**Human Participant Research Proposal**

**IRBF001: EXPEDITED REVIEW REQUEST FORM**

*Institutional Review Board*

*Middle Tennessee State University*

**“Expedited” versus “Full Review” Definition:**

Please note “expedited” does not mean this proposal would be reviewed by a “fast track” mechanism; it merely means the proposed research study does not require a full committee review. Other than the actual review & approval, the procedures and documents requirement are mostly similar.

* *Expedited Review:* [*https://mtsu.edu/irb/ExpeditedProcedures.php*](https://mtsu.edu/irb/ExpeditedProcedures.php)
* *Full Committee Review:* [*https://mtsu.edu/irb/FullReviewProcedures.php*](https://mtsu.edu/irb/FullReviewProcedures.php)

**What does this form contain?**

This form separated into the following sections with added subsections to make the review process swifter. The AY-2021 form also contains space for how the PI **plans to handle potential COVID-19 exposure**.

|  |  |
| --- | --- |
| 1. Project Information
2. VACANT
3. VACANT
4. Expedited Approval Category
5. Research Methods & Instruments
6. Participant Selection & Recruitment
7. Confidentiality
 | 1. Informed Consent
2. CITI Training and Researcher Expertise
3. Mandatory Documents & Attachments
4. Investigators’ Declaration and Assurance
5. *IRB Action (Office Use)*
6. *Additional Procedures APPENDICES*
7. VACANT
 |

**Mandatory requirements**

* Participant recruitment - <https://mtsu.edu/irb/FAQ/Recruitment.php>
* Completed informed consent form(s): <https://mtsu.edu/irb/forms.php>
* All of the investigators must complete all required research-specific CITI training modules - <https://mtsu.edu/irb/requirements.php>
* Study instruments
* Plans to minimize COVID-19 exposure if the participants will have direct physical interactions
* Other documents may be required

**Instructions for document submission.**

* Use Microsoft Office to complete this form; DO NOT use other apps or utilities
* Send all of documents as **separate** files but in a single email to irb\_submissions@mtsu.edu
* Submit all IRB forms in their original MS Word format – DO NOT CONVERT TO PDF
* Student researcher must have the IRB documents submitted by their research advisor
* Please use fresh application templates when starting a new study; do not use older version.
* **Do not begin your Research until you have received a formal approval letter.**

**Review & Timeline**

* The documents will be prescreened for completeness – incomplete applications will be returned
* A reviewer will be assigned after the prescreen; the review is expected to take 2-3 weeks
* This form will be sent back to the investigators with reviewers’ comments and other instructions
* The review process is iterative and it depends on how swiftly the reviewers’ concerns are addressed.
* Once a final approval has been issued, a “locked” version of this form may be sent to the investigators to be used as a guideline for their study.

**Reviewers’ Initial Disclosure**

|  |  |  |
| --- | --- | --- |
| IRB Reviewer |       (optional) | Date Sent       |
| The IRB has expertise needed to review this research. REMARK:       | [ ] Yes [ ] No |
| The IRB member has a conflict of interest on this protocol. REMARK:       | [ ] Yes [ ] No |

**IRB Decision**

**Applicability:**

The Level of risk for this protocol [ ] Minimal [ ] Greater than Minimal

Recommended Interval for Continuing Review [ ] 6 months [ ] 12 Months [ ] Other:

**Implement the following exceptions and restrictions:**

|  |  |  |
| --- | --- | --- |
| Exceptions | [ ] NONE |       |
| RESTRICTIONS |  |       |

**Determination:**

 [ ]  Approve [ ]  Approve pending to revision

 *Approval Category: Choose an item.*

[ ]  Revise & Resubmit for further review

[ ] Refer to Full Committee

[ ] Refer to Full Committee with a request to defer the protocol

 (a protocol once deferred may not be reviewed by MTSU again)

|  |  |
| --- | --- |
|       |       |
| Reviewer | Date |

1. **PROJECT INFORMATION**
	1. **Select the type or Review Mechanism:**

[ ]  Expedited Review [ ]  Full Committee Review

* 1. **Project Title**

**<type here>**

**Primary Investigator (PI)** *Refer to* [*https://www.mtsu.edu/irb/FAQ/ResponsibilitiesOfPI.php*](https://www.mtsu.edu/irb/FAQ/ResponsibilitiesOfPI.php) *for PI responsibilities.*

[ ] Faculty [ ] Staff [ ] Graduate [ ] Undergraduate [ ] Other:

|  |  |
| --- | --- |
| *Name* |       |
| *Email* |       | *Telephone* | XXX-XXX-XXXX |
| *Alternate\* Email* |       *\*if PI is a student* |
| *Department/Unit* |       *College*       |
| *Office Location*  | *Room* #      *Building*       *Box* #      |
| *Contact Address* | MANDATORY if Non-MTSU |
| *CITI Program ID* |       |

* 1. **Faculty Advisor (FA)** *if the PI is a student:* [ ]  NONE

|  |  |
| --- | --- |
| *Name* |       [ ] Faculty [ ] Staff [ ] Other |
| *Email* |       | *Telephone* | XXX-XXX-XXXX |
| *Department/Unit* |       *College*       |
| *Office Location*  | *Room* #      *Building*       *Box* #      |
| *CITI Program ID* |       |

* **Must be completed by an MTSU faculty member or a full time employee of MTSU if the PI is a student.** *Refer* [*https://www.mtsu.edu/irb/FAQ/Faculty.php*](https://www.mtsu.edu/irb/FAQ/Faculty.php)
* The FA must submit the application packet by email to *irb\_submissions@mtsu.edu* indicating that s/he has knowledge of this proposal.

**1.5 Co-Investigators** *(List all researchers other than the PI/FA)*  [ ]  NONE

 *Select this box if there are more than SIX coinvestigators [ ]*

|  |  |  |
| --- | --- | --- |
| **Name/Email/Status of the Co-Investigators** | **Department/Institution** | **CITI Training** |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |
| *Name*:      *Email*:      [ ] Faculty/Staff [ ] Student5 [ ] Non-MTSU [ ] Other |       | [ ]  CompletedCITI ID:       |

* 1. **Research Category** *(select ALL that apply):*

 [ ]  Faculty research [ ]  FRCAC [ ]  Not for Publication [ ]  Class Project

 [ ]  Thesis Dissertation [ ]  URECA [ ]  Publication/Presentation [ ]  Staff research

[ ]  Other

* 1. **Miscellaneous Questions:**

|  |  |  |
| --- | --- | --- |
| **Project Questions** | **Response** | **Remark(s)** |
| Expected start date |       |       |
| Anticipated completion date**The protocol will be closed on this date** |       |       |
| Source of funding (Funding agency, number/ID, and expiration date) |       |       |

**Important Information:**

* Expedited and Full protocols are valid for one year; Annual Progress Report is mandatory
* For studies that require more than one year, the investigator must submit a written request for continuing review and a Progress Report (form available at [www.mtsu.edu/irb](http://www.mtsu.edu/irb) and click on FORMS)
* Each protocol can be continued twice; a new application must be submitted after 3 years

**Review Tracking**

|  |  |  |
| --- | --- | --- |
|  |  | **IRB Comments** |
| **Protocol ID** | **22-#####x** |  |
| **Date Received** |  |  |
| **Prescreen Date** |  |  |
| **Revision Date** (if applicable) |  |  |
| **Review Date** |  |  |
| **Revision Date** (if applicable) |  |  |
| **Approval Date** |  |  |
| **Expiration Date** |  |  |

