**Human Participant Research Proposal**

**IRBF004: EXEMPTION REQUEST FORM**

**“Exempt” Definition:**

It is important that seekers of IRB exemption understand that “exempt” does not reflect its literal meaning but those protocols that qualify for “exempt status” are often reviewed by the MTSU Office of Compliance and do not require an annual continuing review. However, the procedure and documents requirement for exempt protocols are mostly same in comparison to those protocols that require more IRB oversight.

**What does this form contain?**

This new exemption request form contains several newly added features to help researchers to clearly outline their proposal to collect data from living individuals. Although more information is requested from the applicants, the review process is expected to focus on the research and human intervention than on minor issues. This form also contains space for reviewer comments thereby allowing the review process to resemble an informative discussion. The applicant must provide the necessary details for questions in Sections 1-11 (Refer to the following list of contents). The Sections 12 & 13 are for Office Use only.

|  |  |
| --- | --- |
| 1. Project Information 2. Investigator Information 3. Exemption Determination 4. Exemption for Research with minors 5. Selection of Research Category 6. Research Methods & Instruments 7. Participant Selection & Recruitment | 1. Informed Consent 2. CITI Training 3. Mandatory Documents & Attachments 4. Investigators’ Declaration and Assurance 5. *Review (Office Use)* 6. *IRB Action (Office Use)* |

**Mandatory requirements**

* Completed informed consent form - Click
* All of the investigators must complete all required research-specific CITI training modules
* Provide a detailed strategy for avoiding COVID-19 infection if the participants will have direct interaction
* In addition, other documents may be required

**Instructions for document submission.**

* This application and support documents must be submitted by the faculty member who signs Section 11.2.
* Send all 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

**Review & Timeline**

* Once the OC confirms that the application is complete, a complete review will be completed within 2 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 will be sent to the investigators to be used as a guideline for their study.

1. **PROJECT INFORMATION**
   1. **Choose your review type:**   EXEMPT Review
   2. **Enter Project Title**

**<type here>**

* 1. **Primary Investigator or Principal Investigator (PI) Information:**

Faculty4 Staff4 Graduate5,6 Undergraduate5,6 Other5,6

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

|  |  |  |  |
| --- | --- | --- | --- |
| 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. **Investigating Team** *(List ALL Investigators - contact the Compliance Office for more than 6 Co-I’s)*

|  |  |  |
| --- | --- | --- |
| Name/Email/Status | Department/Affiliation | CITI Training |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |
| Name:  Email:  Faculty/Staff Student5 Non-MTSU Other |  | Completed |

**Foot Notes:**

4 Faculty PI must complete and sign Sections 11.1 and 11.2

5 The Student PI must complete Section 11.1 and an MTSU Faculty Advisor/mentor must sign Section 11.2. In addition, the application documents MUST be emailed to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu) by the MTSU Faculty who completes Section 10.2 with a statement of approval in the body of the email.

6 The Students, regardless of their affiliation, MUST complete “Students in Research” module from CITI Program

7 The faculty advisor or sponsor MUST be an MTSU faculty member.

* 1. **Submission Status of this Study:**

New Submission1  Revision2  Previous Protocol ID(s) given to this study3

* 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/Staff research  FRCAC  URECA  Class Project

Thesis Dissertation  Not for Publication  Publication/Presentation

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) |  |  |

This form also contains space for reviewer comments. Therefore, do not convert this to PDF but instead send the completed form to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu) in its original MS Word format.

**Review Tracker**

|  |  |
| --- | --- |
| **Protocol ID** | **21-####** |
| **Application Date** |  |
| **PreScreen** |  |
| **Revision (if applicable)** |  |
| **Review** |  |
| **Revision (if applicable)** |  |
| **Exemption Determination** |  |

**Foot Notes:**

1 Check this box if this is the first time you are submitting this study for IRB review

2 Check this box if you have already submitted this application to the IRB but you have been asked to make revisions to your application or other documents by the IRB or by the Compliance Staff

