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FORM A APPLICATION

RESEARCHERS: This form is to be used for all Research Proposals involving Human Subjects. Please discuss your proposed research project with your Department's Coordinator before preparing this application. Remember that all research using human subjects must be approved before the subjects/participants are contacted and the research begins. Approval of your application indicates that your research is in compliance with campus research policies and procedures.

Form A Header The header on the first page of every Form A should be prepared as follows:
[Note: Please Number ALL Pages of the Form A Application]

FORM A

IR Control Number: # _____

Date Received by RRC:_____

TENNESSEE WESLEYAN UNIVERSITY

Application for Review of Research Involving Human Subjects

I. IDENTIFICATION OF PROJECT

1. **Principal Investigator (PI) or Co-Principal Investigators (Co-PI):**

   - The person or persons responsible for the design and implementation of the research project are considered the PI or Co-PIs and should be listed in this section.
   - For each PI or Co-PI, include the name of their department, the mailing address (home or campus), telephone number, and e-mail address. All communications and correspondence will be directed to the first person listed as principal or co-principal investigator, unless otherwise requested and noted on this form. Also identify PI or Co-PI as undergraduate or graduate student, faculty, or staff.

   Faculty Advisors: For projects that will form the basis of students' project, theses and/or dissertations, students should be listed as investigators and their faculty advisors should be identified in this section. The names of the advisor's department or unit, campus address, campus telephone number, and e-mail address should be included. (Please note

that faculty advisors are not automatically considered project investigators unless they are listed as a PI or Co-PI Section I.)

Department: State the name of the department located in the college.

2. **Project Classification:** Provide an appropriate description (e.g., Research Project, Dissertation, Thesis, etc.) of your project activity.

3. **Project Title:** Provide the title of your project. If a title has not been determined, please provide a tentative title for the project. If external support (grant or other) is sought or has been obtained, use the title of the project listed on the application for external support in creating a title for this project.

4. **Starting Date:** Specify an intended starting date or state "Upon Research Review Committee Approval".

5. **Estimated Completion Date:** Provide a general date estimate including time for completion of data collection, analysis, and reports.

6. **External Funding:** (If this project is not externally funded, enter "N/A" and go on to Section II.): If external funding is sought or was obtained for this project, please provide the following information:

   a. Grant/Contract Submission Deadline:

   b. Funding Agency:

   c. Sponsor ID Number (if known)**:**

   d. RRC Assigned Proposal Number (if known)**:**

II. PROJECT OBJECTIVES:

In this section, please provide a brief rationale for the project. Use non-technical language so that reviewers from other disciplines can understand and identify the objectives and goals of the research project. The statement of objectives must be clear and accurate, revealing to reviewers the anticipated significance of the proposed research. If you are seeking external support for this project, the objectives listed in this section **must** match the objectives and goals made in any application for support. In addition, objectives listed in this section should fully match the objectives described to participants in the consent form. (If investigators have reason to withhold information about objectives from participants, they must justify this action in Section VII.)

III. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

- Describe your participants, number of participants anticipated for recruitment, including criteria for selection and/or exclusion. Explain the rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized

individuals, or any participants whose ability to give voluntary and informed consent may be questioned. Give a rationale for projects that restrict participants based on gender, age, or mental/physical challenges.

- Identify the source of your participants (school systems, hospitals, colleges and universities, private companies, religious groups, governmental entities, community groups, etc.) and describe the methods for recruiting participants. Letters of permission are required from entities other than TWU. Letters of permission should authorize the investigators to contact potential participants, to use of the facilities, or records of that entity. Letters must accompany the Form A application at time of submission for review.
- Describe any potential "conflicts of interest". Disclose any relationship between researchers and participants - such as, teacher/student; employer/employee; or superintendent/principal/teacher.
- If an incentive is to be used, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Keep in mind that the value of incentives to participants is relative, and reviewers may consider highly valued incentives coercive.

Investigators who plan to recruit TWU students and offer extra course credit for student participation must follow the procedures maintained by the department whose classes are used, attaching the Departmental letters of permission to the Form A application.

IV. METHODS AND PROCEDURES

- Clearly and concisely describe in non-technical language the data collection and experimental research methods used in this project that will directly involve human participants. This section should be consistent in every detail with the description provided to participants in the consent form or procedure. (Any omission or deviation in the methods and procedures information provided in the consent process must be justified in Section VII.) Do you need to obtain permissions from anyone for recruiting purposes?
- Include non-technical descriptions of stresses to participants, experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video and audio recordings.
- If the project involves audio taping, videotaping or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes or film, and on what basis they will have access.
- If the tapes or film are to be used in the future, explain the procedures for obtaining participants' informed consent for those uses, and the conditions under which the tapes or film would be used.
- Explain how data collection will be accomplished, including time requirements, and clearly distinguish between control and comparison, and experimental and treatment participant groups. What instruments are you using? In detail, describe how you will analyze and interpret the data.