1. **APPROVAL CATEGORY for EXPEDITED REVIEW**

***Select the category under which this proposal qualifies for an expedited review.*** Refer to <https://mtsu.edu/irb/FAQ/ExpeditedCategories.php> for more details on each of these categories and make your selection after you have familiarized with the categories.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Category Description** | **Select** | **Subcategory** |
| 1 | Clinical studies of drugs and/or medical devices | **[ ]**  |  |
| 2 | Collection of blood samples | **[ ]**  |  |
| 3 | Collection of biological specimens for research purpose | **[ ]**  |  |
| 4 | Data collection through noninvasive procedures like exercise | **[ ]**  |  |
| 5 | Research involving materials (data, documents, records, or specimen) that were collected solely for non-research purpose | **[ ]**  | **N/A** |
| 6 | Analysis of previously recorded voice, video. Images and etc., which were collected for research purposes | **[ ]**  | **N/A** |
| 7 | Research of individual or group characteristics or behavior | **[ ]**  | **N/A** |
| 8 | Continuing review of certain previously approved studies | **[ ]**  |  |
| 9 | Continuing review of studies not conducted under investigational new drug or investigational device.  | **[ ]**  |  |

If multiple modes of data collection is being proposed, then select all the categories that apply. For instance, you propose to collect blood samples and plan to survey the participant behavior, then select categories 2 and 7.

Check the box(es) corresponding to the category under which your study qualifies for an expedited review. Enter the sub-category (<https://mtsu.edu/irb/FAQ/ExpeditedCategories.php>).

1. **RESEARCH METHODS & INSTRUMENTS**

**5.1 HYPOTHESIS:**

Provide the research questions being addressed in this study. Also describe if the study design. (e.g., qualitative, correlation, factorial, etc)

**5.2 BACKGROUND:**

Describe relevant research that has been done previously. Include citations as well as a brief description of relevant methods and important findings. You may limit this section to a sample of the most relevant research.

**5.3 PROTOCOL SUMMARY:**

Provide a short summary of this proposed study by providing the steps to be followed in chronological order. Start from participant recruitment, informed consent, data collection, debriefing, safety monitoring, and etc. Detailed descriptions can be presented in other segments of this application.

***NOTE: The goal of this section is to provide a full picture of the events and methods to the reviewers. The finer details may be presented in the sections provided below.***

**5.4 DATA DESCRIPTION:**

***5.4.1 Primary mode of data collection***

Select ALL applicable options and complete appropriate Appendix sections:

|  |
| --- |
| *5.4.1.1 Select type of interaction* **[ ]  NONE** |
|  [ ]  NO new data collection is done in this study |
|  [ ]  Virtual or online interaction with NO direct physical contact with the participant |
|  [ ]  Direct physical interaction with the participant: Complete Appendix COVID-19 |
|  *[ ]  No social distancing [ ]  No Masks worn [ ]  CDC guidelines not followed* |
|  [ ]  Participant-to-participant direct contacts - Complete Appendix COVID-19 |
|  *[ ]  No social distancing [ ]  No Masks worn [ ]  CDC guidelines not followed* |
|  |
| *5.4.1.2 Non-physical interventions/interactions* **[ ]  NONE** |
|  | [ ]  Social & Behavioral  |  |  *Complete* ***Section 5.4.2*** |
|  | [ ]  Educational |  |  *Complete* ***Section 5.4.2*** |
|  | [ ]  Existing Data (Analysis including investigation of audio/video)  | *Complete* ***5.4.2 & Appendix L*** |
|  | [ ]  Biospecimen – Analysis of previously collected biological samples Complete **Appendix F**) |
|  |  |
|  | ***Please provide a simple definition of what you mean by “data”:*** *Include the parameters to be obtained along with a description of the survey/interview; Please do NOT enter the mode of data collection and do NOT repeat the entire survey or interview.* |
|  |  |       |
|  |
| *5.4.1.3 Other Intervention/interactions***[ ]  NONE** |
|  | [ ] Physical (Appendix K) | [ ]  Psychological (Appendix C) | [ ]  Physiological (Appendix E) |
|  | [ ]  OTHER(s): Explain:       |
|  | ***Please provide a simple definition of what you mean by “data”:*** *Include the parameters to be obtained along with a description of the main outcomes.*      |
|  |       |
|  |

***5.4.2 Data Acquisition****: Complete this section for all types of Social/Behavioral and Education studies:*

|  |
| --- |
| **[ ]  5.4.2.1 Survey8** *Submit Survey either as PDF or as MS Word document* |
|  | [ ]  Paper Survey |   |
| [ ]  Verbal Survey |  |
| [ ]  Telephone |  |
| [ ]  Qualtrics Survey10 | *Visit* [*https://mtsu.edu/irb/FAQ/OnlineDataCollection.php*](https://mtsu.edu/irb/FAQ/OnlineDataCollection.php) *for more information* |
|  Qualtrics Link(s):       |
| [ ]  Email: Explain:       |
| [ ]  Survey through Social Media Explain:       |
| [ ]  OTHER modes |  |
|  Explain:       |
|  |
| [ ]  5.4.2.2 **Interview8** *Submit interview script/topics as a PDF or as a MS Word document* |
|  | [ ]  Face-to-face in person Interview |  |
| [ ]  Telephone  |  |
| [ ]  Social Media Explain:       |
| [ ]  Zoom |  |
| [ ]  Email: Explain:       |
| [ ]  OTHER modes | *Explain below and submit documents* |
|  Explain:       |
|  |  |
| [ ]  5.4.2.3 **Observation9** [ ]  In person [ ]  Zoom |
|  | Explain and describe the instruments        |
|  |
| [ ]  **5.4.2.4 Focus Group(s)9** [ ]  In person [ ]  Zoom |
|  | Explain and describe the instruments:        |
|  |  |
| [ ]  **5.4.2.5 Other** [ ]  In person [ ]  Zoom [ ]  Qualtrics [ ]  Other |
|  | Explain and describe the instruments       |
|  |

**Notes:**

8 *Attach a list of survey/interview questions with the application*

9 *Describe the instruments to be used in the observational study or to be used during focus groups*

10 All of the investigators MUST *complete “Internet Based Research” module under CITI SBR course*

**5.5 DATA ANALYSIS:** What is your plan for analyzing the data**? Include how any personal data, voice recordings, images and other types of identifiable artifacts collected from the participants will be used in the analysis.**

**Reviewers’ Comment on Data Collection & Analysis**

|  |  |
| --- | --- |
| Reviewer: The statement of purpose/hypothesis and the description of the methods including data acquisition plan are adequate. **Critique**:       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The data collection plan is CLEAR and all of the interactions are explained legibly and logically by selection of appropriate boxes. **Critique**:       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The data collection is done in a manner to protect the anonymity and welfare of the participants. **Critique**:       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The data analysis plan proposes to protect the anonymity and welfare of the participants. **Critique**:       | [ ] Yes [ ] No |
| PI Response:        |

Recommended changes to data collection or attached instruments [ ] NONE

|  |
| --- |
| Reviewer**: Recommended Changes:**            |
| PI Response:       |

**5.6 How will this design allow you to address the research question?**

* 1. **RESERVED – No response is needed**

* 1. **DEBRIEFING:** Describe how the participants will be debriefed; attach copies of debriefing statements

*NOTE: In addition to any debriefing materials, an electronic copy of the informed consent must be provided to the subjects if the study is conducted over the internet.*

