**IRBF016: INFORMED CONSENT**

**(Use this consent template for in person or virtual interactions)**

**General Information**

1. Use this consent form for requesting a participant for
	1. In person interviews or other interactions
	2. Virtual interviews or other interactions using Zoom
	3. Online consent via Qualtrics
2. This template is suitable for studies that qualify for Expedited as well as a full review.
3. Alterations and waiver of this template are strongly discouraged. The elements not applicable to the study can be indicated by the provided check boxes with a suitable justification.
4. Web-based Studies – this form is not currently available for web-based administration through Qualtrics.
5. The Faculty Advisor information will be removed at the review/approval stage if the PI is NOT a student.
6. COVID-19: for in person protocols, there is a COVID-19 avoidance plan in the informed consent section. An extra page for collecting participant information to enable contact tracing in the event the participant, or a person the participant came in contact with was found to be positive for COVID-19. This “extra page” is used only for contact tracing and will be destroyed after few days in accordance with CDC guidelines.

**Instructions**

1. This form contains TWO sections:
2. General Information section – signed by the researcher and given to the participant
3. The signature section has to be signed by the participant

Please note that there are multiple options: first one for traditional pen signature, a second option is for virtual administration via Zoom, and a third option for Qualtrics

1. If signature waiver is approved or required by the IRB, then the signature section will be filled by the PI with a random identifier and saved with rest of the research records
2. Other than the actual signatures, the text boxes in two sections must be properly completed before submitting for IRB approval.
3. The investigators have the option for requesting the removal of certain elements in this form by entering their justification in the boxes highlighted in yellow. All of the pre-approval request boxes will be removed at the approval stage.

**IRBF016 – Participant Informed Consent**

1. **INFORMATION AND DISCLOSURE SEGMENT**

**(Participant Copy)**

|  |  |
| --- | --- |
| ***Study Title*** |       |
| ***Primary Investigator(s)*** |       [ ]  **Student**  |
| ***Contact information***  |       |
| ***Department & Institution*** |       |
| ***Faculty Advisor*** |       | ***MTSU Department*** |       |
|  |  |
| ***Protocol ID*** | **21-####** | **Approval:** **NOT APPROVED** | **Expiration:**  |

The following information is provided to inform you about the research project in which you have been invited to participate. Please read this disclosure and feel free to ask any questions. The investigators must answer all of your questions and you must be given 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 without loss of any benefits.
* In the event new information becomes available that may affect the risks or benefits associated with this research study, you will be notified so that you can make an informed decision at that time.

For additional information on your rights as a participant in this study, please contact the Middle Tennessee State University (MTSU) Office of Compliance (Tel 615-494-8918 or send your emails to irb\_information@mtsu.edu. (URL: http://[www.mtsu.edu/irb](http://www.mtsu.edu/irb)).

**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. **What are the prime types of physical contact the participant will have?**

The participant will have the following type(s) of contact(s) with the investigators or/and other participants at least sometimes during this research:

[ ]  1.1 ***Virtual Interactions***

*[ ]  Qualtrics [ ]  Zoom [ ]  Telephone [ ]  Other*

[ ]  1.2 ***In person interactions***

[ ]  With PPE[ ]  Without PPE[ ]  With Social Distancing[ ]  Without Social Distancing

[ ]  1.3 ***In person interactions without PPE:***

[ ]  1.3 ***In person interactions without Social Distancing:***

The participants will be asked to provide their contact details to be used by MTSU COVID-19 task force for contact tracing if needed

1. **What is the main category of this research?**

[ ]  2.1 ***Educational Tests*** [ ]  2.2 Social/***Behavioral Evaluation***

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

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

[ ]  *2.7* ***OTHER***

|  |
| --- |
| **Definitions THIS BOX WILL BE REMOVED AFTER APPROVAL;** **The participants will not see this box****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**Behavioral Evaluations:** Although the study may or may not involve educational tests, the specific aim is to understand social and/or 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.**Psychological Interventions/procedures****Physical Evaluations/procedures****Medical evaluations/Procedures****Other**:       |

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

1. **What type of data will be collected from you?**

1. **What are procedures we intend on doing to collect the above described data?**

[ ]  5.1 ***Audio recording*** [ ]  5.2 ***Video Recording*** [ ]  5.3 ***Photography*** [ ]  5.4 ***NO audio/video recording***

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

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

1. **What are the expected results of this study and how will they be disseminated?**

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**        |

1. **What is the approximate time commitment not including your preparation time for participating in this study?**

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

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**        |

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

1. **What are the risks and bodily harm due to COVID-19 exposure?**

Although the MTSU IRB considers this research as “no more than minimal risk.” the participants will be in physical contact with the PI and other participants during this study. Therefore, the participants will be exposed to the risk of contracting COVID-19.