V. SPECIFIC RISKS, PROTECTION AND CONFIDENTIALITY MEASURES

- Specify all potential risks of the proposed research to participants, in terms of the nature and amount of potential risk, stress, or discomfort, and assess the likelihood and its seriousness.

Describe precautions you will take to minimize risk and assess the effectiveness of these protective measures. Identify specific controls, screening methods, and follow-up to assure no residual physical, psychological, or social damage to the participants.

- Include the methods and provisions by which you will address the issue of anonymity or confidentiality of data. **Note** that anonymity is only possible if the investigator cannot discover the participant's identity from data collected. In either case, describe how you will maintain the confidentiality of the participants' data. Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures. Identify to whom access is given.
- If the confidentiality of the participants' identities or data cannot or will not be protected, please state how you will inform participants of this fact before their participation.

VI. BENEFITS

Evaluate the reasonableness of the risks stated in Section V in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants and/or to society. If the risks are minimal, please state that the risks are minimal and include a statement of anticipated benefits.

Note that in most research projects, the only relevant benefits are those that contribute to generalizable knowledge in a field of research. In these cases, participant benefits are incidental. Please do not inflate the significance of incidental benefits to participants in your Form B application or your informed consent procedures.

Please note that payment for participation in research is an incentive for participation, and should not be considered a "benefit" of the research.

VII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

Please state the methods you will use to obtain legally effective informed consent, assent, or permission (as applicable) from participants or participants' legally authorized representatives. Clearly describe how you will seek consent from participants in a manner that allows them sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence. Indicate that the language used in your informed consent procedure is understandable to your participants or their legally authorized representatives. As you describe your informed consent procedures keep in mind that the following procedures are typically used to obtain legally effective informed consent:

1. Use of a written consent document with all the basic elements of informed consent. This form is signed by the participant or a legally authorized representative and an extra copy provided for participant's use and information.

2. Use of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to each participant or their legally authorized representatives. Written summaries of what is to be said to the participant should be attached to the Form A for approval by the RESEARCH REVIEW COMMITTEE. The "short form" is to be signed by the participant or a legally authorized representative, and by a witness to the oral presentation and participant's signature. An extra copy should be provided for the

participant's use and information.

3. Information sheet - written consent document indicating the basic elements of informed consent. The information sheet is not signed.

VIII. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

Please provide a brief description of the facilities that will be used during the project research, with an evaluation of their adequacy for the intended project. Include a brief description of the equipment to be used for storage and analysis of data.

If a project is to be conducted in a non-TWU facility, an original letter of permission for access and use to this facility must accompany the Form A application. Letters of permission must be on the letterhead of the organization and signed by authorized officials. If public school or school system facilities are to be used, letters of permission from authorized officials in the superintendent of schools office, and possibly from school principals must accompany the Form A.

IX. RESPONSIBILITY OF THE PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S)

You must enter the following information verbatim in Section IX:

By compliance with the policies established by the Research Review Committee of Tennessee Wesleyan University, the principal investigator(s) subscribe to the principles stated in "The Belmont Report" and standards of professional ethics in all research, development, and related activities involving human participants under the auspices of Tennessee Wesleyan University. The principal investigator(s) further agree that:

1. Approval will be obtained from the Research Review Committee prior to instituting any change in this research project.

2. Development of any unexpected risks will be immediately reported to the Research Review Committee section.

3. An annual review and progress report will be completed and submitted when requested by the Research Review Committee.

4. Signed informed consent documents will be kept for the duration of the project and for at least three years thereafter at a location approved by the Research Review Committee.

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X. SIGNATURES

When you submit your Form A application for review note that all signatures must be original. As your Form A application moves through the review process, you should maintain two identical Form A applications both with original signatures. One of these should be kept on file with the PI or Co-PI. The other is to be submitted to the Research Review Committee for review.

Use the following format to prepare your signature section (as needed, add signature lines for all Co-Principal Investigators, collaborating and student investigators, faculty advisors, and additional department heads).

Principal Investigator _____
(Print Name)

Signature _____ **Date** _____

Co-Principal Investigator _____
(Print Name)

Signature _____ **Date** _____

Student Advisor (if any) _____
(Print Name)

Signature _____ **Date** _____

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XI. REVIEW AND APPROVAL

The application described above has been reviewed and approved by:

Department Head _____
(Print Name)

Signature _____ **Date** _____

V.P., Academic Affairs_____
(Print Name)

Signature _____ **Date** _____

Protocol sent to Research Review Committee for final approval on _____
(Date)

Approved by:

Chair, Research Review Committee _____
(Print Name)

Signature _____ **Date** _____