**Debrieifing**

|  |  |
| --- | --- |
| Reviewer: The proposed debriefing process and script are adequate. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:       |

Recommended changes to the debriefing script [ ] NONE

|  |
| --- |
| Reviewer**: Recommended Changes:**            |
| PI Response:       |

* 1. **RISKS:** List the potential risks and discomforts to the participants

**Risk Estimation:**

[ ]  **Minimal Risk –***the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

[ ]  **More than minimal** – a slight increase in risk compared to the definition of minimal risk

[ ]  **Risk** – the subjects may experience reasonably foreseeable **risks** or discomforts

 *Definition: If evaluating a particular****risk****of research associated with a standard of care is a purpose of the research, then in general****OHRP****considers that particular****risk****to be “reasonably foreseeable (45 CFR 46.116(a)(2)).*

* 1. **BENEFITS:** List prospective benefits of conducting this research. Include direct benefits for participants, science, and society

**5.11 RISK to BENEFIT RATIO:** Evaluate the level of risk relative to the potential benefits.

**Reviewers’ Assessment of Risks/Benefits**

Note: Risks may include possible physical, psychological, economic, socil, and legal harms

|  |
| --- |
| Minimization of Risks:1. Reviewer’s description of how the risks to the subjects are minimized

      1. Are the procedures consistent with sound research design and not unnecessarily expose the subjects to risk? [ ] Yes [ ] No

If not, explain:       1. Are the procedures already being performed for diagnostic or treatment purposes? [ ] Yes [ ] No

If yes, explain:        |
| PI Response:        |

|  |  |
| --- | --- |
| Reviewer: The risks described in this application adequately cover all of the risks encountered in the study. **Critique**       | [ ] Yes [ ] No |
| PI Response:       |

|  |  |
| --- | --- |
| Reviewer: The risks to subjects are reasonable in relation to anticipated benefits, as well as, research purpose and setting. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |

|  |  |
| --- | --- |
| Reviewer: There are provisions to protect the rights and welfare of Vulnerable populations. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |

1. **PARTICIPANT DESCRIPTION and RECRUITMENT**

**6.1 Sample Size** (maximum number of participants):

**6.2 Participant Age** (minimum and maximum age group):

**6.3 Description**: Provide a simple description of who your ideal participant(s) would be:

Use separate lines to describe different types of participants to be used in this study

**6.4 Targeting more than one type of participants**: Explain multiple populations would be targeted (Example: parents & their minor children, teachers & their students, doctors & their patients, and etc.) and provide the numbers for each participant type below

**6.5 Participant population** (Select ALL that apply):

|  |  |
| --- | --- |
| Healthy Adults (18 years or older) [ ]  |  Minors (less than 18 years old) [ ]  |
| Adults (not included above) [ ]  |  Prisoners (COMPLETE APPENDIX A) [ ]  |
| MTSU Psychology Research Pool [ ]  (complete section 6.7)  |  Pregnant Women [ ]  Mentally Handicapped [ ]  |
| Amazon Turk Workers [ ]  |  Mentally Disabled [ ]  |
| Qualtrics panel [ ]  |  Physically Ill [ ]  |
| Senior Citizens (65 years or old [ ]  |  Disabled [ ]  |

 Vulnerable: *(financial, hierarchical, etc.)* [ ]

Describe:

 Other (Not listed above) [ ]

Describe:

*The following additional documents are mandatory when targeting special population:*

**Target population Additional Document Requirement**

Pregnant Women Additional Information Page (*Beta Testing*)

Prisoners Additional Information Page (*complete Form F022*)

Minors: Minimal Risk Educational Appendix B (*scroll down this form)*

Minors: Non-educational Research Additional Information Page *(complete Form F021*)

**6.6 Recruitment Scripts & Methods**

*Please visit* [*https://mtsu.edu/irb/FAQ/Recruitment.php*](https://mtsu.edu/irb/FAQ/Recruitment.php) *for more information on participant recruitment.*

***Select the type(s) of recruitment method to be used:***

[ ] IRB Flyer

[ ] IRB Recruitment Email14

[ ] Word of mouth14

[ ] Telephone14

 [ ] Regular Mail14

14Send separate transcripts for each type of recruitment selected above as a separate document. If contacting the participants by email or telephone or regular mail, explain how you originally obtained their contact information.

[ ] Web posting – Explain how the initial contact will be made and submit examples

[ ] Social media – EXPLAIN how the initial contact will be made and submit examples

[ ] OTHER

**6.7 How will participants be recruited and selected for this research?** Describe the recruitment steps starting from the initial contacts. Include compensation (inducement) to participants. Recruitment script(s) must be submitted with this application.

**Refer:** [**https://www.mtsu.edu/irb/FAQ/Recruitment.php**](https://www.mtsu.edu/irb/FAQ/Recruitment.php)

**Describe the recruitment steps:**

NOTE: If the participants are to be drawn from an institution or organization (e.g., hospital, social service agency, prison, school, etc.) which has the responsibility for the participants, then documentation of permission from that institution must be submitted before final approval can be given (<https://www.mtsu.edu/irb/FAQ/PermissionLetters.php>).

**6.8 Inclusion/Exclusion:** Provide a list of inclusion/exclusion criteria for the proposed research and justify any demographics (e.g. sex, race, economic status, sexual orientation) that have been excluded.

**Inclusions:**

**Exclusions:**

* 1. **Inducement and Compensation:** [ ]  NOT Applicable

Explain inducement plan for compensating the participants. Examples are: extra credit, cash, gift card, meals and etc. The inducement has to be fair and should not unfairly influence the decision of the participants. Provide a clear description of the mode of disbursement of the compensation and the requirements for when the compensation would be denied.

[ ] Monetary Compensation (complete Appendix J) [ ]  Compensation has no monetary value

NOTE: most types of monetary compensation used for inducement will require proper documentation for records keeping and IRS accounting. Refer to Appendix J for more information and standard language to be used in the informed consent.

**Assessment of Participant Selection**

|  |  |
| --- | --- |
| Reviewer: The selection of subjects is appropriate (e.g., inclusion/exclusion criteria) in relation to the research purposes and setting. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The recruitment process avoids the potential for undue influence or coercion. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The recruitment materials are appropriate. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |
| Reviewer: The compensation (method/amount) avoids the potential for undue influence or coercion. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |

Recommended changes to the recruitment materials [ ] NONE

|  |
| --- |
| **Recommended Changes:**            |
| PI Response:       |

* 1. **Recruit Psychology Research Pool (SONA):** [ ]  NOT Applicable

**Refer:** (http://mtsu.sona-systems.com/)

**Title:**

**Brief Abstract:**

**Full Description:**

Provide a title, a brief abstract (one or two sentences describing the project) and a full description (including the risks, benefits, and any information necessary for students to make an informed decision about participating). These should be written exactly as they will appear to the Research Pool participants.