* ***The participants must adhere by the following to reduce the risk for infection.*** Provide Detailed Information here - DO NOT LEAVE BLANK
* ***The investigator will follow these precautions:*** Provide Detailed Information here - DO NOT LEAVE BLANK

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**       **This is mandatory for all in person studies and will not be waived** |

* ***COVID-19 Contact Tracing:***  The participants will be asked to provide their contact details will be given to the MTSU COVID-19 task force if someone you came in contact with tested positive for COVID-19. Your contact details provided in this form will be destroyed after a few days if no positivity of COVID-19 is detected. ADD additional information if necessary.
1. **What are the anticipated benefits from this study?**
	1. ***The benefits to science and humankind that may result from this research:***

* 1. ***The direct benefits to you which you may not receive outside the context of this research:*** DEFAULT - There are no direct benefits to the partipants
1. **How will you be compensated for your participation?**

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

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**        |

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

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**        |

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

|  |
| --- |
| **Pre-Approval Requests: THIS BOX WILL BE REMOVED AFTER APPROVAL****The participants will not see this box****[ ]  NOT APPLICABLE; Justification:**        |

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

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

1. **Contact Information.** If you should have any questions about this research study or possibly injury, please feel free to contact       by telephone       or by email       OR my faculty advisor,      , at      . For additional information about giving consent of your rights as a participant in this study, to discuss problems, concerns and questions, or to offer input, please feel free to contact the MTSU IRB by email: compliance@mtsu.edu or by telephone (615) 494 8918.
2. **Confidentiality.** All efforts, within reason, will be made to keep your personal information 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.
3. **Confidentiality and COVID-19:**  Your information will be provided to the University COVID-19 task force or other public health officials in the event you or one of the research participants or investigators should test positive for COVID-19. Complete the COVID-19 Contract Tracking Page after you agree to consent.

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

[ ]  SIGNATURE Consent: Please enter your name and age in the attached Segment B document and sign in the space provided.

**[ ]** ANONYMOUS Consent: Please give consent by entering your age and initials in Segment B

**[ ]** VERBAL Consent: Give consent verbally and no signature needed in Section B

**[ ]** VIRTUAL Consent: Give consent verbally via Zoom. The PI will schedule an interview via the virtual platform Zoom. The PI will also give you directions on how to setup Zoom in your PC or mobile device. You will be given an opportunity to review the research again before the Zoom session and the PI will use Section B (Segment 2) to confirm and document your consent.

**[ ]** TELEPHONE Consent: Give consent verbally over telephone. The PI will schedule an interview by telephone. You will be given an opportunity to review the research again before the telephone interview and the PI will use Section B (Segment 2) to confirm and document your consent.

**[ ]** ONLINE Qualtrics Consent: Give consent by clicking the appropriate boxes. Please read the following questions and respond by clicking appropriate boxes

Consent obtained by:

Researcher’s Signature Name and Title Date

---- The following reviewer section will be revealed only at the review stage------------------------------------------

**For Office Use Only**

**Reviewer’s Assessment of the Informed Consent – Part A**

|  |  |
| --- | --- |
| The proposed informed consent reflects the details and procedures provided in the protocol application **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The risks and discomforts are clearly explained. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| Revisions are needed in the disclosure Part A (Describe the deficiencies with appropriate item number.**Recommended Revisions:**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |
| The PI’s request to omit certain elements is reasonable and the justification provided is satisfactory. **Critique**       | [ ] Yes [ ] No[ ] N/A |
| PI Response:        |

