**Truman State University**

**Application for Approval of Investigations**

# Involving the Use of Human Subjects

This application can be found at http://irb.truman.edu

*Handwritten applications will not be accepted!*

This application must be completed by the Investigator and sent to the Grants Office, or to the appropriate Departmental Peer Review Committee. Peer Review Committees **may not** review projects that: (1) are externally funded; (2) place the subject(s) at more than minimal risk; 3) involve minors or other vulnerable populations; (4) investigate behaviors and or experiences related to sensitive topics; (5) are used as partial fulfillment of Master's Degree requirements.

For questions about the review process contact the Grants Office or the IRB member in a specific academic department.

1. Investigator(s) Name(s): Academic Department:

2. Project Title:

3. Expected Starting Date: Expected Completion Date:

4. E-mail:

5. Phone:

6. Is this project:  A Master's thesis  An MAE case study

A class project  Being conducted in a foreign country

Publishable research  Being submitted for external support

7. Has this project previously been considered by the IRB or by a peer review committee?

O Yes O No If yes, give approximate date of review:

8. If you are a student, complete the following:

Faculty Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*\*\*\* If submitted externally, a complete copy of the proposal must be submitted to the IRB. \*\*\*\*

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## Certification and Approval

**Certification by Investigator**: I certify that (a) the information presented in this application is accurate, (b) only the procedures approved by the IRB or Peer Review Committee will be used in this project, and (c) modifications to this project will be submitted for approval prior to use.

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Signature of Investigator Date

**Faculty Sponsor**: If the Investigator is a student, his/her Faculty Sponsor must approve this application.

I certify that this project is under my direct supervision and that I accept the responsibility for ensuring that all provisions of approval are met by the investigator.

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Signature of Faculty Sponsor Date

1. **Description of the Subjects**
2. Approximately how many subjects will be involved? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

B. Subject Population (check all that apply)

 Adults  Minors  Prisoners

 Intellectually Disabled  Mentally Ill  Physically Ill

 Disabled  Special Education  Other (explain below)

Describe:

C. How will subjects be recruited? What criteria will be used to select subjects AND/OR what criteria will be used to exclude individuals? (If advertising for subjects, include a copy of the proposed advertisement.)

D. For projects conducted on minors (PreK - 12) in schools or academic settings:

What grade are the students in? Approximate age of students?

What subject (secondary)? How many classes involved?

Name of School Location

\*Signed Principal's Consent Form should be attached

1. **What is the Purpose of this project?**
2. **Activities Involving Human Subjects**
3. Describe in detail the activities and procedures involving the subjects. Include the expected amount of time subjects will be involved in each activity and where the activities will be conducted.

### Confidentiality and Anonymity

How will the data be collected? (Check all that apply)

 questionnaires (submit a copy)  observations (describe how they will be conducted)

 interviews (submit sample of questions)  standardized tests (attach copy if possible; list names)

 test (submit a copy if possible)  task(s) (briefly explain)

 video tapes (how will they be used)  computer entries (explain)

 audio tapes (how will they be used)  other (explain below)

Description of above or explain if applicable:

1. Explain the procedures for collecting, recording and storing data during the study.
2. Who will have access to the data during the study? (Access should be limited to protect the identity of subjects and confidentiality of subject responses)
3. Explain what will happen to the data once the study in completed. Is there a need to keep the data or will it be destroyed? If kept, how long and where will it be stored, how will confidentiality be ensured, who will have access to it? If you plan to keep data, be sure you have asked for permission to keep the data in your consent document.

### Informed Consent

Unless authorized by the IRB, no investigator may involve a human being as a subject in research under the auspices of the University unless the investigator has obtained the informed consent of the subject and/or the subject's legally authorized representative.

**Attach a copy of all consent documents that will be used to this application.**

For further information about the informed consent processes review the information on the IRB web site in the Forms section under 'Consent Form Template.'

1. Explain the procedures that will be used to obtain consent:

B. Federal regulations require that each of the following elements should be provided to each subject.

Please mark any component that is NOT included in your consent document and explain below.

 An explanation of the purpose of the project and the expected duration of the subject's participation.

 An explanation of the activities or procedures to be followed.

 A description of any risks or discomforts to the subject.

 A description of any benefits of the project to the subject or to others.

 A statement that participation in this project is voluntary and the subject may withdraw at any time.

 A statement describing the extent to which confidentiality of records identifying the subject will be maintained.

 An explanation of whom to contact with questions regarding the study.

Explain request for waiver of any component listed above or other special conditions related to informed consent.

1. **Benefits, Risks, and Costs of this Study**
2. What are the potential benefits to the subjects, to the field or discipline, or to the University?
3. Will compensation (money, extra credit, etc.) be offered to the subjects? If so, how will it be dispersed?
4. What risks or discomforts are most likely to be encountered by the subjects? Please consider carefully.

 employability  embarrassment, emotional stress or discomfort

 financial or personal reputation  loss of confidentiality

 criminal or civil liability  deception (debriefing required)

 physical stress or discomfort  other (explain below)

1. What safeguards will you use to eliminate or minimize these risks? If there is the possibility of adverse reactions by the subjects, explain where the subjects can receive help (and include this information in the consent document).