* 1. **Recruiting Amazon Mechanical Turk workers** [ ]  NOT Applicable

Complete *MTurk Additional information Page* (Form F023 from <https://mtsu.edu/irb/forms.php>)

 **MTurk Additional Page is attached:** [ ]  NO (The protocol will not be reviewed) [ ]  Yes

* 1. **Enrolling Qualtrics Panel members as participants** [ ]  NOT Applicable

Complete *Qualtrics Panel Additional Information Page* (Form F023b from <https://mtsu.edu/irb/forms.php>)

 **Qualtrics Panel Additional Page is attached:** [ ]  NO (will not be reviewed) [ ]  Yes

**Assessment of Participant Selection from MTurk/Qualtrics Panel**

|  |  |
| --- | --- |
| Reviewer: The selection of subjects is appropriate (e.g., inclusion/exclusion criteria) in relation to the research purposes and setting. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The recruitment process avoids the potential for undue influence or coercion. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| Reviewer: The recruitment materials are appropriate. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |
| Reviewer: The compensation (method/amount) avoids the potential for undue influence or coercion. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |

Recommended changes to the recruitment materials [ ] NONE

|  |
| --- |
| **Recommended Changes:**            |
| PI Response:       |

1. **CONFIDENTIALITY**

**7.1 Personal Information:** Select ALL those apply from the following list of identifying information (but not limited to) that will be recorded from your research participants.

|  |  |
| --- | --- |
| [ ]  Full name [ ]  Identification numbers (SSN, etc.)[ ]  Telephone number[ ]  Street address[ ]  E-mail address[ ]  IP address [ ]  Health records[ ]  Simple demographics[ ]  Criminal/probation records[ ]  Academic performance records | [ ]  Photographs [ ]  video recordings[ ]  Voice recordings[ ]  Handwriting samples[ ]  Digital/online/social media Identity[ ]  Financial details [ ]  Driver's license/vehicle registration[ ]  Genetic/DNA/Dental information etc.[ ]  Detailed demographics[ ]  Employee records |
| [ ]  Other – Explain  |

The above personal information are collected as research data [ ]  Yes [ ]  No

The above personal information are collected for administrative purposes [ ]  Yes [ ]  No

Provide additional explanation if needed:

**7.2 JUSTIFICATION -** Provide a justification for why each type of information listed above is necessary for this study and also explain how that information will be protected/destroyed

**7.3 DATA STORAGE -** Where will research materials be stored? If anywhere other than an MTSU faculty researcher’s office, please describe why the faculty researcher’s office is not secure; include an address where data will be stored.

***Mandatory Data Storage Requirements:***

* All Study related records (documentation of informed consent, surveys, study notes, data records, and all correspondence) be stored securely for **at least 3 years** after data collection ends.
* Additionally, the Tennessee State data retention requirement may apply (*refer MTSU Policy 129:*  <https://www.mtsu.edu/policies/general/129.php>).
* Records must be stored securely in a faculty member’s office on campus for 3 years. (Or another secure location if there is reason to believe the faculty member’s office is not secure. These arrangements must be approved).
* Subsequently, the data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.
* **Assessment of Subject Protection**

|  |  |
| --- | --- |
| The study proposes the following safety monitoring:       | [ ] N/A |
| The investigator must implement these safety monitoring provisions:       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |
| This proposal makes adequate provision to maintain the confidentiality of data. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |

**7.4 List anyone other than the Investigators mentioned in page 1 who will have direct access to the research participants or their primary data.** Consider research assistants, transcribers, statisticians, and others who may be present during the research or have access to the data records. These individuals must also submit Human Subjects Training Certificates.

1. **INFORMED CONSENT**
* Adult participants only; Use Appendix B for describing the consent process involving minors
* Refer <https://www.mtsu.edu/irb/FAQ/ConsentAndAssent.php> for more information

**8.1 Will informed consent be obtained from the participants?**

 [ ]  Yes

[ ]  NO complete Appendix G with justification for add supporting documents

**Consent waiver is permitted only in rare conditions.**

**8.2 Will you collect signed consent forms?**

 [ ]  Yes

[ ]  NO complete Appendix G with justification for why signature is not collected

**Each participant must be provided with a copy of the informed consent signed by the PI/FA regardless if participant signatures are collected or not.**

**8.3 Will you obtain consent verbally?**

 [ ]  Yes complete Appendix G with justification for verbal consent

 [ ]  NO

Each participant must be provided with a copy of the informed consent signed by the PI/FA regardless if participant signatures are collected or not.

**8.4 Will you administer the informed consent by VIRTUAL/ONLINE methods?**

[ ]  NONE – The informed consent will be administered in person

[ ]  Virtual (Zoom): **Complete Appendix G** (Section G.6)

[ ]  Telephone Interview: **Complete Appendix G** (Section G.6)

[ ]  Online using Qualtrics: minimal risk studies only: Complete Appendix G (Section G.5) with explanation

 ***Paste the Qualtrics link for the proposed online study here:***

Refer <https://mtsu.edu/irb/FAQ/OnlineDataCollection.php> for more information*.*

**Reviewer’s Assessment of Documentation of Informed Consent**

|  |
| --- |
| The PI requests:1. [ ]  SIGNED informed consent with participant name and age
2. [ ]  ANONYMOUS informed consent with participant signature and age
3. [ ]  VERBAL consent with age
4. [ ]  ONLINE informed consent with age-verification

Reviewer’s Comments       1. [ ]  Alteration of informed consent (Details in Appendix G)

Reviewer’s Comments       1. [ ] Waiver of informed consent

Reviewer’s Comments       1. Is the chosen process and documentation of consent appropriate for this study? [ ] Yes [ ] No

Add Remarks if NO and instruct what type of informed consent must be used in this study: Reviewer’s Recommendation:        |
| PI Response:        |

* 1. **Will the participants receive compensation/inducement for enrolling?**

[ ]  NO

 [ ]  Yes Explain:

[ ] The compensation has monetary value – **Complete Appendix J**

*.*

**8.6 Give a description of your consent “process”. Include who is administering the consent information, where is it obtained, how is it administered and etc.?**

Use Section 5.6 to describe the consent process when involving ADULT participants. When enrolling **minors**, use **Appendix B** for explaining **parental consent and child assent**.

**8.7 MANDATORY Informed Consent Elements Check List:**

Select “yes”if the element appears in your consent document, if it does not check “no”. If you check no to any item you must complete the request for waiver of consent. See Appendix G.

|  |  |
| --- | --- |
| A statement that the study involves research and the true purpose of the research (If using deceit, check no and justify in Appendix G). | Yes [ ]  NO [ ]   |
| A description of all the procedures in detail to be followed and the expected duration | Yes [ ]  NO [ ]   |
| Foreseeable risks or discomforts to the participant | Yes [ ]  NO [ ]   |
| Benefits to the participant or others (NOT COMPENSATION) | Yes [ ]  NO [ ]   |
| Disclosure of appropriate alternative procedures or courses of treatment N/A [ ]   | Yes [ ]  NO [ ]   |
| A statement describing the extent of confidentiality of records identifying the subject will be maintained | Yes [ ]  NO [ ]   |
| Explanation for compensation (inducement) for participation (not listed under the benefits section) along with any requirements and qualifications for receiving the proposed compensation | Yes [ ]  NO [ ]   |
| A statement regarding compensation to participants in case of injury | Yes [ ]  NO [ ]   |
| Contact information for the researcher and the Compliance Officer | Yes [ ]  NO [ ]   |
| A statement that participation is voluntary, there are no penalties for refusal to participate, and participation can be discontinued at will without loss of benefits. | Yes [ ]  NO [ ]  |

**Reviewer’s Assessment of the Informed Consent process**

|  |  |
| --- | --- |
| The proposed plan to administer informed consent is appropriate. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The study procedures in this application match the submitted informed consent. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The online informed consent reflects the consent document presented for this review. **Critique**       | [ ] Yes [ ] No [ ] N/A |
| PI Response:        |
| The risks described in the application are consistent with the consent document or online/verbal consent script. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |

