JUDSON UNIVERSITY INSTITUTIONAL REVIEW BOARD
RISK ASSESSMENT FOR RESEARCH INVOLVING HUMAN SUBJECTS

This protocol must be approved by the Judson University Institutional Review Board *before* data are collected. Please refer to the Judson University IRB Procedures and Policies manual available at www.judsonu.edu/irb.

_____ _____

Name Date

_____ _____

Program or Department Supervising Professor

_____

Title of Proposed Research (from IRB application)

Read the following *Risk Level Assessment Form* (next page) and mark **all** items in **each** risk category that apply to your research. Record the totals from each category below:

No risk: _____ Minimum risk: _____

Moderate risk: _____ High risk: _____

Be sure your IRB Application thoroughly describes the following:

If your research involves vulnerable populations, include the following in the IRB application.

1. If your subjects are MINORS: Describe how you will obtain each child's verbal or written assent as well as written consent from the child's legal guardian. Note: At ANY level of risk, informed consent must be obtained from both the parent or guardian AND the minor before data is collected. If consent is given by the minor, but not by the parent or guardian, data should not be collected. Describe the means to be taken to reduce risks and to safeguard the subjects. Describe why alternative, less risky methods of research would not be possible.

2. If your subjects are VULNERABLE TO "UNDUE INFLUENCE": For example, anyone over whom you have authority or anyone in your care is vulnerable to your influence (students, clients, parishioners, employees, etc.). Describe how the subject's right to decline participation without negative consequences will be preserved. Describe the means to be taken to reduce risks and to safeguard the subjects. Describe why alternative, less risky methods of research would not be possible.

3. Other "VULNERABLE POPULATIONS": For example, those who are institutionalized or are unable to make their own decisions are vulnerable. Describe the vulnerability of the subjects and how the risk caused will be minimized. Describe actions to be taken to reduce risks and safeguard the subjects. Describe why alternative, less risky methods of research would not be possible.

If the Principal Investigator is a student:

Signature of supervising professor _____

Date _____

RISK LEVEL ASSESSMENT FORM

This checklist is provided to help researchers, reviewers, and the IRB to consider thoroughly the research proposal in light of the potential risk to human subjects and does not **in itself** determine the decision or recommendations of the IRB. It is not the intent of the IRB to use this risk level assessment tool to comment on the merits, quality, or design of the research beyond the potential risks to human subjects.

Based on your research purpose, population, and methods, **check all items in each category that apply to your research, and indicate the totals on p. 1.** It is not uncommon for items to be checked in multiple categories, and it may take only one risk factor to place the entire research project in a particular category. You may be able to justify the value of a research project being at a particular risk level, or you might describe procedures that reduce the potential impact of an acknowledged risk factor in your IRB application.

NO RISK LEVEL CRITERIA:

____ People will be observed randomly in a public place where there is no personal identification of subjects.
____ Subjects are not aware of the observation and do not have direct contact with the researcher.
____ Only public information will be utilized, such as phonebooks, directories, or other widely published lists.
____ Data are collected without any identifying information. There is no possible or imaginable way to trace responses back to subjects.
____ Data will be used collectively in a statistical manner, and no one individual's response can or will be tracked.
____ **TOTAL for NO RISK**

MINIMAL RISK LEVEL CRITERIA:

____ Subjects are interviewed or otherwise contacted to solicit participation.
____ Inquiries are made regarding to basic identifying information such as age, gender, ethnicity, etc.
____ Subjects are asked to answer general questions regarding non-personal information.
____ Subjects are asked to give opinions or attitudes toward commonplace matters such as general trends or other benign topics.
____ The research will not in any way influence or affect the subject socially, psychologically, or spiritually.
____ The collection of required information will not take more than 4-5 minutes of the subject's time.
_____ **TOTAL for MINIMAL RISK**

MODERATE RISK LEVEL CRITERIA:

____ The subject is asked to reveal personal information regarding individual opinions, background, behaviors, attitudes, or beliefs.
____ Subjects will be selected to participate based upon a particularly unique characteristic or group membership (similar position, training, background)
____ Subjects will be selected to participate based on an extraordinary life experience.
____ Topics or questions raised are politically, emotionally, culturally, spiritually, or psychologically sensitive.
____ Individual or group presentations, phone calls, or questionnaires will be used to solicit participation in the research.
____ The research objective is not revealed at the outset to the subject in a direct and straightforward manner, such as research that requires that the subject be naïve regarding the research in order to participate objectively.
____ Subjects are required to reflect on their own behavior, values, relationships, or self in such a way that one might be influenced or affected, and/or anxiety or concern might be raised about the subject matter of the research.
____ The subject may have regrets, concerns, afterthoughts, or reactions to the research method after data collection is completed.
____ The subject may become tired, weakened, or be mentally or physically affected as a result of the research method.
____ The research may inconvenience subjects by causing a delay or intrusion into their routine or schedule.
____ Involvement in the research will require more than 5 but less than 60 minutes of the subject's time (outside of normal learning activities if the study is conducted in a classroom.)
____ **TOTAL for MODERATE RISK**

HIGH RISK LEVEL CRITERIA:

____ Subjects are asked or led to reveal highly personal information in areas such as close relationships, trauma, sexuality, or potentially immoral, unethical, or illegal acts.
____ The topic or research methodology will raise issues that are highly charged politically, emotionally, culturally, psychologically, socially, or spiritually.
____ The research will involve minors who do not have the authority and/or ability to give fully informed consent to participate.
____ The research will intentionally, or by design, involve persons who may be of legal age yet who are dependent on others due to a chronic or crisis health concern, developmental delays, advanced age, a language barrier, and/or incarceration, which may impair the subject's ability to give fully informed consent.
____ Subjects will be selected to participate based upon a particular diagnosis, disorder, or physical or mental health concern.
____ The subject is likely to be affected emotionally, socially, or psychologically through the research over the short and/or long term, to the extent that debriefing or other reparative interventions are built into the research design (not solely for preventative purposes).
____ The research design calls for deception of the subject at any level.
____ The research involves physical manipulation, contact or touching either with the researcher or between subjects, physical exercise, and/or any medical procedure.
____ The research itself or the information obtained from the subjects may have immediate and/or long term political, legal, economic, and/or social consequences for the subjects.
____ Involvement in the research will require more than 60 minutes of the subject's time (outside of normal learning activities if the study is conducted in a classroom.) or significantly influence the person's routine and/or activities.
____ **TOTAL for HIGH RISK**