is greater than minimal risk or

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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's or medical supervisor's name*) at _____ . [*For **greater than minimal risk** research add information for one (or a combination) of the following as a contact for subjects to use in case of illness or injury during his/her participation in the study:*

1. *a dedicated pager number;*
2. *a dedicated cell phone number;*
3. *other reliable 24-hour contact option at your discretion, and/or*
4. *as deemed necessary, in addition to one or more of the above, referral to 911 for an emergency.*]

_____ (*LI's or medical supervisor's name*) will determine what type of treatment, if any, that is best for you at that time.

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 costs. Therefore, the medical costs related to your care and treatment because of research related harm *(add study specific language by selecting appropriate options… e.g.),*

will be your responsibility; **or**

will be paid by the sponsor (*only option if industry sponsored and industry trial) (insert sponsor's name here*) 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 directions. **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 Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.
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 costs. The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

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

Address whether or not subjects will be compensated for participation. Select and include the statements that apply to your research:

- You will not be paid for taking part in this research.
- You will have the opportunity to enter a raffle. The raffle is for $___[cash/check/gift card]. You have a 1 in ___ chance of winning
- For taking part in this research, you may be compensated a total of $ [cash/check/gift card]. Your compensation will be broken down as follows:
  - Describe payment schedule (i.e., how payment will be prorated in circumstance of incomplete participation or time-based payments). State in terms of amount of compensation.
  - Describe when and how payments 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]. Your compensation will be broken down as follows:
  - Describe the distribution schedule (i.e., how will compensation be prorated in circumstance of incomplete participation or time-based compensation). 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 biospecimens, when appropriate, include the following statement:

Your specimens, even if identifiers are removed, may be used for commercial profit. You [will or will not] share in this commercial profit.

Who can answer my questions about this research?

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Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, _____ at _____. 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 form to take with you.

STATEMENT OF CONSENT (The statement of consent should be on a page by itself)

I have had the opportunity to consider the information in this form. I have asked any questions needed for me to decide about my participation. I understand that I can ask additional questions throughout 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 form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to consent again prior to my continued participation.

If using audio/video/photography in the research include the following:

As described above, you will be [audio/video recorded and/or photographed] while performing the activities described above. [Recordings/photographs] will be used for [data analysis only/included in conference presentations/used for educational purposes, etc.].

- Initial the space below if you consent to the use of [audio/video or photographs] as described.

___ I agree to the use of [audio/video recording or photography]

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 [e.g., conferences, published reports] about this study.

- Initial in the space below if you consent to the use of your name as described.

___ I agree to the use of my name [and any other pieces of information]

Name of Adult Participant	Signature of Adult Participant	Date

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

I have explained the research 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 participate.

Name of Research Team Member	Signature of Research Team Member	Date

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