3 Check this box and provide the IRB ID if you are trying to extend a previously approved IRB protocol

1. **EXEMPT DETERMINATION QUESTIONAIRE**

|  |  |  |
| --- | --- | --- |
|  | **Vulnerable Subjects -** Are the subjects from a vulnerable group, such as, prisoners, seriously ill, cognitively impaired, protected minorities and/or *etc.*? | **Yes**  No |
|  | **Risk to the Subjects -** Does the research involve the collection of behavioral data which, if known outside the research, could reasonably place the subjects at risk for criminal or civil liabilities or be damaging to the individual’s financial standing, employability or reputation? | **Yes**  No |
|  | **Sensitive Topics -** Will you be collecting information regarding sensitive topics or personal aspects of a subject’s behavior, such as, drug or alcohol use, illegal conduct, sexual behavior, mental health an/or etc.? | **Yes**  No |
|  | **Video/audio -** Will you be audio/video recording participant’s response? | **Yes**  No |
|  | **Discomfort(s) to the Subjects -** Will this study expose the subjects to discomfort or stress beyond the levels encountered in daily life? | **Yes**  No |
|  | **Research with Minors -** Does your research involve *collection of data from minors* or *use of data collected previously from minors*? Complete Section 4 if Yes | **Yes**  No |

Other than question 3.6, if you answered “YES” to any of the above questions, then t research is DISQUALIFIED from obtaining an exempt designation

1. **RESEARCH WITH MINORS**

***Additional information for data collection from minors and use of data previously collected from minors***

If the intended delivery of the educational materials to the minors is not to verify a research question, then this study may qualify for exempt status. The investigating team must *complete the CITI SBR modules “Research with Children”* and *“Research in Public Elementary and Secondary Schools.”*

The study involves: Active participation of minors Complete 4.1 through 4.4

Use of data previously collected from minors Complete 4.1 and 4.2

|  |  |  |  |
| --- | --- | --- | --- |
| **4.1** | Will this study involve activities other than the delivery of education **or the use of data from non-educational activities**? ***If YES, then NOT Exempt*** | | **Yes**  No |
| **4.2** | If answered “NO” for 4.1, then will/did the delivery of education entail(ed) typical curriculum? ***If NO, then this study is NOT Exempt*** | | Yes  **No** |
| **4.3** | The students will be tested to evaluate or assess a research question?  ***If YES, then this study is NOT Exempt*** | | **Yes**  No |
| **4.4** | Parental Consent Question:  Will all of the minors do the same activity/activities or will the subjects will be selected from a class using a random sampling scheme? | |  |
|  | Yes | *No further action is necessary if the study passed the other exemption tests* | |
|  | No | If the students will be purposefully selected, then study may still qualify for exemption but you must obtain **PARENTAL CONSENT** and administer **the CHILD ASSENT**. Use the forms from the Expedited Review section for both of these processes. | |

1. **RESEARCH CATEGORIES**

The Federal Code [45 CFR 46 (46.101)] identifies the activities that fall within the following six categories as exempt. You MUST select the appropriate exemption category that apply to this study.

|  |  |  |
| --- | --- | --- |
|  | **Exemption Category - research activities that are exempt from continuing review** |  |
| **1** | Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as, (i) research on regular and special education **instructional strategies**, or (ii) research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods |  |
| **2** | Research involving the use of **educational tests** (cognitive diagnostic, aptitude, achievement), **survey procedures, interviews or observation of public behavior**, UNLESS  (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; AND  (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation |  |
| **3** | Research involving the use of **educational tests** (cognitive diagnostic, aptitude, achievement), **survey procedures, interviews or observation of public behavior** that is not exempt in 5.2 of this section if:  (i) the human subjects are elected or **appointed public officials or candidates for public office**; OR  (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |  |
| **4** | Research involving the collection or study of **existing data, documents, records** (pathological specimens or diagnostic specimens) if publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects or the data were collected through a different protocol approved by an ethics committee such as the IRB |  |
| **5** | Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine:  (i) **Public benefit or service programs**;  (ii) procedures for obtaining benefits or services under those programs;  (iii) possible changes in or alternatives to those programs or procedures; OR  (iv) possible changes in methods or levels of payments for benefits or services under those programs |  |
| **6** | **Taste and food quality evaluation and consumer acceptance studies:**  (i) if wholesome foods without additives are consumed, OR  (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Services of the US Department of Agriculture |  |
|  | **NONE OF THE ABOVE? – This study may not qualify for exemption.** |  |

1. **RESEARCH METHODS & INSTRUMENTS**

*Fill or paste with appropriate text in the editable spaces provided. The “”Review Questions” shown within closed boxes are locked and cannot be edited until a review has been completed.*

* 1. **Protocol Summary – Use this section to summarize the entire protocol using all the steps presented in this protocol.** Provide a step-by-step account all of the procedures and interventions/interactions to be experienced by the participants starting from the recruitment till debriefing. Also include time and resource commitments to the participants. Use subtitles or separate steps using paragraphs.