Recommended changes to the informed consent template [ ] NONE

|  |
| --- |
| **Recommended Changes:**            |
| PI Response:       |

1. **TRAINING and EXPERTISE**

**This application WILL NOT be reviewed if training is incomplete**

**9.1 Will this research involve specialized procedures or methods that will require specific training or expertise?**

[ ]  NO

[ ]  YES Explain:

**9.2 Provide a list of qualifications possessed by the investigating team to address any potential challenges during this study.**

**9.3 CITI Training** *The following CITI course(s) and modules are mandatory. Review your CITI training certificate and check boxes for all those modules that have been completed by the entire research team.*

* The entire investigating team must complete “Social and Behavioral Research” basic course
* Students must also complete “Students in Research” module in addition
* Study-specific and participant-specific modules/training must also be completed
* [**Click here**](http://www.mtsu.edu/irb/requirements.php) **or visit** [**http://www.mtsu.edu/irb/requirements.php**](http://www.mtsu.edu/irb/requirements.php) **to learn more**

|  |
| --- |
| [ ]  Social & Behavioral Research (SBR) |
| Modules for All Researchers | Modules required based on researcher status and the study |
|  [ ]  Belmont Report and CITI … (ID: 1127) [ ]  History and Ethical Principles - SBE (ID: 490)  [ ]  Defining Research ….. - SBE (ID: 491)  [ ]  The Federal Regulations - SBE (ID: 502) [ ]  Assessing Risk - SBE (ID: 503) [ ]  Informed Consent - SBE (ID: 504) [ ]  Privacy and Confidentiality - SBE (ID: 505) [ ]  Conflicts of Interest in …. (ID: 488) [ ]  MTSU Module DEMO (ID 1073) | [ ]  Students in Research (ID 1321) **MANDATORY FOR STUDENTS**[ ]  Research with Prisoners – SBE (ID: 506)[ ]  Research with children – SBE (ID 507)[ ]  Research in Public ….. Schools – SBE (ID 508)[ ]  International Research – SBE (ID 509)[ ]  International Studies (ID 971)[ ]  Internet-based research – SBE (ID 510)[ ]  Research and HIPAA …. (ID 14)[ ]  Research on Workers/Employees (ID 483)[ ]  Hot Topics (ID 487)[ ]  IRB Member module (ID 816) [ ]  IRB Administrators …. (ID 13813) |
| [ ]  Health Information Privacy & Security (HIPS) Course – ***Required when collecting protected physical or psychological health information*** |
| [ ]  Click and provide additional qualifications, training and certificiation |
| [ ]  Click and provide additional qualifications, training and certificiation |

**Investigators’ Qualifications**

|  |  |
| --- | --- |
| Reviewer: Study personnel appear appropriate and qualified. **Critique**       | [ ] Yes [ ] No |
| PI Response:       |

# APPLICATION CHECKLIST

**10.1 Check List:** To be completed by the PI Please READ and INITIAL each item. Incomplete applications will NOT be prescreened.

[ ]  The application is complete

[ ]  Faculty Advisor information and signature included if the PI is a student

[ ]  CITI certificates attached

[ ]  Participant information and methods to enroll is provided

[ ]  Recruitment materials/scripts for enrolling participants is/are attached

[ ]  Signup information for Psychology Department Research Pool (if applicable) is provided

[ ]  Consent template(s) for all types of proposed data collection methods is/are included

[ ]  Alteration to consent process or changes to the standard consent template are justified

[ ]  Surveys, questionnaires, tests, interview forms/scripts attached – include a PDF of the entire survey if the study is being administered via Qualtrics

[ ]  Qualtrics link(s) for studies conducted online is/are provided

[ ]  Appendix section(s) for additional methods are completed

[ ]  Permission letters on official letterhead for conducting research at non-MTSU sites

[ ]  Other:

**10.2 Additional Procedural Information**

Indicate below whether this study involves additional procedures listed below. Be sure to complete the selected appendices below the signature section

 **Appendix Additional Procedure Information**

 [ ]  COVID-19 Risk for COVID-19 infection

 [ ]  A Risk

 [ ]  B Minors as Participants

 [ ]  C Psychological Intervention

[ ]  D Deception

[ ]  E Physiological Intervention

[ ]  F Biomedical Procedures & Biospecimen

[ ]  G Changes to Informed Consent

[ ]  J Monetary compensation for participation

[ ]  K Physical interaction (intervention/assessment & other)

[ ]  L Analysis of existing data not eligible for exemption

1. **DECLARATION**

**Sign by entering your name in the fields below. Student PI’s MUST enter their name by logging into their MTSU account. Although not mandatory, faculty researchers and advisors are encouraged to enter their name by logging to their MTSU account.**

* 1. **PI Signature:**

I certify by entering my name below that:

1) the information provided for this project is accurate;

2) no other procedures will be used in this project;

3) any modifications in this project will be submitted for approval prior to use; AND

4) I have read and fully understand my responsibilities as the PI (<https://www.mtsu.edu/irb/FAQ/ResponsibilitiesOfPI.php>)

|  |  |
| --- | --- |
|  | **mm/dd/yyyy** |
| **\*Name of the Investigator (PI)** | **Date** |

Enter your full name

**11.2 Faculty Advisor** (if the PI is a student)

 By entering my name below I certify that this project is under my direct supervision and that I am responsible for insuring that all provisions of approval are complied with by the investigator.

|  |  |
| --- | --- |
|  | **mm/dd/yyyy** |
| **Name of the Faculty Advisor (FA)\*\*** | **Date** |

Enter your full name and date

**--------------------------------------------------------------**

**APPENDIX SECTION – ADDITIONAL PROCEDURAL INFORMATION**

* Complete only those apply to your research

**APPENDIX COVID-19**

**MANDATORY if the investigators will have direct physical contact with the participants**

Complete this Appendix if human subjects participating in this proposed research project may be directly in physical contact with the investigator(s)

1. Identify how and where the participant faces the potential risk for COVID-19 exposure

1. JUSTIFICATION. Explain why you believe the potential exposure to COVID-19 to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept the risks. Discuss the alternative ways of conducting this research and why the one chosen is superior.

1. Will all the investigators who come in contact with the participants be fully vaccinated?

1. Will all the participants be fully vaccinated against COVID-19?

1. Describe how you plan to minimize the risk for viral infection

1. What steps do you plan to take prior to the physical interaction?

1. What is your strategy to screen for health condition of the investigator(s) on the day of the prospective research interaction?

1. What is your strategy survey the participants for potential infection?

1. What steps do you plan take in the event an investigator or a participant should test positive for COVID-19?

---------- End of Appendix COVID-19 ----------

**APPENDIX A**

**SUBJECTS AT RISK MANDATORY if the participants are prisoners**

Complete this Appendix if human subjects participating in this proposed research project may be exposed to higher probability of harm, including physiological, psychological, economic, or social harm.

1. Identify and describe the probable RISKS, including physiological, psychological, economical, or social harm, to which subjects involved in the proposed research project may be exposed.

1. JUSTIFICATION. Explain why you believe the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks. Discuss the alternative ways of conducting this research and why the one chosen is superior.

1. Explain fully how the RIGHTS AND WELFARE of such subjects at risk will be protected. (e.g., equipment closely monitored, medical examination given prior to procedures, psychological screening of prospective subjects, etc.)

