**IRBF016**

**INFORMED CONSENT**

**(Use this consent template when recruiting adult participants not considered as “vulnerable”)**

**General Information**

1. Use this form for requesting consent for enrolling participants in your study
2. The participants must be 18 years or older AND they must not be classified as “vulnerable” by other OHRP guidelines. Minors under the age of 18, women who are pregnant and prisoners are classified as vulnerable in addition to certain individuals whose cognitive ability to give consent is reduced due to any medical, physical, financial or other situations.
3. This template is suitable for studies that qualify for exemption as well as those which are reviewed by the expedited or full review mechanisms.
4. Alterations and waiver of this template are strongly discouraged.
5. Web-based Studies (adult participants only):
	1. Use the same text when requesting ONLINE consent from the participants. The online consent link must be provided in the protocol.
	2. The first page of the research must display this approved informed consent text.
	3. Participants’ consent to participate must be entertained by two distinct response: one to consent and one to decline
	4. The participant age must be verified through a separate question
	5. Agreeing to consent and age verification must both be true before the online instrument can be administered.
6. The Faculty Advisor information will be removed at the review/approval stage if the PI is NOT a student.

**Instructions**

1. This form contains two sections:
2. Information section – signed by the researcher and given to the participant
3. The signature section has to be signed by the participant:
4. If signature waiver is approved or required by the IRB, then the signature section will be filled by the PI with a random ID and saved with rest of the research records
5. Barring the actual signatures, the text boxes in two sections must be properly completed before submitting for IRB approval.

**IRBF016 – Participant Informed Consent**

1. **INFORMATION AND DISCLOSURE SECTION**

**(Participant Copy)**

|  |  |  |
| --- | --- | --- |
| Primary Investigator(s) |        | **Student** [ ]  |
| Contact information  | MTSU Office (If applicable), Telephone and Email ID |
| Department Institution |       |
| Faculty Advisor |       | Department |       |
| Study Title |       |
| **IRB ID** | **NOT APPROVED** | **Expiration** | **NOT APPROVED** |

The following information is provided to inform you about the research project and your participation in it. Please read this disclosure carefully and feel free to ask any questions you may have about this study and the information given below. You must be given an opportunity to ask questions, and your questions must be answered. Also, you must receive a signed copy of this disclosure.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Middle Tennessee State University (MTSU) Office of Compliance (Tel 615-494-8918 or send your emails to irb\_information@mtsu.edu. Please visit [www.mtsu.edu/irb](http://www.mtsu.edu/irb) for general information on MTSU’s research participant protection policies.

**Please read this section and sign Section B if you wish to enroll in this study. The researcher will provide you with a copy of this disclosure form for you to keep for your future reference.**

1. **Purpose of the study:** You are being asked to participate in this research study because

1. **Classification of procedures to be followed and approximate duration of the study:**

[ ]  2.1 ***Educational Tests –*** Study involves either standard or novel education practices which consists educational testing and such studies expose the participants to lower than minimal risk

[ ]  2.2 ***Behavioral Evaluation –*** Although the study may or may not involve educational tests, the specific aim is to understand behavioral characteristics. .

The following classifications indicate that the participant will be asked to perform or part-take in physical activities or procedures. Examples of such studies simple physical exercises, medical or clinical intervention, pharmaceutical testing and etc. Due to the nature of these studies, you may be exposed risky situations thay may exceed normal day-to-day scenarios.

[ ]  2.3 ***Psychological intervention or procedures*** [ ]  2.4 ***Physical Evaluation or Procedures***

[ ]  2.5 ***Medical Evaluation or Clinical Research*** [ ]   ***2.6 OTHER***

 Provide further specificis

1. **What are procedures we intend on doing in this study?**

Provide a list of all the prorcedures to be carried out in the study

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

List the involvement of the volunteers

1. **What are we planning to do with the data collected using your participation?**

Elaborate how you plan to use the data collected from the participant, including any identifiable data.

1. **What are your expected costs to you, your effort and your time commitment?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **What are the potential discomforts, inconveniences, and/or possible risks that can be reasonably expected as a result of participation in this study?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **How will you be compensated for your participation?**

PROVIDE detailed information on compensation for the study. DO NOT repeat the benefits.

1. **What are the anticipated benefits from this study?**

PROVIDE the direct benefits to the participants other than the compensation.

1. **Are there any alternatives to this study such that you could receive the same benefits?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **Will you be compensated for any study-related injuries?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **Circumstances under which the researcher may withdraw you from this study:**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **What happens if you choose to withdraw your participation?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **Can you stop the participation any time after initially agreeing to give consent/assent?**

Provide Detailed Information here - DO NOT LEAVE BLANK

1. **Contact Information.** If you should have any questions about this research study or possibly injury, please feel free to contact PI Name by telephone PI Telephone or by email PI's email ID OR my faculty advisor, Faclty's Name - ENTER N/A if PI is not a student), at Enter a valid email ID and a telephone number.
2. **Confidentiality.** All efforts, within reason, will be made to keep the personal information in your child’s research record private but total privacy cannot be promised. Your information may be shared with MTSU or the government, such as the Middle Tennessee State University Institutional Review Board, Federal Government Office for Human Research Protections, *if* you or someone else is in danger or if we are required to do so by law.

You do not have to do anything if you decide not to participate. If you wish to enroll, then follow the direction next to the checked box below:

[ ]  Enter your name and age in the attached Section B document and sign in the space provided.

**[ ]** Anonymous: Just your age and give consent by signing in the bottom of the space provided.

**[ ]** Verbal Consent: Give consent verbally; this is done to protect your identity.

Consent obtained by:

Researcher’s Signature Name and Title Date

1. **Signature Section**

**(Researchers’ Copy)**

|  |  |  |
| --- | --- | --- |
| Primary Investigator(s) |        | **Student** [ ]  |
| Contact information  | MTSU Office (If applicable), Telephone and Email ID |
| Department/Institution | Enter PI's Department/Affiliation |
| Faculty Advisor (FA) |       | Department | Enter FA's Affiliation |
| Study Title |       |
| **IRB ID** | **NOT APPROVED** | **Expiration** | **NOT APPROVED** |

**PARTICIPANT SECTION**

***(To be filled by the participant and return to the researcher)***

|  |  |  |
| --- | --- | --- |
| Participant Name or ID | (print)       | Age:  |

[ ] No [ ] Yes I have read this informed consent document pertaining to the above identified research

[ ] No [ ] Yes The research procedures to be conducted have been explained to me verbally

[ ] No [ ] Yes I understand each part of the interventions and all my questions have been answered

[ ] No [ ] Yes I am aware of the potential risks of the study

By signing below, I affirm that I freely and voluntarily choose to participate in this study. I understand I can withdraw from this study at any time without facing any consequences.

Follow the signage instruction next to the box checked below:

[ ]  Enter your name and age above and sign below to enroll in the study

**[ ]** Anonymous: Just enter your age above and sign below; DO NOT ENTER YOUR NAME

**[ ]** Verbal Consent: The participant will give consent verbally to protect the participant’s identity.

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Date Signature of the Participant

**RESEARCHER SECTION**

***(To be filled by the researchers)***

Informed Consent obtained by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signature Print Name & Title

Faculty Verification if the PI is a student:

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Date Faculty Signature Print Name & Title

**DO NOT begin this Research before IRB approval**