* 1. **Study Description –** Describe this study using the outline provided below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Purpose | | |  | |
|  |  | | | |
| Background | |  | | |
|  |  | | | |
| Rationale | |  | | |
|  |  | | | |
| Study Design | | | |  |
|  |  | | | |
| Other | |  | | |
|  |  | | | |

|  |
| --- |
| REVIEW QUESTION A: Is the purpose of this protocol and the associated procedures/interventions clearly described to make a rational decision?  Reviewer Comments:  Investigator Response: |

* 1. **Data Type –** Check all those apply and provide additional information as directed

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Existing data *(complete 6.3.6)* | | Biospecimen *(complete 6.3.7)* | | Educational *(complete 6.3.1-5)* |
| Social *(complete 6.3.1-5)* | | Behavioral *(complete 6.3.1-5)* | |  |
| Physical interventions | | Psychological interventions | **THESE ARE DISQUALIFIED** | |
| OTHER(s) |  | | | |

* + 1. ***COVID-19 Risk Assessment – Select one of the following***

|  |
| --- |
| Virtual or online interaction with NO direct physical contact with the participant |
| **Direct physical interaction with the participant: Complete Section 6.6** |

* + 1. ***Data Acquisition - 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 |
| Virtual Interview (Eg. Zoom) | 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*

* + 1. **Provide a short description of what is collected in section 6.3.2 above:**
    2. **Explain how the data described in 6.3.2 will be collected:**
    3. **Describe how the data collected from 6.3.2 will be analyzed:**
    4. ***Existing Data – OTHER THAN BIOSPECIMEN***
* *Definition:* “Existing Data” corresponds to the generalizable information generated or collected from living individuals using an approved IRB protocol. If the data were already collected without an IRB protocol, then IRB approval will not be granted.
* *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 – complete Section 4

OTHER

**Explain the data in detail and describe how they were originally collected:**

* + 1. ***Biospecimen collected through a previously approved IRB protocol***
       1. *IRB DETAILS: Provide the IRB information on how the bio-specimen was originally collected*
       2. *INFORMED CONSENT: Explain if the participants consented for subsequent secondary studies:*
       3. *PROPOSED METHODS: Explain all of the methods to be used for analyzing the bio-specimen:*
       4. *AMENDMENT TO RESEARCH: Explain if the specimens are used for a different research:*
       5. *SPECIMEN IDENTITY: Describe the reasons why the bio-specimen may be “re-identified”:*

|  |
| --- |
| REVIEW QUESTION B: Is the data acquisition, usage and analysis clearly explained?  Reviewer Comments:  Investigator Response: |

* 1. **Research Site(s) - Where will the research be conducted?**

MTSU – Department(s)/Building(s)

Public Place(s)

OTHER12

*12 Permission letter(s) from non-MTSU organizations must be provided as a scanned PDF of a message written on an official letter head signed by an official from the organization who has such authority. Forwarded emails, text messages and other non-verifiable formats will NOT be accepted.*

* 1. **What are the risks for the participants? –** Describe in detail how this proposed study presents no more than minimal risk13 to the participants.

*13 “Minimal risk” describes the probability and magnitude of harm or potential discomfort anticipated in the research are not greater than those ordinarily encountered in daily life. Also note that research that involves more than minimal risk will disqualify this study from exemption.*

* 1. **If the participants will direct interactions with other participants or with the investigators, then complete this section to describe how this protocol will address the risk due to COVID-19.** Describe in detail

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?

|  |
| --- |
| REVIEW QUESTION C: If risks are necessary, are they minimized to an extent such that the participants are only exposed to the same amount of risk they would experience in their normal life?  Reviewer Comments:  Investigator Response: |

* 1. **What are the benefits of this study?**

|  |
| --- |
| REVIEW QUESTION D: Does this study result in benefits that outweigh the potential risks?  Reviewer Comments:  Investigator Response: |

1. **PARTICIPANT INFORMATION**
   1. **Research Participant Recruitment –** Describe how you will recruit the participants (recruitment materials MUST be submitted with this form), indicate whether the participants are 18 years of age or older,estimate the approximate number of research participants and describe inclusion/exclusion criteria used in selecting the participants. 
      1. ***Recruitment Tool(s) – Visit*** [***https://mtsu.edu/irb/FAQ/Recruitment.php***](https://mtsu.edu/irb/FAQ/Recruitment.php)

