**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 COVID-19 infection.

|  |  |
| --- | --- |
| 1. Project Information 2. RESERVED 3. RESERVED 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. RESERVED |

**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](mailto: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 letter of IRB approval!**

**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 investigators are able to address all reviewers’ concerns.
* 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>**

* 1. **Primary Investigator (PI)** 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 |  | | |

*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 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 |  | | |

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

* **Must be completed by an MTSU faculty or a FTE if the PI is a student.**
* **The FA must submit the application packet by email to** [***irb\_submissions@mtsu.edu***](mailto: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

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

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

Social/Behavioral/Educational Research  Biomedical Research

Clinical Research  Quality Assurance/Evaluation

* 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

**Office Use Only**

|  |  |
| --- | --- |
| **Protocol ID** | **21-####** |
| **Date Received** |  |
| **Date Prescreen** |  |
| **Revision (if applicable)** |  |
| **Date of Review** |  |
| **Date of Revision** |  |
| **Approval 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 voice, video. Images and etc., for research purpose |  | **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 - What is the research question being addressed in the 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 of this proposed study. Provide detailed descriptions in other segments of this application.

***NOTE: although many of the steps, such as, recruitment, informed consent, data collection, debriefing, are also elaborated elsewhere, it is crucial to provide a chronological account of the study in this section to allow the reviewer to get a full picture of all of the methods in context.***

**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*** | | | | | |
| Virtual or online interaction with NO direct physical contact with the participant | | | | | |
| Direct physical interaction with the participant: Complete Appendix COVID-19 | | | | | |
| ***5.4.1.2 Non-physical interventions/interactions*** | | | | | |
|  | Social & Behavioral | Educational | | Complete **Section 2.4.2** | |
|  | Existing Data – Analysis studies including investigation of audio/video Complete **Appendix L** | | | | |
|  | Biospecimen – Analysis of previously collected biological samples Complete **Appendix F**) | | | | |
|  | ***If you selected one of the above, then provide a simple definition of what you mean by “data” in this research:*** | | | | |
| ***5.4.1.3 Other Intervention/interactions*** | | | | | |
|  | Physical (Appendix K) | | Psychological (Appendix C) | | Physiological (Appendix E) |
| OTHER(s) – Not listed above and the PI will be directed to provide further information  Explain:  ***If you selected one of the above, then provide a simple definition of what you mean by “data” in this research:*** | | | | | |

***5.4.2 Data Acquisition*** *(Mandatory for all types of data selected in 6.4.1)*

***Select all that apply***

|  |  |  |
| --- | --- | --- |
| **Survey8** | | |
|  | Paper Survey | *Submit survey script/topics* |
| Online Web-based Survey10 | *Insert Weblink for the survey* |
| Qualtrics Link(s):  Visit <https://mtsu.edu/irb/FAQ/OnlineDataCollection.php> for more information | |
| Verbal Survey  Telephone  Email | *Submit survey script/topics* |
| Survey through Social Media | *Submit screen shots* |
| OTHER modes | *Explain below and submit documents* |
| Explain: | |
|  | | |
| **Interview8** *Submit interview script/topics* | | |
|  | Face-to-face Interview | Telephone |
| Internet-based (eg. Skype, FaceTime) | Social Media |
| Email: Explain: | |
| OTHER modes | *Explain below and submit documents* |
| Explain: | |
|  |  | |
| **Observation9** | | |
|  | Explain and describe the instruments | |
|  | | |
| **Focus Group(s)9** | | |
|  | Explain and describe the instruments: | |
|  |  | |
| **Other** | | |
|  | Explain and describe the instruments | |
|  | | |

**Foot 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**

**5.8 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.*

**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: |

**5.9 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)).*

**5.10 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.**

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

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

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

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

**6.3 Targeting more than one type of participants**: Explain below if the target population would consist subsets of groups (Eg. Parents and their minor children, teachers and their students, doctors and their patients, etc.)

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

|  |  |
| --- | --- |
| 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:

**NOTE:**

* Research with Pregnant Women – Complete Additional Information Page (Beta Testing)
* Research with prisoners – Complete Additional Information Page (Form F022)
* Research with minors:
  + Educational Research with minimal risk – Complete Appendix B (scroll down this form)
  + Non-educational Research – Complete Additional Information Page (Form F021)

**6.4 Recruitment Tools**

***Visit*** [***https://mtsu.edu/irb/FAQ/Recruitment.php***](https://mtsu.edu/irb/FAQ/Recruitment.php) ***for more information***

IRB Flyer IRB Recruitment Email14

Word of mouth14 Telephone14 Regular Mail14 (Submit sample)

14Send separate transcripts for each type of recruitment transcript as a separate 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

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

**6.6 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.**

**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. **Recruitment through the Psychology Research Pool (SONA):**  NOT Applicable

**Refer:** (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. **Recruiting Amazon Mechanical Turk workers**  NOT Applicable

Complete MTurk Additional information Page Form F023 (<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 the IRB Forms page (<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.

Federal guidelines require

* 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
* 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).
* **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 participants?**  (Consent waiver)

Yes

NO complete Appendix G with justification and add supporting documents.

**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 ONLINE? (minimal risk studies 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*

**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

**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.*

**9.6 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**

**8.1 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.**

**9.2 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

The hidden additional procedural pages will be unlocked during the prescreening step.

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** |

\*Students PIs must enter their name by logging into their MTSU account

**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.

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

\*\*Although not mandatory, faculty PI/FA are encouraged to enter their name by logging into their MTSU account

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

**APPENDIX SECTION – ADDITIONAL PROCEDURAL INFORMATION**

* Appendices are labeled A through L
* Complete those apply to your research
* Some appendices are hidden for space consideration. In such cases, please check the appropriate box to request the section to be displayed and submit this form. The IRB PreScreener will unlock the relevant section and send this form back to you.

**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)

Please provide the information requested in the following items:

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. 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?

**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.

Check here to request this hidden section to be displayed. The hidden section will be revealed after

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.

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.)

**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. 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: |

**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:

Check here to request this hidden section to be displayed

* 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.

**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.

Check here to request this hidden section to be displayed

* 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.

**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:

Check here to request this hidden section to be displayed

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.

**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”:*

**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.

**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:

Consent administered online (Complete Appendix Section G.5

**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 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?

**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 web link:

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 selection, make a selection below:

Locked online consent template is used

Unlocked free format online consent template is used

The online web link for the consent script must be provided for IRB review. The link must be tested by the PI it is submitted to the IRB.

***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 administered to someone who is not familiar with the study (enter name:      ) and 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) |

**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.

Check here to request this hidden section to be displayed

***Inducement details***

1. Total Compensation Amount:
2. Compensation for each trial:
3. Disbursement method:

Gift card Check Cash Direct Deposit

Other Explain:

***Record keeping***

*Make selection below*

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 you selected YES for both (i) and (ii), then document the following for each participant.
   * Gift card/Check or other Transaction Number
   * Date of Issue
   * Amount disbursed
   * Participant Signature
4. If you selected NO for (i) but checked YES for (ii), then document the following for each participant.
   * All of the particulars from A above
   * Full name (if the IRB approval notice clearly allows this)
5. If you 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 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.**

**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: |

**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:

Check here to request this hidden section to be displayed

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.

**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

Check here to request this hidden section to be displayed

**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)**:**