---------- End of Appendix A (Risk) ----------

**APPENDIX B**

 **RESEARCH INVOLVING MINORS AS SUBJECTS**

**Refer to** [**https://www.mtsu.edu/irb/FAQ/WorkinWithMinors.php**](https://www.mtsu.edu/irb/FAQ/WorkinWithMinors.php)

If some or all of the subjects of the proposed research will be minors (under the age of 18), please provide the information requested in the following items. Additional supporting documents and IRB templates will be needed depending on the proposed study.

**CITI Training Requirements:**

1. Complete the “Social and Behavioral Research” (SBR) main course
2. Student researchers must complete “Students in Research” SBR supplemental module.
3. All of the researchers must complete
4. *Research with Children;* and
5. *Research in Public Elementary and Secondary Schools* SBR supplemental modules.

.

**Research Type Selection:**

 [ ]  Education/Behavioral Research that involve minimal risk – Complete this Appendix

[ ]  Non-Education/Interventional Research – Complete this Appendix AND complete Minors Additional Information Page ([www.mtsu.edu/irb](http://www.mtsu.edu/irb) and click IRB forms

**Description of minor-specific interactions:**

1. COVID-19:

|  |  |  |
| --- | --- | --- |
| a. | Does the research plan involve direct interaction with the minors?Skip 1b-d if you selected NO; Complete 1b if you said Yes | [ ] Yes [ ] No |
| b. | Will this interaction happen in a designated site like a school or a center? | [ ] Yes [ ] No |
| c. | If yes to 1b, does the school or center has its own COVID-19 management plan, that includes safe practices and contact tracing? | [ ] Yes [ ] No |
| d. | If you said no to 1b, provide a description of how you plan to protect the minors from potential COVID-19 exposure. Describe plans on how you plan to inform parents and others should a child or anyone who came in contact with the children should test positive for COVID-19 | [ ] Yes [ ] No |
|  |       |

1. PARENTAL CONSENT: Specify how parental permission will be obtained and documented with a description of a how the parents will be approached initially and the signed consent forms would be returned.

Attach copies of all recruitment letters, notices and parental consent forms. There are age-specific differences in the parental consent templates. Use the right forms to avoid delays

1. CHILD ASSENT: Specify provisions for soliciting the assent of minor subjects by describing how child assent will be administered:

**The child assent must be administered independently by one of the investigators with no influence of the parents unless determined otherwise by the IRB**

* 1. **Provide additional details on verbal assent:**

Attach copies of assent forms or script of oral permission.There are age-specific differences in the parental consent templates. Use the right forms to avoid delays

1. COERCION: Specify provisions for minimizing coercion on minors to participate.

1. RESEARCH SITES: List all of the research sites (schools, museums, public places, and etc.) in which the research will be conducted:

Submit documentation of PERMISSION from research site. For instance, school district(s) to conduct the research. Letters of permission from Principal and Superintendent on letterhead are required. (NOTE - Provisional approval can be given pending receipt of documentation from school districts, but research cannot be conducted until such documentation is received)

1. BUCKLEY AMENDMENT: Where necessary, specify procedures for complying with the “Buckley Amendment” (Students’, or parents if students are under 18 years of age, rights to inspect and review their educational records).

1. Document Attachments:
	1. The following training courses/modules have been completed:

 [ ] Social and Behavioral Research Basic Course

 [ ] Students in Research (for student investigators)

 [ ] Research with Children

 [ ] Research in Public Elementary and Secondary Schools

 [ ] The investigating team has the following additional qualifications/expertise to do this project:

* 1. The following forms are attached:

 [ ] Parental Consent (12 years or older)

 [ ] Parental Consent (less than 12 years)

 [ ] Child Assent (less than 12 years)

 [ ] Child Assent (12 years or older)

 [ ] Combined Parental Consent and Child assent forms for 12 years or older

 [ ] Minors Additional Information Page

**Process and Documentation of Parental Consent**

|  |
| --- |
| 1. [ ] Written parental consent

Explain       1. [ ] Alteration of parental consent is requested

Explain:       1. [ ] Waiver of parental consent is requested

Explain:       1. Is the chosen process and documentation of consent appropriate for this study? [ ] Yes [ ] No

Add Remarks:        |
| PI Response:        |

|  |  |
| --- | --- |
| The mechanism proposed in this Appendix for seeking parental cosent is acceptable. . **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The study procedures in this application adequately match the attached parental consent. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The risks described in the application are consistent with the consent document or online/verbal consent script. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |

**Recommended changes to the parental consent template [ ] NONE**

|  |
| --- |
| **Recommended Changes:**        |
| PI Response:       |

**Process and Documentation of Child Assent**

|  |
| --- |
| 1. [ ] Written child assent
2. [ ] Verbal child assent

Explain       1. [ ] Alteration of child assent requested

Explain:       1. [ ] Waiver of child assent is requested

Explain:       1. Is the chosen process and documentation of assent appropriate for this study? [ ] Yes [ ] No

Add Remarks:        |
| PI Response: NC  |

|  |  |
| --- | --- |
| The mechanism proposed in this Appendix for soliciting child assent acceptable. . **Critique**       | [ ] Yes [ ] No |
| PI Response:        |
| The study procedures in this application adequately match the attached assent. **Critique**  | [ ] Yes [ ] No |
| PI Response:        |
| The risks described in the application are consistent with the assent document or online/verbal assent script. **Critique**       | [ ] Yes [ ] No |
| PI Response:        |

**Recommended changes to the child assent**

|  |
| --- |
| **Recommended Changes:**        |
| PI Response:       |

---------- End of Appendix B (Minors in Education Research) ----------

**APPENDIX C**

**RESEARCH INVOLVING PSYCHOLOGICAL INTERVENTION**

If the subject(s) of the proposed research will be exposed to any psychological intervention such as contrived social situations, manipulation of the subject’s attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences, please provide the information requested in the following items:

* 1. Identify and describe in detail the PSYCHOLOGICAL INTERVENTION.

* 1. Identify and describe in detail the BEHAVIOR expected of subject(s) and the context of the behavior during the psychological intervention.

* 1. Describe how DATA resulting from this procedure will be gathered and recorded.

* 1. Identify anticipated and possible psychological, physiological, or social CONSEQUENCES of this procedure for the subject(s).

* 1. Indicate the investigator’s competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Given name, title, department, address, and telephone number of the individual(s) who will supervise this procedure.

---------- End of Appendix C (Psychological Intervention) ----------

**APPENDIX D**

**DECEPTION**

A study is deceptive if false information is given to subjects, false impressions created, or information relating to the subjects’ participation is withheld that might result in adverse effects on subjects.

* 1. Describe in detail the DECEPTION involved, including any instructions to subjects or false impressions created.

* 1. JUSTIFICATION. Explain in detail why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator.

* 1. Describe, in detail, the plan for DEBRIEFING subjects. Attach a copy of any debriefing statement.

---------- End of Appendix D (Deception) ----------

**APPENDIX E**

**RESEARCH INVOLVING PHYSIOLOGICAL INTERVENTION**

If the subject(s) of the proposed research will be exposed to any physiological treatments or intervention upon the body by mechanical, electronic, chemical, biological or any other means, please provide the information requested in the following items:

1. Identify and describe in detail the PHYSIOLOGICAL INTERVENTION.

1. Identify and describe in detail the MEANS used to administer the intervention.

1. Identify and describe in detail the BEHAVIOR expected of subject(s) and the behavior of the investigator during the administration of the physiological intervention.

