**HUMAN PARTICIPANT RESEARCH**

**IRBF004IC INFORMED CONSENT - EXEMPT**

Dear Researcher,

The IRB and MTSU reminds you that the two essential components of research involving human subjects are adequate informed consent and the protection of participant’s rights, such as autonomy and confidentiality). Therefore, MTSU requests its faculty, staff and students to take the consent process of the human subject research very seriously – it is a conversation and not a mere document. If you cannot disclose a certain activity or an intervention to the participants, then you must not include such processes in your study. Moreover, the law requires the administration of the informed consent, but it does not clearly state how many times. Researchers are encouraged to remind the participants of their rights as many times as it is needed. In order to qualify for exemption, the informed consent document or a process must satisfy the following minimum requirements:

1. Summative descriptions of the purpose of the study and the specifics on what is expected from the subjects in order for them to be research participants
2. Participation is fully voluntary and they can withdraw at any time without penalty or prejudice
3. An overview on what will be required from the participants
4. Clear disclosures of possible discomforts and/or potential risks as a result of the participation
5. Total time to be taken in the study and other factors that would influence the participants
6. Contact information for the principal investigator and the faculty sponsor if the PI is a student.

We also would like to remind our researchers that working with human participants is not an academic right; it is a true privilege.

MTSU IRB

**Instructions**:

This template is meant for obtaining informed consent from a human participant by providing a paper copy to disclose the research-related activities. The same text and structure must be used for online surveys, verbal interviews through telephone or in person, and other means of collecting data.

1. **Participant Copy** – *Give this copy to the participant once it is signed by the PI*:
	1. Fill in all of the unprotected spaces – Do not leave any of the fields empty
	2. The research team must give disclosure of what is expected from the participant and provide a description of the study – Please note that “N/A” is not an accepted response.
	3. Once the form receives IRB approval, the PI must sign the document and hand it to the participant to read – the faculty advisor must also sign if the PI is a student
	4. In addition to allowing the participant to read this form, the investigators must also explain the procedures verbally. The investigators must encourage the participants to ask questions.
2. Researcher Copy – *Retain this copy for your records:*
	1. Fill in all of the unprotected spaces
	2. The participant will accept his/her participation by entering his/her initials.



**IRB**

**INSTITUTIONAL REVIEW BOARD**

Office of Research Compliance,

010A Sam Ingram Building,

2269 Middle Tennessee Blvd, Murfreesboro, TN 37129

**INFORMED CONSENT – RESEARCHERS’ DISCLOSURES**

(Part A – Participant’s Copy)

|  |  |  |
| --- | --- | --- |
| Study Title | *Click and Enter Title* | Office Use |
| Principal Investigator | **Enter PI's Name** | *IRB ID:* *NOT APPROVED* |
| Faculty Advisor | Enter FA's name if PI is a student - Type "N/A" if otherwise | Approval Date: mm/dd/yyyy |
| Contact Information | PI's email and telephone number | Expiration Date: N/A |

Dear Participant,

On behalf of the research team, the Middle Tennessee State University (MTSU) would like to thank you for considering to take part in this research study. You have been contacted by the above identified researcher(s) to enroll as a participant in this study because you met its eligibility criteria.

This consent document describes the research study for the purpose of helping you to make an informed decision on whether to participate in this study or not. It provides important information related to this study, possible interventions by the researcher(s) and proposed activities by you. This research has been reviewed by MTSU’s internal oversight entity - Institutional Review Board (IRB) - for ethical practices in research (visit [www.mtsu.edu/irb](http://www.mtsu.edu/irb) for more information).

As a participant, you have the following rights:

* You should read and understand the information in this document before agreeing to enroll
* Your participation is absolutely voluntary and the researchers cannot force you to participate
* If you refuse to participate or to withdraw midway during this study, no penalty or loss of benefits will happen
* The investigator MUST NOT collect identifiable information from you, such as, name, SSN, and phone number
* The researcher(s) can only ask you to complete an interview or a survey or similar activities and you must not be asked to perform physical activities or offer medical/psychological intervention
* Any potential risk or discomforts from this study would be lower than what you would face in your daily life

After you read the following disclosures, you can agree to participate in this study by completing “Part B” of this informed consent document. You do not have to do anything further if you decide not to participate.

