**MIDDLE TENNESSEE STATE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**IRBF001 - HUMAN PARTICIPANTS RESEARCH REVIEW FORM**

***Instructions:***

* Visit <http://www.mtsu.edu/irb/requirements.php> and complete appropriate training
* Use Microsoft Office to complete this form; DO NOT use online utilities as they will break the formatting and remove the embedded macros
* Submit completed form along with all supporting documents to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu)
* Student researcher must have the IRB documents submitted by their research advisor
* **Do not begin your Research until you have received a formal letter of IRB approval!**

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

Request for Expedited Review  Request for Full Review

* 1. **Project Title**

**<type here>**

* 1. **Principal Investigator (PI)** Faculty/Staff Graduate Undergraduate Other

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  | | |
| Email |  | **Telephone** | XXX-XXX-XXXX |
| Alternate Email | \*if PI is a student | | |
| Department/Unit | College | | |
| Contact Address |  | | |
| CITI Program ID |  | | |

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

* 1. **Faculty Advisor (FA) if PI is a student:** Refer <https://www.mtsu.edu/irb/FAQ/Faculty.php>

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

If the principal investigator is a student, complete the information for the faculty supervisor. Please note that **THE FACULTY ADVISOR MUST INDICATE KNOWLEDGE AND APPROVAL OF THIS PROPOSAL BY EMAILING THIS FORM TO THE COMPLIANCE OFFICE WITH A STATEMENT OF APPROVAL IN THE BODY OF THE EMAIL. Students should not email forms directly to the IRB.**

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

|  |  |
| --- | --- |
| **Name(s)** |  |
| **Email address(es)** |  |
| **Department/Unit/Affiliation** |  |
| **CITI Program ID(s)** |  |

**1.6 Type of Study:** Faculty/Staff research Thesis  URECA

Program Evaluation  Class Project Dissertation

* 1. **Source of funding for project with grant ID:**
  2. **Expected starting date for project**:
  3. **Is this project expected to continue for more than one year?**

No  YES – the researcher must complete annual continuing review

* 1. **Anticipated completion date:**       (the protocol will be closed on this day)

**Important Information:**

* Expedited and Full protocols are valid for one year.
* If more than one year is needed to complete data collection and analysis, 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; After three years a new application must be submitted.

1. **PROTOCOL DESCRIPTION**

**2.1 HYPOTHESIS - What is the research question being addressed in the study?**

**2.2 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.

**2.3 PROTOCOL DESCRIPTION and METHODS -** Describe in detail each step of your proposed study. Provide a description of all procedures to be followed, describe any experimental groups and/or manipulations. Also, give a brief description of your study design. (e.g., qualitative, correlation, factorial, etc)

**2.4 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.

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

**2.6 Provide a list of qualifications necessary to complete this project and how will the researcher(s) meet these qualifications?**

Refer to <https://www.mtsu.edu/irb/requirements.php> for mandatory training requirements.

**2.7 DEBRIEFING - How will participants be debriefed? (In addition to describing the debriefing procedure, attach a copy of all debriefing information)**

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.

**2.8 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)).*

**2.9 BENEFITS – list prospective benefits of conducting this research. Include direct benefits for participants, science, and society**

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

**Note:** If your study involves risk (including sensitive information), minors as participants, psychological intervention, deception, physiological intervention, or biomedical procedures, you should also complete the appropriate section at the end of the form.

1. **PARTICIPANT DESCRIPTION and RECRUITMENT**

**3.1 Maximum Number of Participants (Sample Size):**

**3.2 Minimum and maximum age of the participants:**

**3.3 Participant population** (Select ALL that will be specifically targeted):

Healthy Adults (18 years or older)

MTSU Psychology Research Pool (complete section 3.7)

Adults (Participants 18 years or older but not included above)

Minors (less than 18 years of age) (COMPLETE APPENDIX B)

Prisoners (COMPLETE APPENDIX A)

Pregnant Women

Mentally Handicapped

Mentally Disabled

Physically Ill

Disabled

Senior Citizens (65 years or older)

|  |
| --- |
| VULNERABLE (financial, hierarchical, etc.)  Describe: |
| OTHER: (not listed above)  **PLEASE SPECIFY:** |

**3.4 How will participants be selected for this research?** Describe the recruitment (initial contacts) methods and compensation (inducement) to participants. If any advertising or recruitment devices will be used they must be attached to the application.

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

**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**](https://www.mtsu.edu/irb/FAQ/PermissionLetters.php)**).**

**3.5 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.

* 1. **Inducement and Compensation:** 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.

**NOTE: most types of monetary compensation used for inducement will require proper documentation for records keeping and IRS accounting.**

* 1. **If using the Psychology Research Pool:** (http://mtsu.sona-systems.com/)

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.

