RESEARCH AND EXPERIMENTATION REVIEW BOARD
TEXAS LUTHERAN UNIVERSITY

PROTOCOL REVIEW REQUEST FOR HUMAN PARTICPANTS

Research and Experimentation Review Board is responsible for protecting the welfare and rights of individuals who are subjects of any research conducted by faculty, staff, or students of Texas Lutheran University. Approval by the Safeguards Committee must be obtained prior to the initiation of a project, whether conducted on-campus or off-campus.

Please submit this form electronically to the Committee Chair; include any research-related materials such as informed consent forms, questionnaires, or other documents to be utilized in data collection or may be needed by each committee member to review the research protocol. Send **one copy** of the complete proposal and a signed research protocol to the chair. Should data collection include videos or other types of media, one copy is required.

Date: _____

1. **Project Title:**

   a. Project Period:

   b. Application type: _____New _____Revision _____pilot

2. **List the name and Faculty/Students/Staff status of the person(s) conducting the research.**

   a. Principal Investigator and preferred contact information:

   b. Faculty Spenser and Department:

   c. Others investigators and roles:

3. **Funding (complete this portion only if you have a grant that is connected to the execution of your project)**

   a. Agency:

   b. Amount Requested:

   c. Due date for application:

4. Summarize the objective(s) of the research, including what you expect to learn or demonstrate:

5. Describe subject population and plans for the recruitment of subjects and the consent procedures to be followed. Is participation completely voluntary? May subject withdraw at any time without a penalty? Will any kind of incentive be offered to participants? Include a copy of Informed Consent Form, which must include, at a minimum: statement of purpose of research, duration of participation for the subject, procedures, description of any experimental procedures, description of possible risks/discomforts and benefits, measures to protect confidentiality, compensation, statement regarding voluntary participation, ability to withdraw without penalty, procedure for withdrawal, who to contact at the university should there be questions about the research. This information should include name, title, address, and phone number of the principle investigator and faculty sponsor. There should be space at the bottom of the form for the date and both the printed name and signature of the participant and the person obtaining the informed consent.

6. Provide a detailed step-by-step summary of the procedures to be utilized during the course of the project. Specifically identify those procedures, tests, or activities, which will be used with attached appendices listed and provided for all materials. If pilot work is being done, sample materials are appropriate as long as they are representative of the type of materials being used.

7. Describe how the procedures reflect respect for the privacy, feelings, and dignity of subjects, avoid an unwarranted invasion of privacy, and minimize risks as much as possible. If protected health information (PHI) is to be collected, describe the procedures of de-identification, the minimum information necessary to be disclosed, and who will have access to the information. In addition, describe conditions for a designated individual's access to the PHI.

8. Describe and assess any potential attendant risks. Risk can be defined as "the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant" Indicate any physical, psychological, social, or privacy risks which subject may incur. (This includes any request for the subject to reveal any PHI and/or embarrassing, sensitive, or confidential information about themselves or others). If any deception is to be used, describe it in detail. Include plans for debriefing.

9. Describe the procedures to assure confidentiality in the use, storage, and disposal of the primary data. (Upon completion of the research, copies of subjects' signed consent and PHI authorization forms are to be stored separately from the data). If PHI is to be re-identified at a later date, describe the procedures in doing so.

10. Describe how the outcomes of this project will contribute to a professional body of knowledge and/or benefit human welfare.

11. Provide proof that you have completed the computer-based training for Human Participant Protection Certification
http://phrp.nihtraining.com/users/login.php

12. Attachments (attach the following items)

a. Consent form
b. All appendices from section(s) #6 & #7
c. Human Participant Protection Certification
d. Curriculum Vita of principle investigator
e. Contractor assurances when applicable
f. Any other supporting documentation

Principal Investigator Name (Printed):_____ Date: _____

Principal Investigator Signature: _____

Preferred Contact information for the Principle Investigator: _____

Faculty Sponsor: _____ Date: _____

Fall xxx

STATEMENT OF CONSENT

I, the undersigned, do hereby give my informed consent to my participation in the _____ Experiment. I have been informed concerning the procedures
(name of experiment)

I am likely to encounter by participating in this study. (Include a brief general description of Procedures e.g. filling out survey, etc) and I understand that I may withdraw at any time before or during the experiment at my option. I understand my rights and responsibilities as a research participant and I agree to participate.

Recognizing the importance of avoiding bias in the results of this experiment, I agree not to discuss any of the details of the procedure with other participants. I understand that all of the research and evaluation materials will be confidentially maintained. The means used to maintain confidentiality are:

1. My data will be given a code number for research identification, and my name will be kept anonymous.
2. Data, along with consent forms, will be kept in a locked file cabinet.
3. Only the principal investigator, faculty sponsor, and research assistants (insert names) _____will have access to my identification data.

I understand that if I have questions concerning the research, I contact the following persons:

Dr. _____, Faculty Sponsor
Department of Psychology
xxx-xxx-xxxx

_____, Student Research Assistant
Ext. xxxx

_____ _____
Participant's Name (PLEASE PRINT) Date

_____ _____
Participant's Signature Phone Number

_____ _____
If for credit, Professor, class and times E-mail