1. **What is the purpose of this study?**

<Type or Paste - Do not Leave Blank>

1. **What will I be asked to do in this study?**

<Type or Paste - Do not Leave Blank>

1. **How many times should I participate or for how long?**

<Type or Paste - Do not Leave Blank>

1. **What are the risks and benefits if I participate?**

<Type or Paste - Do not Leave Blank - INCLUDE INFORMATION ON ANY COMPENSATION>

1. **What will happen to the information I provide in this study?**

<Type or Paste - Do not Leave Blank>

1. **What will happen if I refuse to participate and can I withdraw if I change my mind in the middle?**

<Type or Paste - Do not Leave Blank>

1. **Whom can I contact to report issues and share my concerns?**

You can contact the researcher(s) by email or telephone (**Enter email and telephone numbers for both PI AND FA**). You can also contact the MTSU’s Office of Research Compliance by email – irb\_information@mtsu.edu. Report compliance breaches and adverse events by dialing 615 898 2400 or by emailing compliance@mtsu.edu.

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**Confidentiality Statement:**

All efforts, within reason, will be made to keep the personal information in your research record private but total privacy cannot be promised, for example, your information may be shared with the MTSU IRB. In the event of questions or difficulties of any kind during or following participation, you may contact the Principal Investigator as indicated above. For additional information about giving consent or your rights as a participant in this study, please feel free to contact our Office of Compliance at (615) 898 2400.

**Compensation:**

Unless otherwise informed to you by the researcher(s), there is no compensation for participating in this study. The investigator must disclose if the participant would be compensated in the benefits section.

**Study-related Injuries:**

MTSU will not compensate for study-related injuries.

**Exemption Criteria:**

This study was submitted to the MTSU IRB – an internal oversight entity to oversee research involving human subjects. The IRB has determined that this investigation consists of lower than minimal risk and it is exempt from further IRB processes based on the criteria: *“*Choose a category*.”*

**Note to the Participant**

You do not have to do anything if you decide not to participant in this study. But if wish to enroll as a participant, please complete “Part B” of this informed consent form and return it to the researcher. Please retain the signed copy of “Part A” for your future reference.

**IRB**

**INSTITUTIONAL REVIEW BOARD**

Office of Research Compliance,

010A Sam Ingram Building,

2269 Middle Tennessee Blvd, Murfreesboro, TN 37129

**INFORMED CONSENT**

(Part B – Researcher’s Copy)

|  |  |  |
| --- | --- | --- |
| Study Title | *Click and Enter Title* | Approval Information |
| Principal Investigator | **Enter PI's Name** | IRB ID: *NOT APPROVED* |
| Faculty Advisor | Enter FA's name if PI is a student - Type "N/A" if otherwise | Approval Date: mm/dd/yyyy |
| Contact Information | PI's email and telephone number | Expiration Date: N/A |

You have been contacted by the investigator(s) because the researchers believe you meet the eligibility criteria to participate in the above referenced research study. Be aware that you must NOT be asked by the investigator(s) to do anything that would pose risk to your health or welfare, such as:

* Identifiable information – name, phone number, SSN, address, College ID, social media credentials (FaceBook page, twitter, etc.), email, identifiable information of closest relatives and etc.
* Physical activities – like exercise studies
* Medical intervention – testing drugs, collection of blood/tissue samples or psychological questions
* Nothing risky – any proposed activity that would expose you to more risk than what you would face on a day to day basis is not approved by the IRB

However, you can do the following:

* Withdraw from the study at any time without consequences
* Withdraw the information you have provided to the investigators before the study is complete
* Ask questions so the researcher must explain the procedures used in the research verbally.

The investigators must give you enough time to ask any questions. Once you have had a chance to read “Part A” (Participant’s Copy), indicate your acceptance by checking the appropriate boxes:

|  |  |  |
| --- | --- | --- |
|  | **NO** | **YES** |
| * I have read investigator(s)’ disclosure (Part A) for the above identified research
 | [ ]  | [ ]  |
| * The researcher(s) explained the procedures to be conducted verbally
 | [ ]  | [ ]  |
| * I understand each part of the interventions and all my questions are answered
 | [ ]  | [ ]  |
| * The researcher(s) gave me a signed copy of the disclosure page (Part A)
 | [ ]  | [ ]  |

By initialing below, I give my consent to participate in this study. I understand that I can withdraw from the study at any time without facing any consequences.

**X**

**------------------------ ------------------------------ NON-IDENTIFIABLE PARTICIPANT ID# \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant initial Date**

*Initial this copy and return it to the researcher and retain Part A for your reference in case you have questions or you wish to get in touch with the researcher or with the MTSU IRB*