1. Describe how DATA resulting from this procedure will be gathered and recorded.

1. Identify anticipated and possible physiological, psychological, or social CONSEQUENCES of his procedure for the subject(s).

1. Indicate in detail specific steps that will be taken to assure the proper OPERATION AND MAINTENANCE of the means used to administer the intervention. Give particular attention to prevention of accidental harm or injury to the human subject(s).

1. Indicate the investigator’s competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Give name, title department, address, and telephone number of the individual(s) who will supervise this procedure.

---------- End of Appendix E (Physiological Intervention) ----------

**APPENDIX F**

**BIOMEDICAL PROCEDURES**

If the proposed research involves biomedical procedures (e.g., the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision), please provide the information requested in the following items.

**Select the relevant options:**

 [ ]  Collection of new specimen/samples – Complete F.1 below

 [ ]  Analysis of biospecimen collected by IRB-approved protocol – Complete F.2 below

 [ ]  Analysis of biospecimen collected for non-research purpose – Complete F.3 below

[ ]  Check here to request this hidden section to be displayed

**F.1: Collection of new specimen/samples:**

* 1. Describe in detail the biomedical PROCEDURES involved in this project.
	2. dentify anticipated and possible physiological CONSEQUENCES of these procedures of the subject(s).
	3. **I**dentify the SITE where the procedure is to be carried out.
	4. Indicate the investigator’s competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Give name, title, department, and telephone number of the individual(s) who will supervise this procedure.

**F.2: Analysis of biological specimen collected through an IRB-approved protoc**

* 1. *Describe the Biological samples:*

* 1. *IRB DETAILS: Provide the IRB information on how the bio-specimen was originall collected:*

* 1. *INFORMED CONSENT: Explain if the participants consented for subsequent secondary studies:*

* 1. *PROPOSED METHODS: Explain all of the methods to be used for analyzing the bio-specimen:*

* 1. *AMENNT TO RESEARCH: Explain if the specimens are used for a different research:*

* 1. *SPECIMEN IDENTITY: Describe the reasons why the bio-specimen may be “re-identified”:*

**F.3: Analysis of Biospecimen collected non-research purpose**

1. Describe the biological samples to be tested/studied:

1. Describe in detail the biomedical PROCEDURES used to collect them.

1. Describe the originally intended purpose for collecting and storing the samples

1. Describe why IRB approval was not obtained.

1. Outline any informed consent process used in the collection and storage of the samples:

1. *SPECIMEN IDENTITY: Describe the reasons why the bio-specimen may be “re-identified”:*

---------- End of Appendix F (Biomedical Research) ----------

**APPENDIX G**

**REQUEST FOR ALTERNATIVE CONSENT PROCESS**

Starting from AY 2021, this appendix will be used to provide additional details on various types of consent processes and their documentation. Please complete this appendix if you do not plan to obtain traditional in person informed consent with participant signature.

Under 45 CFR 46.116(d) the IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that all of the following four criteria are met:

1. the research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration;
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**G.0 Type of changes to informed consent:**

[ ]  Web-based informed consent using Qualtrics – Complete G.5

[ ]  Zoom or Telephone interviews – Complete G.6

[ ]  Other – Continue to G.1

**G.1 Are you requesting a waiver of obtaining informed consent?** (i.e., you will not obtain informed consent at all. e.g., observational study and informing participants that they are in a research study would make the research impossible.)

[ ]  Yes [ ] NO

Explain if Yes:

**G.2 Are you requesting that physically signed consent forms are not obtained?** (e.g., you are conducting research online and cannot obtain signatures; you wish to not obtain signatures to protect the participants, etc)

[ ]  Yes [ ] NO

Explain if Yes:

**G.3 Are you requesting approval to alter the consent form such that not all the required elements of consent are included?** (i.e., you checked “no” to some elements in the checkbox for informed consent)

[ ]  Yes [ ] NO

Which elements from the informed consent are you seeking to alter or remove?

**G.4 If you answered yes to G.1 through G.3, then complete this link:**

1. How does the research involve no more than minimal risk?

1. How will a waiver of informed consent not adversely affect the rights and welfare of the participants?

1. Why could the research not practicably be carried out without the waiver or alteration?

1. If appropriate, how will subjects be provided with additional pertinent information after participation?

**G.5 Online informed consent:**

Refer <https://mtsu.edu/irb/FAQ/OnlineDataCollection.php>

Describe the process administering informed consent starting with how the participants will access the Qualtrics:

***Qualtrics data collection – Mandatory consent requirements:***

* *All exclusion inclusion criteria must be clearly disclosed prior to the consent*
* *The first page of the study must be the informed consent form*
* *Consent to participate must be explicitly asked and separate responses must be entertained by clearly indicated boxes to accept or deny*
* *An age-verification question with an active response must be added*
* *The text for informed consent should be provided to the participant as part of debriefing or a follow up email whichever is approved by the IRB*

Visit [www.mtsu.edu/irb](http://www.mtsu.edu/irb) and click on IRB Forms to download one of the informed consent templates meant for online administration. Based on your which form you downloaded, make a selection below:

[ ]  Locked online consent template is used

[ ]  Unlocked free format online consent template is used

The Qualtrics link for administering informed consent provided for IRB review AFTER the link has been tested by the PI. Use the following check list to test the Q

***Test the online consent before completing this check list***

|  |  |
| --- | --- |
| [ ]  Yes | The protocol ID, study title, name of PI and faculty advisor (if applicable) and space for approval/expiration dates are provided legibly. |
| [ ]  Yes | All inclusion and exclusion requirements are clearly stated and additional click box items are added if necessary |
| [ ]  Yes[ ]  N/A | Compensation information and adequate disclosure for eligibility are clearly stated and additional click boxes are inserted if necessary |
| [ ]  Yes | Contact details for the researchers and the office compliance are provided |
| [ ]  Yes | Consent to participant is entertained by two distinct responses |
| [ ]  Yes | Age verification of the participant is also done as in the consent question above |
| [ ]  Yes | The survey will not begin unless all necessary boxes are clicked |
| [ ]  Yes | If a participant fails to consent or ignores one or more of the clickable boxes, then one of the following action is done:[ ]  The survey ends and the participant is directed to a “Thank You” page[ ]  A good faith reminder is given and the survey will move to debriefing if the participant continues to not click the mandatory boxes |
| [ ]  Yes | The survey has been administered to someone who is not familiar with the study. The person who took and tested the survey is:      (***enter the full name of the person***) and this person found that the time duration for completing the entire survey is compatible with what is displayed in the consent script.  |
| [ ] Yes | The consent script displayed online is identical to the consent document submitted for IRB review (minor formatting/font changes are allowed) |

**G.6 Interview by Telephone or Zoom:**

 **Instruction:**

1. *Zoom Interview:*

The participants will receive a copy of the informed consent via email. S/he will physically sign and send a scan back to the investigator. Or, the participant will simply write a response text indicating s/he is interested in the study. The PI will go ahead and arrange the zoom meeting. Prior to the interview, the PI will refresh the participant with the important steps of the study and ensure the participant read the informed consent script sent by email. The PI will then document the informed consent process and store in his/her records.

