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| **INSTITUTIONAL REVIEW BOARD**  **Texas Wesleyan University**  **1201 Wesleyan**  **Fort Worth, TX 76105** |  |



**USE OF HUMAN PARTICIPANTS**

**INITIAL REVIEW PROPOSAL FORM**

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| **Date Submitted:** |  |
| **Title of Project:** | |
| **Principal Investigator:** | **Telephone Number:**  **E-mail:** |
| **Faculty Sponsor:** If student is principal investigator | **Faculty Sponsor Telephone:** |
| **Sponsoring Department:** | **School:** |
| **Multi-year Project:** Yes  No | **Project Period:** Enter in months the time span needed for project completion |
| **External Funding Agency:** Enter any fund granting entities (e.g., NIH) | |



**PRINCIPAL INVESTIGATOR ASSURANCE**

I agree to use procedures that safeguard the human participants involved in this research and that conform to TWU policies and DHHS and FDA regulations. If significant changes in the project procedures involving human participants are warranted, I shall seek prior approval for such changes from the Institutional Review Board (IRB), and I shall agree to follow the advice of the IRB. Exceptions may occur when it becomes necessary to eliminate apparent hazards to the human participants. I further agree to report to the IRB any unanticipated complications or untoward incidents with respect to human participants as soon as they occur. (Principal investigator signs here)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator Date**



**SCHOOL DEAN ACKNOWLEDGEMENT**

I understand that the proposed research project will be conducted with the School’s sponsorship. My signature as School Dean signifies that the proposed research has been reviewed by me for the purpose of answering any questions that may be brought to my attention

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**School Dean Date**

**USE OF HUMAN PARTICIPANTS CHECKLIST**



The purpose of this checklist is to indicate those aspects of your application, which require particular consideration to assure protection of human research participants. Please complete the checklist and return it with your application. Using the outline provided, attach a summary of your project and include the consent form that you intend to use.

Please submit your completed application either electronically or in hardcopy to Dr. Lisa Dryden at ldryden@txwes.edu. Make sure to include **all** research-related materials such as informed consent forms, external permission to collect data, questionnaires, and/or any other documentation used in conducting the project so that board members may review the research proposal accurately. Failure to provide these

documents may delay IRB approval.



Check the response and complete the blanks for each of the following that best describe the research.

1. Risk Category: No Risk \_\_\_ Minimal Risk \_\_\_ More than a Minimal Risk \_\_\_

2. Benefit Category: Benefit to Participants: Yes \_\_\_ or No \_\_\_ Benefit to Others: Yes\_\_\_ or No \_\_\_

3. Requested Category of IRB Review: Exempt \_\_\_\_ Expedited \_\_\_ Regular \_\_\_ Emergency \_\_\_

4. If an emergency review is requested, explain in a cover letter the nature of the emergency.



5. Participant Population: Indicate whether the following are involved as the **focus** of the research project. It is not necessary to mark each group that *might* participate (such as pregnant women).

|  |  |  |  |
| --- | --- | --- | --- |
| General Population (no protected group) |  | Senior participants (Over 65 years old) |  |
| Minors (less than 18 years old) |  | Students |  |
| Fetuses: \_\_ Nonviable \_\_ Viable |  | Minorities |  |
| Pregnant Participants |  | Inpatients |  |
| Prisoners |  | Outpatients |  |
| Mentally Retarded |  | Non-English Speaking |  |
| Mentally Impaired |  | Immigrants/Aliens |  |
|  |  | Other |  |

For each group selected, include justification for their participation in Section 3 of Project Summary.



6. Additional Information:

A. Sex of participants: Male  Female  Both

1. Participant age range: \_\_\_\_\_\_\_\_\_ C. Estimated number of participants involved:
2. Estimated duration of study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Duration of each participant’s time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Will participants be paid to participate? Yes  No
5. State type and amount of incentive to be offered:
6. Will incentive be prorated for participants who withdraw from participation? Yes  No

**PROJECT SUMMARY**



**Title:** Be specific; a short, descriptive title is better than the long title for a thesis or dissertation.

1. **Purpose**

In one sentence state the purpose of the research. In a brief paragraph, summarize the objectives of the research, including what you expect to find or demonstrate

**II. Background**

In one to two paragraphs describe the research literature most related to the research purpose.

**III. Recruitment of Participants**

Describe participants, plans for recruitment, and consent procedures to be followed. Include criteria for participant inclusion/exclusion. Is participation voluntary? May participants withdraw without penalty? Any incentive for participating?

**IV. Research Materials & Procedures**

Briefly describe the procedures used in the project. Describe specific methods, measurement tools, and data collection activities that will be used. If measures do not belong to the public domain, have you acquired permission to use them?

**V. Potential Risks**

Assess and describe any potential risks to participants. Identify any physical, psychological, social, or privacy risks that participants may incur.

**VI. Procedures to Maintain Confidentiality**

Describe the procedures used to assure confidentiality in the use, storage, sharing, and disposal of the data collected. If participant identifiers are collected, indicate why they are needed and how they will be protected.

**VII. Potential Benefits**

Describe how the outcomes of this project will contribute to the body of knowledge in this research area and/or the benefits to human welfare.

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**CONSENT TO PARTICIPATE IN RESEARCH**

**Title of Project:**

**Principal Investigator:**

**Sponsor:**

**Principal Investigator/Sponsor Contact Information:**

Include how and when participants may reach PI. Include email address or phone numbers for day, night, and weekend use.

You are being asked to participate in a research study. Persons who participate in research are entitled to certain rights. These rights include but are not limited to the participant’s right to:

1. Be informed of the nature and purpose of the research;
2. Be given an explanation of the procedures to be followed in the research, and any drug or device to be utilized;
3. Be given a description of any attendant discomforts and risks reasonable to be expected;
4. Be given a disclosure of any benefits to the participant reasonable to be expected, if applicable;
5. Be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the participant, their relative risks and benefits;
6. Be informed of the alternatives of medical treatment, if any, available to the participant during or after the experiment if complications arise;
7. Be given an opportunity to ask any questions concerning the research and the procedures involved;
8. Be instructed that consent to participate in the research may be withdrawn at any time, and the participant may discontinue participation without prejudice;
9. Be given a copy of the signed and dated consent form;
10. And be given the opportunity to decide to consent or not to consent to participate in research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the participant’s decision.



**CONSENT TO PARTICIPATE IN RESEARCH**

**Title of Project:** Be specific

**Project purpose:** Describe the project in language the subject can easily understand

**What participants will be asked to do in the project:**

Explain specifically what they will be asked to do; specify time committment and how data will be used; are responses recorded?

**Possible risks and discomfort:**

Include any foreseeable risks or discomforts which the subject may experience or state that “No foreseeable risks are involved in this study"

**Possible benefits:**

Include any foreseeable benefits to the subjects or state that “This study is not expected to be of any direct benefit to you” and explain how the study will benefit others or contribute to your field of study

**Alternatives to participation:**

Indicate whether participants are compensated for their participation and if there is an alternative to participating

Your signature below indicates that you have read or have had read to you all of the above, you understand your rights as a research participant, and you voluntarily consent to participate in this study. Note: the participant signs this page, NOT the researcher.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant’s Printed Name**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant Signature Date**