**IRBF016 – Participant Informed Consent**

1. **Consent Segment 1 - IN PERSON INTERACTION**

**(Researchers’ Copy)**

|  |  |  |
| --- | --- | --- |
| ~~Primary Investigator(s)~~ |  | **~~Student~~** ~~[ ]~~  |
| ~~Contact information~~  |  |
| ~~Department/Institution~~ |  |
| ~~Faculty Advisor (FA)~~ |  | ~~Department~~ |  |
| ~~Study Title~~ |  |
| **~~IRB ID~~** | **~~NOT APPROVED~~** | **~~Expiration~~** | **~~NOT APPROVED~~** |

**PARTICIPANT SECTION**

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

|  |
| --- |
| **Instruction to the PI:** *Note: This box and the first column will be removed in the approved template** Consent items are listed below; please SELECT the consent items applicable to your research by checking the box in the first column.
* Some mandatory items are preselected; however, requests to remove the preselected items may be provided with justification in Appendix G of the Expedited/Full application.
* The participant will give consent by checking yes/no in the right column
* The investigator may add more disclosures in the blank fields provided below.
 |
| **PI Select** |  | **Participants give consent** |
| [x]  | I have read this informed consent document | [ ] No [ ] Yes |
| [x]  | The research procedures to be conducted have been explained to me verbally | [ ] No [ ] Yes |
| [x]  | I understand all of the interventions and all my questions have been answered | [ ] No [ ] Yes |
| [x]  | I am aware of the potential risks of the study | [ ] No [ ] Yes |
| [ ]  | I understand that I will be  and analyzed | [ ] No [ ] Yes |
| [ ]  | I agree to allow my information to be retained by the investigator for use in future research studies | [ ] No [ ] Yes |
| [ ]  | I give permission to share any information collected from me, including audio/video data, with individuals outside this research study | [ ] No [ ] Yes |
| [ ]  | I give permission to be contacted in the future | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |

**Please SELECT the consent text applicable to your research by checking the box; The check box and unselected texts will be removed in the final version.**

**[ ]** By entering my name and 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.

**[ ]** By entering my initial and my age, I affirm ANONYMOUSLY 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.

**[ ]** I am giving consent verbally to 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.

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

CLICK HERE and make a selection Date Participant’s Age

**RESEARCHER SECTION**

***(To be filled by an investigator and the FA if applicable)***

|  |  |  |
| --- | --- | --- |
| Informed Consent obtained by:  |  | Faculty Verification (if administered by a student) |
|  |  |  |
| Name Signature Date |  | Name Signature Date |

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

---- The following reviewer section will be revealed only at the review stage------------------------------------------

**For Office Use Only**

**Reviewer’s Assessment of the Signature Section – Section B (In Person Interaction)**

|  |  |
| --- | --- |
| The selections by the PI and the checkable consent items are appropriate. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| This disclosure is necessary but the following may be omitted. **Recommended Revisions:**       | [ ] Yes [ ] No |
| PI Response:        |
| Additions are needed. The following check box items be added to this section to accurately reflect the protocol. **Recommended Revisions:**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |

**COVID-19 Contact Tracing**

**PARTICIPANT SECTION**

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

**Confidentiality and COVID-19:**

Your information will be provided to the University COVID-19 task force or other public health officials in the event you or one of the research participants or investigators should test positive for COVID-19.

|  |
| --- |
| ***Name:******Contact Address:******Telephone:******Email Address:*** |

***Office Use:***

Information Date: (Today’s Date)

Expiration Date: (Date on which this sheet will be destroyed if no COVID-19 is detected)

***Instruction to PI:***

* Destroy this page if no COVID-19 is detected by the expiration date above
* If positivity for COVID-19 is known, then provide the participant contact information to MTSU’s COVID-19 task force

Ensure to cut the box out when providing the participant’s contact details and hide any protocol details from being transmitted.

