

ST. EDWARD'S UNIVERSITY
APPLICATION TO THE HUMAN SUBJECTS REVIEW BOARD

Title of Study _____

Principal Investigator _____
Name (type or print) _____ Tel. No. _____ E-mail _____

Faculty Sponsor(s) _____
Name (type or print) _____ Tel. No. _____ E-mail _____

School _____

Reason for conducting research: Professional Master's Project
 Class Assignment Other _____

Funding Agency _____ Contract or Grant Number _____

TO BE COMPLETED BY THE RESEARCHER

Please provide a description of the project with special reference to the involvement of human subjects.

_____ I request that my proposed research be granted exemption from Human Subjects Review. The basis for the exemption is number(s) _____ from the Reasons for Exemption List (on reverse side of page). I have provided one copy of the proposal.

_____ My research does not qualify for exemption and needs to be reviewed by the Human Subjects Review Board. I am submitting six copies of the proposal and appropriate forms (see reverse side of this page).

Researcher's Signature _____ Date _____ Sponsor's Signature _____ Date _____

TO BE COMPLETED BY THE HUMAN SUBJECTS REVIEW BOARD

_____ 1. This project is exempt based on category number(s) _____ from the *Reasons for Exemption* list.

_____ 2. This project is not exempt but has been approved the Chair of the Human Subjects Review Board.

_____ 3. This project is not exempt and is being submitted to the HSRB for review.

Signature, Chair HSRB _____ Date _____

REASONS FOR EXEMPTION

1. Subjects are legal adults AND
2. Subjects will not be placed at risk of physical harm
If subjects will be placed at risk, complete the At Risk Form
3. Subjects will not be placed at risk of psychological harm
If subjects will be placed at risk, complete the At Risk Form
4. Subjects will not be misled or deceived
If subjects will be deceived complete the Deception Form
5. Subjects' confidentiality will be maintained
If confidentiality will not be maintained complete the Confidentiality Form

HSRB RISK/BENEFIT ASSESSMENT

R I S K

Regulatory definition of minimal risk: Minimal risk means that 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 (45 CFR 46.102(h)(i)).

Check appropriate risk category:

1. _____ The research involves no more than minimal risk to subjects.
2. _____ The research involves more than minimal risk to subjects.
 - _____ The risk(s) represents a minor increase over minimal risk, *OR*
 - _____ The risk(s) represents more than a minor increase over minimal risk.

B E N E F I T

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

1. _____ The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
2. _____ The research involves the prospect of direct benefit to individual subjects.

*CONSENT FORM FOR A PROJECT IN WHICH
PARTICIPANTS ARE AT MORE THAN MINIMAL RISK*

Identification of Project Project Title _____

Statement of Age I state that I am over 18 years of age, in good physical health, and wish to participate in a research study being conducted by _____ at St. Edward's University, School of _____

Purpose The purpose of the research is

Procedures The procedures involve

Confidentiality All information collected in the study is confidential, and my name will not be identified at any time.

Risks I understand that as a result of the study, I may

Benefits I understand that the experiment is not designed to help me personally, but that the investigator hopes to learn

I understand that I am free to ask questions or to withdraw from participation at any time without penalty.

Name, address, phone number _____

Signature of participant _____ *Date* _____

*HUMAN SUBJECTS REVIEW BOARD
AT RISK FORM*

Risk refers to physical or mental discomfort, embarrassment, and/or invasion of privacy. Complete this form and attach it to the application form. If there are risks, participants must also sign an Informed Consent form that specifically warns them about foreseeable risks. Attach a copy of your consent form to the application.

THE RISK FACTORS

Describe the specific risks to participants (for example, any use of painful stimuli, or situations designed to arouse, stress, or embarrass subjects). Sensitive topics such as sexuality or mental illness may involve risks.

THE BENEFITS

What are the potential benefits of this research?

STEPS TO AMELIORATE RISKS

How will risks be minimized and what are the plans for handling participants who are harmed (include appropriate referral services)?

*HUMAN SUBJECTS REVIEW BOARD
DECEPTION FORM*

Deception involves misleading participants as to the purpose of the study or any of the procedures they will undergo. It is not deception if specific details are omitted from the Informed Consent form or not explained to the participants (e.g., the specific research hypothesis is not described) as long as the general purpose of the study and the procedure are described accurately. However, if a "cover story" or bogus hypothesis is used or if the participant is misled about the procedure, then deception has been used. Complete this form and attach it to the application form. Also attach copies of the instructions to participants, including the deception, copies of any instruments, and the debriefing statement.

THE DECEPTION

What is (are) the specific deception(s) employed in this project?

THE RATIONALE

How would the research be compromised if deception were not employed?

DEBRIEFING

How will debriefing be handled?

*HUMAN SUBJECTS REVIEW BOARD
CONFIDENTIALITY FORM*

Anonymity is maintained when a participant's identity is in no way associated with the data obtained from the participant. The participant's name and any other identifying information (description, social security number, etc.) must not be associated with data obtained from him or her. Anonymity is not required, however; if anonymity is not maintained, then confidentiality must be. Confidentiality requires that the data be stored in a secure manner and that all persons who have access to the data be bound not to discuss the data. Complete this form and attach it to the application form if data will not be obtained anonymously. Attach a copy of the data form(s) you will use.

PARTICIPANT IDENTIFICATION

What is the extent of participant identification on the raw data form and in subsequent data analyses?

DATA HANDLING PROCEDURES

What are your procedures for collecting, processing, and securely storing data (including who will have access to it)?

DATA DISPOSAL

What will be done with the data when the study is complete?