Flyer

Word of mouth14 Email14 Telephone14 Regular Mail14 (Submit sample)

14Send the recruitment transcript as a separate file for IRB review. 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

Social media – EXPLAIN how the initial contact will be made

OTHER

* + 1. **Describe the recruitment strategy including the recruitment steps to be followed using the recruitment tools stated above:**
  1. **Participant Description – Complete this section for all types of research including analysis of existing data** (if previously collected data are used, then describe the source from whom the data were originally collected).

|  |  |
| --- | --- |
| ***7.7.1 Participants’ Age*** |  |
| ***7.7.2 Participant Description*** |  |
| ***7.7.3 Sample Size*** |  |
| ***7.7.4 Inclusion Criteria*** |  |
| ***7.7.5 Exclusion Criteria*** |  |
| ***7.7.6 Compensation*** |  |

All recruitment materials must be submitted for IRB approval, including transcripts of personal correspondences. If the participants are to be drawn from an institution or an organization that has the authority to allow its members to participate in human subject research, then proper approval notifications from that institution MUST be submitted with this application

* 1. **Recruitment of participants through the Psychology Research Pool:**

Complete this section ONLY if you plan to involve the students registered under this research pool. The information provided here will be relayed as it appears here to the student volunteers of the Psychology Research Pool.

|  |
| --- |
| **7.8.1 Title:** |
| **7.8.2 Abstract:** Provide a short abstract (2-3 sentences) |
| **7.8.3 Description:** Complete a short description of this project by elaborating the risks, benefits and other information necessary for the research pool volunteers to make an informed decision. |

Visit [**http://capone.mtsu.edu/wlangsto/ResearchPoolPage.html**](http://capone.mtsu.edu/wlangsto/ResearchPoolPage.html) for further information**.**

|  |
| --- |
| REVIEW QUESTION E: Did you find the recruitment practice to be proper?  Reviewer Comments:  Investigator Response: |

|  |
| --- |
| REVIEW QUESTION F: Does the proposed inducement sound reasonable without conflicts of interest or coercion?  Reviewer Comments:  Investigator Response: |

* 1. **Confidentiality –** Describe in detail how you propose to protect the confidentiality of the information obtained from the participants

* 1. **Data Storage -** Where will the data/records relating to the human participants be stored?

The data and records must be stored by the PI (Faculty advisor if the PI is a student) for at least THREE years after the study has been completed.

|  |
| --- |
| REVIEW QUESTION G: Has/Have the researcher(s) done everything possible to protect the participants’ anonymity and confidentiality?  Reviewer Comments:  Investigator Response: |

1. **INFORMED CONSENT**

Investigators must remember that the consent process is like a conversation; it is not merely a document. Therefore, this process must be one of the center theme of your protocol in addition to protecting the autonomy and confidentiality of the subjects. The investigators are required to fully inform the participants on all of the activities to be carried out in the study and they must obtain consent from the latter prior to data collection. An informed consent document can be obtained from the MTSU IRB website. **Respond to these questions after completing the** [**MTSU-approved informed consent template**](http://www.mtsu.edu/irb/docs/IRB-InformedConsentEXEMPT.docx)**:**

|  |  |  |
| --- | --- | --- |
| **8.1 Who will obtain informed consent?**  (Full Name(s)) | |  |
| **8.2 How will the consent be obtained?**  (Describe how consent will be administered and obtained) | |  |
| **8.3 What language(s) is the text?** | |  |
| ***8.4 Where will the consent be obtained?*** | |  |
| REVIEW QUESTION H: Is there enough evidence that the subjects are adequately informed and the autonomy of the participants respected?  Reviewer Comments:  Investigator Response: | | |

|  |
| --- |
| REVIEW QUESTION I: Are the informed consent processes/documents fair and appropriate?  Reviewer Comments:  Investigator Response: |

1. **CITI TRAINING**

**This application WILL NOT be reviewed if the training for all of the investigators is incomplete**

* The entire investigating team must complete “Social and Behavioral Research” basic training module
* 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**

*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.*

|  |  |
| --- | --- |
| 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 | |

|  |
| --- |
| REVIEW QUESTION J: Are the reseachers’ experience/qualification/training adequate?  Reviewer Comments:  Investigator Response: |

1. **ATTACHMENTS AND ENCLOSURES**

**Documents or Websites Included in this IRB submission:**

Informed Consent form  Surveys/questioners/interview scripts

Recruitment materials and transcripts  Official Permission Letter(s)

Prescreening/debriefing materials  CITI certificates

OTHER(S), Specify:

Online link(s):

Separate the links by “;” for materials to be reviewed (video clips, literature data and etc.)