1. Telephone Interview:

*Similar to the Zoom informed consent described above. The participants will receive a copy of the informed consent via email. S/he will physically sign and send a scan back to the investigator. Or, the participant will simply write a response text indicating s/he is interested in the study. The PI will go ahead and arrange the telephone interview. Prior to the interview, the PI will refresh the participant with the important steps of the study and ensure the participant read the informed consent script sent by email. The PI will then document the informed consent process and store in his/her records. The main difference between the Zoom and telephone informed consent is that the latter would be much shorter*

 **Description:**

1. Have you read and understand the instructions above?

1. Do you plan to make any changes to the informed consent process and documentation from what is described above?

1. How will a consent through Zoom or a telephone call not adversely affect the rights and welfare of the participants?

1. If appropriate, how will subjects be provided with additional pertinent information after participation?

---------- End of Appendix G (Informed Consent) ----------

**APPENDIX J**

**MONETARY COMPENSATION**

MTSU Business Office (BO) requires that all MTSU funds are adequately accounted to comply federal and state finance laws. But the researchers are also required to protect participant anonymity. Since both federal/state laws must be followed, the MTSU IRB and the BO have an arrangement to document monetary disbursement of funds without compromising participant identity.

***Mandatory Compensation Disclosures:***

* *All of the eligibility requirements to receive the compensation must be clearly disclosed in the informed consent as well as in the recruitment script*
* *The participants must be awarded the promised compensation or a portion of once they enroll; they are not required to complete the tasks to the satisfaction of the investigators*
* *If funds for the compensation are disbursed through the MTSU Business Office, then documentation requirement for receipt of compensation, such as obtaining W9 forms. This must also be clearly disclosed in the informed consent as well as the recruitment scripts*

***J.1 Inducement Details***

1. MTSU funds disbursed by MTSU Business Office are used OR this project is being funded by an agency/entity that requires the participants to produce a receipt for reporting purposes:

[ ]  NO – Jump to Section J.5

[ ]  Yes- Continue to step 2 below

1. Total compensation per participant for the entire study:
2. Compensation for each trial per participant:
3. Disbursement method:

[ ] Gift card [ ] Check [ ] Cash [ ] Direct Deposit

[ ] Other Explain:

***J.2 Record keeping & Reporting***

Make selections below to evaluate what type of record keeping is necessary:

1. The inducement per trial (line 2 above) is less than $70 [ ] Yes [ ] NO
2. The inducement per year (line 1 above) is less than $600 [ ] Yes [ ] NO
3. If selected YES for (i) AND (ii), then document the following:
	* Gift card/Check or other Transaction Number
	* Date of Issue
	* Amount disbursed
	* Participant Signature

The Informed Consent must include the following disclosure in the compensation section:

“*The participants receiving compensation will be asked to sign a receipt along with the date, amount received, and any reference ID of the money received (such as gift card number). This receipt will be sent to the University’s Business Office for accounting purposes only. Participants who are non-US citizens who do not have a Permanent Resident status would be asked to provide additional documentation. The study details or the participant responses will not be released at any cost.”*

1. If selected NO for (i) and YES for (ii), then document the following:
	* All of the particulars from A above
	* Full name (if the IRB approval notice clearly allows this)

The Informed Consent must include the following dislocure in the compensation section:

The Informed Consent must include the following disclosure in the compensation section:

“*The participants receiving compensation will be asked to sign a receipt along with their full name, date, amount received, and any reference ID of the money received (such as gift card number). Additional documentation may be asked if necessary. This receipt will be sent to the University’s Business Office for accounting purposes only. Non-US citizens and individuals who are not lawful permanent residents will be asked to submit more documents. The study details or the participant responses will not be released at any cost.”*

1. If selected NO to (ii), then document the following for each participant.
	* All of the particulars from A and B above.
	* Obtain participant’s W9 form

The Informed Consent must include the following disclosure in the compensation section:

“*The participants receiving compensation will be asked to submit a filled W9 signed by the participant.*

*This W9 will be sent to the University’s Business Office for accounting purposes only. Non-US citizens and individuals who are not lawful permanent residents will be asked to submit more documents. The study details or the participant responses will not be released at any cost.”*

* **The compensation dispatch record must not contain any other identification on the protocol in which the participant enrolled.**
* **Do not make copies of the records. Store the records in a safe place and deliver them to the Business Office in a timely manner.**

***J.4 Acknowledgement***

By entering my name below, I acknowledge that I have read these instructions listed above and I will maintain records of the inducement in a manner such that the participant anonymity is maintained.

|  |  |
| --- | --- |
| PI:       | Faculty Advisor:       |
| Date:       | Date:       |

Please skip J.5 if you completed rest of the sections above (J.1 through J.4)

***J.5 Documentation Waiver***

*Complete this if MTSU funds will NOT be used to pay for the participant compensation*

By entering my name below, I affirm that MTSU funds are not used to pay for research compensation. I am aware that no records of participants must be retained and any identifiable information must be destroyed.

|  |  |
| --- | --- |
| PI:       | Faculty Advisor:       |
| Date:       | Date:       |

---------- End of Appendix J (Participant Compensation) ----------

**APPENDIX K**

**PHYSICAL INTERACTON/INTERVENTION or ASSESSMENT**

If the subject(s) of the proposed research will be exposed to any physical activities that may include an intervention or assessment or even just an interaction, such as contrived social situations, manipulation of the subject’s attitudes, opinions or self-esteem, psychotherapeutic procedures, or other physical influences, physical exercise, measurements and etc., please provide the information requested in the following items:

1. Identify and describe in detail the PHYSICAL activity.

*Select all applicable physical activities:*

[ ] Intervention [ ] Assessment [ ]  Active Interaction [ ]  Passive Interaction

[ ] Involves Physical Movement (such as exercise or stepping on a scale)

[ ] Other

1. Identify and describe in detail the BEHAVIOR expected of subject(s) and the context of the behavior during the above identified activity.
2. Describe how DATA resulting from this procedure will be gathered and recorded.
3. Identify anticipated and possible psychological, physiological, or social CONSEQUENCES of this procedure for the subject(s).
4. Indicate the investigator’s competence and identify his/her QUALIFICATIONS, by training and experience, to conduct this procedure. Given name, title, department, address, and telephone number of the individual(s) who will supervise this procedure.

---------- End of Appendix K (Physical Intervention) ----------

**APPENDIX L**

**RESEARCH INVOLVING ANALYSIS OF EXISTING DATA**

* *Definition:* “Existing Data” corresponds to the generalizable information generated or collected from living individuals either through an IRB protocol or recorded for non-research purpose.
* *Data Release:* If the existing data are not publicly available, a **Data Release Certification** may be needed from the original owner of the data in order to obtain IRB approval

**Select all types of “existing data” to be used:**

[ ]  Collected through a protocol previously approved by an IRB – Provide previous IRB details and be prepared to submit additional documents if directed by the IRB:

[ ] Literature data/Public records- May qualify for an “exclusion” from IRB oversight

[ ] Student records – Knowledge and expertise in FERPA regulations is mandatory

[ ] Personal information - Complete *“Research and HIPPA …”*

[ ] Health records - Complete “Health Information Privacy and Security” training through CITI

[ ] Employee information – Complete *“Research and HIPPA …”* and *“Research involving workers”*

[ ] Proprietary information – Data release agreement mandatory

[ ] Data collected from MINORS

[ ] Data collected from PREGNANT WOMEN

[ ] Data collected from PRISONERS

[ ] Audio data

[ ] Video data

[ ] Digital images

[ ] Sensitive data

[ ]  OTHER

**Explain all of the selected types of data in detail and describe how they were originally collected** (in separate paragraphs)**:**

---------- End of Appendix L (Existing data/materials) ----------