**GO TO THE NEXT PAGE if Administering Informed Consent via Zoom**

**IRBF016 – Participant Informed Consent**

1. **Consent Segment 2 – VIRTUAL INTERACTION**

**(Researchers’ Copy)**

|  |  |  |
| --- | --- | --- |
| ~~Primary Investigator(s)~~ |  | **~~Student~~** ~~[ ]~~  |
| ~~Contact information~~  |  |
| ~~Department/Institution~~ |  |
| ~~Faculty Advisor (FA)~~ |  | ~~Department~~ |  |
| ~~Study Title~~ |  |
| **~~IRB ID~~** | **~~NOT APPROVED~~** | **~~Expiration~~** | **~~NOT APPROVED~~** |

**PARTICIPANT SECTION**

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

***The investigator will fill this section to document Informed Consent:***

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

***The investigator will read these questions and record the responses from the participants:***

|  |
| --- |
| **Instruction to the PI:** *Note: This box and the first column will be removed in the approved template** Consent items are listed below; please SELECT the consent items applicable to your research by checking the box in the first column.
* Some mandatory items are preselected; however, requests to remove the preselected items may be provided with justification in Appendix G of the Expedited/Full application.
* The participant will give consent by checking yes/no in the right column

The investigator may add more disclosures in the blank fields provided below. |
| **PI Select** | ***Consent Question*** | **Participant Response**  |
| [x]  | You confirm that you have read this informed consent document | [ ] No [ ] Yes |
| [x]  | You confirm that the research procedures to be conducted have been explained to you verbally | [ ] No [ ] Yes |
| [x]  | You understand all of the interventions? | [ ] No [ ] Yes |
| [x]  | Did we answer all of your questions? | [ ] No [ ] Yes |
| [x]  | You are aware of the potential risks and discomforts? | [ ] No [ ] Yes |
| [ ]  | You understand that you will be and analyzed | [ ] No [ ] Yes |
| [ ]  | Do you agree to allow my information to be retained by the investigator for use in future research studies? | [ ] No [ ] Yes |
| [ ]  | You give permission to share any information collected from me, including audio/video data, with individuals outside this research study? | [ ] No [ ] Yes |
| [ ]  | Can we contact you in the future for questions related to this study or recruitment for a different study? | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |

***The investigator will read the following and record the responses from the participants:***

You affirm that you freely and voluntarily choose to participate in this study. You also understand you can withdraw from this study at any time without facing any consequences.

 ***Participant’s Response:***

 [ ]  YES

 **[ ]** NO

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

|  |  |  |
| --- | --- | --- |
| Informed Consent obtained by:  |  | Faculty Verification (if administered by a student) |
|  |  |  |
| Name Signature Date |  | Name Signature Date |

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

**GO TO THE NEXT PAGE for Administering Informed Consent via Qualtrics**

**IRBF016 – Participant Informed Consent**

1. **Consent Segment 3 – ONLINE QUALTRICS CONSENT**

**SIGNATURE SECTION**

***(To be completed by the participant)***

***Please ENTER your name and AGE***

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

***Your name will be used only to confirm you gave consent via Qualtrics. Once the subsequent research processes have been completed, your identity will be removed.***

|  |
| --- |
| **Instruction to the PI:** *Note: This box and the first column will be removed in the approved template** Consent items are listed below; please SELECT the consent items applicable to your research by checking the box in the first column.
* Some mandatory items are preselected; however, requests to remove the preselected items may be provided with justification in Appendix G of the Expedited/Full application.
* The participant will give consent by checking yes/no in the right column

The investigator may add more disclosures in the blank fields provided below. |
| **PI Select** | ***Consent Question*** | **Participant Response**  |
| [x]  | You confirm that you have read this informed consent document | [ ] No [ ] Yes |
| [x]  | You confirm that the research procedures to be conducted have been explained to you verbally | [ ] No [ ] Yes |
| [x]  | You understand all of the interventions? | [ ] No [ ] Yes |
| [x]  | Did we answer all of your questions? | [ ] No [ ] Yes |
| [x]  | You are aware of the potential risks and discomforts? | [ ] No [ ] Yes |
| [ ]  | You understand that you will be and analyzed | [ ] No [ ] Yes |
| [ ]  | Do you agree to allow my information to be retained by the investigator for use in future research studies? | [ ] No [ ] Yes |
| [ ]  | You give permission to share any information collected from me, including audio/video data, with individuals outside this research study? | [ ] No [ ] Yes |
| [ ]  | Can we contact you in the future for questions related to this study or recruitment for a different study? | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |
| [ ]  |       | [ ] No [ ] Yes |

You affirm that you freely and voluntarily choose to participate in this study. You also understand you can withdraw from this study at any time without facing any consequences.

 ***Participant’s Response:***

 [ ]  YES

 **[ ]** NO

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

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