1. **DECLARATION**

PI Status:

Student – Complete 11.1 and have faculty advisor/sponsor must fill 11.2

Faculty/Staff – Complete 11.1 AND 11.2

**11.1 Primary Investigator’s Assurance**

|  |  |  |
| --- | --- | --- |
| I, , hereby certify that | Indicate acceptance by entering initials | |
| 1. As the PI of this study, I assure that this application packet has been fully completed by providing all essential and required information. |  |
| 1. The information provided for this exemption request is accurate to the best of my knowledge. |  |
| 1. All of the investigators have completed all research-specific CITI training; I will inform the IRB immediately if training deficiencies should occur. |  | |
| 1. Email addresses and contact information for all investigators are given. |  | |
| 1. Surveys, questionnaires, tests, interview forms etc. have been included. |  | |
| 1. Recruitment materials (OR/and) signup information for using Psychology research pool is completed *(Enter N/A if not applicable).* |  | |
| 1. A filled informed consent form is attached. |  | |
| 1. PDF scan of all signed permission letters for researching at outside institutions (e.g., schools), is provided on official letterhead (Enter N/A if not applicable). |  | |
| 1. Once this protocol has been approved,  * I will make every effort to protect the safety and welfare of the participants. I will inform the IRB immediately of any adverse events to the participants. |  | |
| * Any deviations from the proposed methods will be reported immediately and changes will be implemented only after IRB approval. |  | |
| * I will submit a status report of this study if directed by the IRB. |  | |
| * I am aware of potential liabilities and sanctions for failure to adhere to my proposed protocol from IRB and non-IRB entities within MTSU and I agree to comply with those requirements. |  | |
| * I assure that the data collected during this study and other records will be stored in a secure place within MTSU, such as the office of an MTSU faculty member. I also assure that the records will be stored for at least three years after the active data collection has been ceased. |  | |
| PI14 Enter full name using an MTSU Computer | Date: mm/dd/yyyy | |

14Student PIs must complete this section using their MTSU FSA account

**11.2 Faculty Investigator’s Assurance**

This section must be completed by an MTSU faculty member regardless if the PI is a student or not. An MTSU faculty member must read and endorse this section if the applicant is a student. Preferably use your MTSU FSA account when completing this section. If using a home computer, please ensure that you use a licensed version of MS Office for capturing the identity of the signee. Please visit the Faculty Information page <http://www.mtsu.edu/irb/FAQ/Faculty.php> before signing off this form.

|  |  |  |
| --- | --- | --- |
| I, , hereby certify that | Indicate acceptance by entering initials | |
| 1. This project will be carried out under my direct supervision |  |
| 1. The investigators are competent and professional to work with human subjects and they comply with all of the provision required for the approval of this protocol |  |
| 1. I have read this application thoroughly and I attest to its scientific merit. |  |
| 1. I am fully aware of the activities to be performed under this exemption request. |  |
| 1. All of the investigators, including myself, have completed all research-specific CITI training; I will inform training deficiencies to the IRB immediately. |  | |
| 1. Once this protocol has been approved,  * I will report any significant or adverse events related to this study to the IRB within 72 hours of when I become aware of such incidents. I will also report breaches, such as, negligence or compromise to participant confidentiality or study-related injuries/discomforts to the participant. |  | |
| * I take full responsibility to review any future changes or alterations to this study before a formal request is submitted to the IRB. Any deviations from the proposed methods will be reported immediately and changes will be implemented only after IRB approval |  | |
| * I am aware of potential liabilities and sanctions for failure to adhere to my proposed protocol from IRB and non-IRB entities within MTSU and I agree to comply with those requirements16 |  | |
| * I assure that the data collected during this study and other records will be stored in a secure place in my Office or in my Department Office. I also assure that the records will be stored for at least three years after the active data collection has been ceased. |  | |
| * I agree to meet with the investigators on a regular basis to monitor the study progress and compliance. I will retain records of such meetings, like email transactions and other verifiable communication records. I will also document specific conversations that would entail the welfare of the participants and other courses of actions |  | |
| Faculty15 Enter name using your FSA Account  15Preferably complete this section using using your MTSU FSA account  16Faculty Sponsor Responsibilities - <http://www.mtsu.edu/irb/FAQ/Faculty.php> | Date: mm/dd/yyyy | |

