****

**INSTITUTIONAL REVIEW BOARD APPLICATION FORM**

**PROJECT TITLE:**

**PRINCIPAL INVESTIGATOR**

Name:

Department:

Degree(s):

Campus Mailing Address:

Campus Phone Number:

Email Address:

**FACULTY SPONSOR (completed by students only)**

Name:

Department:

Degree(s):

Campus Mailing Address:

Campus Phone Number:

Email Address:

**CO-INVESTIGATORS:** Provide name, Institution, Contact information (add as many as needed)

1.

2.

3.

**FUNDING SOURCES** (if applicable):

**CHECKLIST:**

\_\_\_ Research proposal

\_\_\_ Participation Population form

\_\_\_ Informed Consent form

\_\_\_ Human Subjects Research Certification (NIH, or CITI)

**If applicable:**

\_\_\_ Parental consent form

\_\_\_ Child assent form

\_\_\_ Questionnaires, testing instruments, interview protocols

\_\_\_ Cover letters, instructions to participants

\_\_\_ Written permission to use copyrighted material

\_\_\_ Recruitment documents (flyers, emails, letters, etc.) \_\_\_ Documentation of Approval by Another IRB

**Participant Population**

Anticipated number: Male \_\_\_\_\_\_\_\_\_\_\_ Female \_\_\_\_\_\_\_\_\_\_\_ Total \_\_\_\_\_\_\_\_\_\_\_\_

Age Range (check all that apply):

\_\_\_\_ 0 - 7 yrs. (submit child assent form and parental permission form)

\_\_\_\_ 8 - 17 yrs. (submit child's assent form, parental permission form)

\_\_\_\_ 18 - 64 yrs. (submit consent form)

\_\_\_\_ 65+ yrs. (submit consent form)

Source/type of participants: (check all that apply)

\_\_\_\_ Lubbock Christian University employees

\_\_\_\_ Lubbock Christian University students

 \_\_\_ Other: specify

Location of participants during research data collection (check all that apply):

\_\_\_\_ Participant’s home

\_\_\_\_ Lubbock Christian University locations: specify

\_\_\_\_ Local hospitals: specify

\_\_\_\_ Community settings: specify

\_\_\_\_ Other academic institutions: specify

\_\_\_\_ Elementary schools: specify

\_\_\_\_ Secondary schools: specify

\_\_\_\_ Other: specify

 Special populations to be included in the research (check all that apply):

\_\_\_\_ Minors under age 18

\_\_\_\_ Pregnant women

\_\_\_\_ Fetus/fetal tissue

\_\_\_\_ Prisoners

\_\_\_\_ Economically disadvantaged

\_\_\_\_ Mentally impaired or disabled

\_\_\_\_ Other: specify

**Research Proposal**

1. State your hypothesis or research question:
2. State the problem and the purpose of the proposed research. Include the present knowledge relevant to it and significance of the results. Include your research questions. Cite appropriate literature.
3. Describe the research procedure. Explain step by step what the participants will be asked to do.
4. State expected sample size and characteristics
5. If you are using special populations, provide rationale for doing so. Special populations are considered “vulnerable” or require special consideration by the federal regulatory agencies and by the IRB (ex. children, pregnant women, mentally impaired or disabled, economically disadvantaged, prisoners.)

# Recruitment Procedures

1. Describe how participants will be identified and recruited.
2. Attach all recruitment information, e.g. Advertisements, bulletin board notices, recruitment letters, electronic appeals, chapel announcements, scripts for in-person announcements. Include information for all possible forums you will want to use to do your recruiting. Make note here of attachment(s).
3. Will participants receive incentives before or rewards after the study? If yes, explain. (Note: this information must be outlined in the consent document.)

# Risks and Benefits of the Research

1. Check all risks (current and potential) that apply. Include any potential late effects.

 \_\_\_\_\_ Administration of drugs, chemical agents, biological agents

 \_\_\_\_\_ Administration of physical stimuli

 \_\_\_\_\_ Changes in diet or exercise

 \_\_\_\_\_ Use of private records (medical/educational)

 \_\_\_\_\_ Possible invasion of privacy of participant or family

 \_\_\_\_\_ Physical deprivation (sleep, nutrition, sensory, social)

 \_\_\_\_\_ Psychological distress

 \_\_\_\_\_ Possible economic risks (missed work, loss of job)

 \_\_\_\_\_ Legal risks

 \_\_\_\_\_ Collection of personal/sensitive information

 \_\_\_\_\_ Other (please specify)

1. Describe the expected frequency, degree of severity and potential reversibility of all risks marked above.
2. Describe the precautions taken to minimize risk and the appropriate credentials of the researchers involved.
3. Why are the risks and inconveniences mentioned above reasonable? What is the expected scientific yield from the project? Please justify the risks in relation to the anticipated benefits to the participants and in relation to the importance of the knowledge that may reasonably be expected to result from the research.
4. Benefits of participation: List any anticipated *direct* benefits of participation in this research project. If none, state that fact here and in the consent form. Payment is not considered to be a benefit of participation. Any benefits of treatment should be listed as potential benefits. Note that the knowledge gained from the study could produce a benefit to society rather than the individual.

# Confidentiality of Data

1. Describe provisions made to maintain confidentiality of data. How will the data be coded? Will it be necessary to track subjects over time and match them with the data? If tracking is necessary, how will it be done?
2. Who will have access to raw data? Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel (e.g., school officials, medical personnel)? If yes, who, how, and why? Describe the procedure for sharing data.
3. Where will the data be kept? How will the data be secured?
4. How will survey responses, notes, audio and video tapes be disposed of? (Disposition of notes, survey responses audio and video tapes should be included in consent form.)
5. When will the data used for analysis be eliminated from computers (the standard is three years if the study is not a longitudinal study)?

# Informed Consent Process

1. Capacity to consent. Will all adult participants have the capacity to give informed consent? If not, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined.
2. Is the informed consent document attached?
3. How will participants’ understanding be assessed? What questions will be asked to assess the participants’ understanding; will there be written responses; will understanding be assessed at other points in time? Will participants be given an opportunity to ask questions?
4. In relation to the actual data gathering, when and where will consent be discussed and documentation obtained, for example, immediately prior to the data collection or several days before? Be specific.
5. Will the investigator(s) be securing all of the informed consents?
6. If no, name the specific individuals who will obtain informed consent and include their job title and a brief description of your plans to train these individuals to obtain consent and answer participants’ questions.

***PRESENTATION OF FINDINGS***

1. Where will the findings be presented?

Please attach all questionnaires, testing instruments, interview protocols, cover letters, instructions to participants, written permission to use copyrighted material, recruitment documents, etc.