**Title:**

**Brief Abstract:**

**Full Description:**

1. **CONFIDENTIALITY**

**4.1 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  Telephone number  Street address  E-mail address  IP address  Vehicle registration plate number | Photographs or video tapes  Voice recordings  Handwriting samples  Digital Identity  Credit card numbers  Driver's license number  Genetic/DNA/Dental information etc. |
| 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:

**4.2 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

**4.3 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.

Federal guidelines require

* All study related documents (documentation of informed consent, surveys, study notes, data records, and all study-related correspondence) be stored securely for **at least 3 years** following completed research.
* Materials 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).

**4.4 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**

Refer <https://www.mtsu.edu/irb/FAQ/ConsentAndAssent.php> for more information

**5.1 Will informed consent be obtained from participants? (Consent waiver)**

Yes

NO complete Appendix G with adequate justification and add supporting documents.

**5.2 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**

**5.3 Will you obtain consent orally?**

Yes complete Appendix G with justification for why signature is not collected

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

**5.4 Will you administer the informed consent ONLINE? (Adult participants only)**

NO

Yes Complete Appendix G with explanation and follow instructions listed below

Paste the weblink for the proposed online study here:

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

NO

Yes Explain:

**Mandatory compensation disclosures:**

* *All eligibility and requirement to receive the compensation must be clearly disclosed*
* *The participants must receive the compensation or a portion of once they enroll*
* *Documentation requirement for disbursing compensation, such as obtaining W9 forms and other records must be clearly disclosed before enrollment.*

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

**5.7 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 | 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 the research is voluntary, there are no penalties for refusal to participate, and participation can be discontinued at any time without penalty or loss of benefits. | Yes  NO |

# APPLICATION CHECKLIST

**6.1 Investigator(s)**: Please **read** and **initial** each item.

|  |  |
| --- | --- |
| Checklist item | Initial |
| Is all information typed? |  |
| Is documentation of IRB training attached for each investigator and for the faculty supervisor? |  |
| Are the investigator email address and other contact information included? |  |
| If student research, is the faculty supervisor email and other contact information included? |  |
| Are surveys, questionnaires, tests, interview forms / scripts attached? |  |
| Is the number of participants indicated? |  |
| Is the method of participant selection indicated? |  |
| If using the Psychology Department research pool, is signup information included? |  |
| If a consent form is being used, is a copy of the consent form attached? |  |
| If consent form does not match the template available at our website, or you are requesting a waiver of the requirement for consent, is the Request for Waiver or Alteration Form attached? |  |
| For research involving minors, is an assent form attached? |  |
| For research at outside institutions (e.g., schools), are permission letters on official letterhead attached? |  |

**Incomplete applications will NOT be reviewed.**

**6.2 ADDITIONAL PROCEDURAL INFORMATION**

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

Risk (Appendix A)

**SEE THE APPENDIX INDICATED FOR A MORE DETAILED DESCRIPTION OF THESE CATEGORIES**

Minors as Participants (Appendix B)

Psychological Intervention (Appendix C)

Deception (Appendix D)

Physiological Intervention (Appendix E)

Biomedical Procedures (Appendix F)

1. **SIGNATURES**

(If possible, use electronic signature- if not type your name in the space provided.)

**7.1 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 the webpage <https://www.mtsu.edu/irb/FAQ/ResponsibilitiesOfPI.php> and I am fully aware of my responsibilities

|  |  |
| --- | --- |
|  |  |
| **Name of the Investigator (PI)** | **Date** |

**7.2** **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.

|  |  |
| --- | --- |
|  |  |
| **Name of the Faculty Advisor (FA)** | **Date** |

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

**APPENDIX SECTION – ADDITIONAL PROCEDURAL INFORMATION**

* Appendices are labeled A through G.
* Only fill out the appendix that are relevant to this study
* Type all your responses

**APPENDIX A**

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

If human subjects participating in this proposed research project may be exposed to the probability of harm, including physiological, psychological, economic, or social harm, please provide the information requested in the following items:

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.

2. 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.

3. 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.)

**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)

**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 *(i) Research with Children;* and *(ii) Research in Public Elementary and Secondary Schools* SBR supplemental modules.

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. Documents in the Office of Sponsored Programs provide additional information on these points.

1. Specify how PARENTAL CONSENT, when required, will be obtained and documented. Attach copies of all letters and consent forms.

2. Specify provisions for soliciting the ASSENT of minor subjects. Attach copies of assent forms or script of oral permission.

3. Specify provisions for minimizing COERCION on minors to participate.

4. List all schools in which the research will be conducted and provide documentation of PERMISSION from the 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).

5. 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).

**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.

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

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

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

5. 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.

**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.

2. 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.

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

**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.

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

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

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

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

6. 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).

7. 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.

**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.

1. Describe in detail the biomedical PROCEDURES involved in this project.

2. Identify anticipated and possible physiological CONSEQUENCES of these procedures of the subject(s).

3. Identify 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.

**APPENDIX G**

**REQUEST FOR WAIVER OR ALTERATION OF CONSENT**

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.

**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:

**Are you requesting that 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:

**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?

**If you answered yes to any above, answer the following questions:**

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?**