***INSTRUCTIONS FOR SUBMISSION:***

* This application and support documents must be submitted by the faculty member who signed Section 11.2.
* Send all documents as separate files but in a single email to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu)
* If multiple emails had to be sent due to memory insufficiency, then provide a proper explanation in each email
* Submit all IRB forms in their original MS Word format – DO NOT CONVERT TO PDF

***The REVIEW STEPS***

* The Office of Compliance (OC) will issue an IRB ID if the submission is determined to be complete
* If the application is incomplete, then the IRB request will be returned with no action
* Once the OC confirms that the application is complete, a reviewer will inspect the application packet and will enter any comments or request for additional information in the appropriate space provided within this form
* This form will be sent back to the investigators with reviewers’ comments
* The investigators will receive any review comments, request for clarifications or recommended revisions along with other concerns. 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 will be sent to the investigators to be used as a guideline for their study.

**12. REVIEWER SECTION**

**(Office Use Only)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exempt Pre-Review Checklist** | **Y** | **N** | **N/A** | **Reviewer Comments** |
| Application is complete |  |  |  | . |
| Informed consent is complete |  |  |  |  |
| Recruitment/Debriefing is provided |  |  |  |  |
| Link for web-based research – TRAINING REQD |  |  |  |  |
| CITI Training Complete (PI, FA, Co-Investigators) |  |  |  |  |
| Application Appendices |  |  |  |  |
| Faculty Endorsement |  |  |  |  |
| Off-site Permission Letters |  |  |  |  |
| Research Instruments and Tools (i.e. Surveys) |  |  |  |  |
| Grant Information/Source of Funding Provided |  |  |  |  |
| Participant Pool |  |  |  |  |
| Sample Size |  |  |  |  |
| Restrictions |  |  |  |  |

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| --- | --- | --- | --- |
| **Exempt Designation Criteria** | **Y** | **N** | **Reviewer Comments** |
| Subjects are considered “Vulnerable” according to OHRP’s subpart definition [Examples – prisoners, cognitively impaired, seriously ill, pregnant women, minors (other than educational research) ] |  |  |  |
| Behavioral information collected in this study could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the individual's financial standing, employability or reputation |  |  |  |
| Data involves sensitive information or personal aspects of the subject's behavior (drug/alcohol use, illegal conduct, sexual behavior, mental health, etc.) |  |  |  |
| Except for researching normal education practices, will this study involve minors (under 18)? |  |  |  |
| The subjects may be exposed to discomfort or stress beyond the levels encountered in daily life |  |  |  |
| Video- or audiotaping is conducted |  |  |  |

**MINOR Revisions and Modifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Document Type (Application, recruitment, application etc) | Page/ Item# | Specific Modification(s) | Investigator response(s) |
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**MAJOR Revisions and Modifications**

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| --- | --- | --- | --- |
| Document Type (Application, recruitment, application etc) | Page/ Item# | Specific Modification(s) | Investigator response(s) |
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1. **IRB ACTION**

**Review Summary: Yes No**

Is the purpose of this protocol clear?

Did you find the recruitment practice to be proper?

Does the proposed inducement sound reasonable?

Are the researchers’ experience adequate?

Is there enough evidence that the subjects are adequately informed?

Are the informed consent process/documents appropriate?

Will the researchers protect the participants’ confidentiality?

If risks are necessary, are the minimized to the maximum extent?

Does this study result in benefits that outweigh the potential risks?

Did the researcher(s) clearly explain the data usage?

If there is any reason why you may not be able to check “Yes” for all of the above questions, then please summarize your concern below:

**Applicability:**

Choose the criteria for IRB exemption: Choose an item.

**Correspondences -** Enter review correspondences and paste email threads in the space below:

Recommendation:

Level of Risk:  Lower than Minimal  Greater than Minimal

Exemption DecisionExempt  Revise and Resubmit

Defer (Expedited/Full)  Not a “research”

     

(Reviewer’s OC ID) (Date of Determination)