**INSTITUTIONAL REVIEW BOARD PROTOCOL REVIEW REQUEST**

**Please delete these instructions before submitting to the IRB.**

The TCU Institutional Review Board (IRB) is responsible for protecting the welfare and rights of the individuals who are participants of any research conducted by faculty, staff, or students at TCU. Approval by the IRB must be obtained prior to initiation of a project, whether conducted on-campus or off-campus. While student research is encouraged at both the undergraduate and graduate level, only TCU faculty or staff may serve as Principal Investigator and submit a protocol for review.

Please submit this protocol electronically to IRBSubmit (MS Word preferred). Also submit a consent document, HIPAA form if applicable, Protecting Human Research Participants Training certificates, recruitment materials, data collection sheets (MS Excel) and any questionnaires or other documents to be utilized in data collection. **We prefer that you submit protocol and informed consent materials as separate Word documents**. You may include other related documents as a pdf. A template for the consent document and HIPAA form, instructions on how to complete the consent, and a web link for the Protecting Human Research Participants Training are available on the [TCU IRB webpage](https://research.tcu.edu/research-compliance/irb/). Submission of Full Board protocols should be submitted at minimum two weeks prior to the next Full Board meeting. All others can be submitted on a rolling basis.

\*NIH Guidelines require IBC review for any genetic engineering research that receives NIH funding or takes place at sites receiving NIH funding. Regardless of funding if you will be working with Recombinant DNA and synthetic nucleic acid molecules, Infectious agents, Biological toxins, or **Human-derived tissues, fluids (blood or saliva), cells** an IBC application must be submitted and approved prior to receipt of IRB approval.

1. **Date:**
2. **Study Title:**
3. **Principal Investigator (must be a TCU faculty or staff):**
4. **College/School:**
5. **Other Investigators: List all faculty, staff, and students conducting the study. For those not affiliated with TCU, please provide their names and institution.**

1. **If you *have internal or* external funding for this project –**

**Funding Agency:**       **Project #:**       **Date for Funding:**

1. **If you *intend to seek/are seeking* internal/external funding for this project –**

**Funding Agency:**       **Amount Requested From Funding Agency:**

**Due Date for Funding Proposal:**

1. **Purpose: Describe the objectives and hypotheses of the study and what you expect to learn or demonstrate:**
2. **Background: Describe the theory or data supporting the objectives of the study and include a bibliography of key references as applicable.**

1. **Location: Specifically describe where the research will take place. If on TCU campus please list the exact location. If off campus please describe the exact location(s) where you plan to conduct your research and be prepared to provide a** [**letter of support**](https://research.tcu.edu/wp-content/uploads/2021/08/Letter-of-Support-Guidelines_8.2021.docx) **with your submission. If research is multi-site please refer to the** [**reliance request form**](https://tcu.box.com/shared/static/7z7yf37a5kxp7wr70o26by9l0xmzmwyx.docx)**.**

1. **Subject Population: Describe the characteristics of the participant population.**

**Please list out and state the age range (for adults and/or children), inclusion and exclusion criteria and the total number of participants you plan to recruit:**

1. **Recruitment Procedure: Describe your recruitment strategies in great detail including how and where the potential participants will be approached and by whom. Will recruitment involve a point of contact on behalf of the study team? Who and how will recruitment material(s) be distributed? Describe precautions that will be taken to minimize the possibility of undue influence or coercion. Include copies of the recruitment emails, flyers, social media post, etc. in your submission as attachments or appendices following the** [**recruitment guidelines**](https://research.tcu.edu/wp-content/uploads/2020/09/Recruitment-Guidelines_celan.docx)**.**

1. **Consenting Procedure: Describe the consenting procedure, whether participation is completely voluntary, whether the participants can withdraw at any time without penalty, the procedures for withdrawing, and whether an incentive (describe it) will be offered for participation. If students are used as participants, indicate an alternative in lieu of participation if course credit is provided for participation. If a vulnerable population is recruited, describe the measures that will be taken to obtain surrogate consent (e.g., cognitively impaired participants) or assent from minors and permission from parents of minors. If you need to request consent or HIPAA waivers you can do so in this section. If including Non-English-speaking participants, please include a plan to have consent documents translated after initial approval, by either student or faculty that is fluent in the desired language (give names and document translation and back translation) or a translation service/vendor. If the study involves deception** **explain the process of debriefing statement that will be given to participants and attach the script that will be used by the investigators to orally explain the study.**

1. **Study Procedures: Provide a chronological description of the procedures, tests, and interventions that will be implemented during the course of the study. Indicate the number of visits, length of each visit, and the time it would take to undergo the various tests, procedures, and interventions. If blood or tissue is to be collected, indicate exactly how much in volume and all procedures that will be done with collected samples. Describe when, where and how collection will take place. Flow diagrams may be used to clarify complex projects. For Non-TCU study team members please explain their study team role in detail. If the study involved deception justify the use of deception and explain why deception is necessary to achieve the goals of the study. Explain if alternative methods not involving use of deception were considered and why these methods are not being used.**

1. **Potential Risks and Precautions to Reduce Risk: Include, as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks as well as risks to privacy and/or confidentiality. Also describe what measures have been or will be taken to prevent and minimize each of the risks identified. If any deception is to be used,** **explain if use of deception is likely to cause the participant psychological discomfort (i.e., stress, loss of self-esteem, embarrassment) while the deception is taking place. Explain how this risk will be minimized during the experiment and after the experiment is complete (i.e. full debriefing).**

1. **Potential Benefits: Describe the potential benefits of the research to the participants, to others with similar problems, and to society (Compensation is not a benefit to participation). If using deception describe how the potential benefits of the research justify the deception.**

1. **Compensation: Describe in detail if participants will be compensated for their time and effort to complete the study procedures. Compensation can take on many forms and can include monetary (cash, gift cards, etc.) and/or non-monetary (gifts, course credit, extra credit, SONA credit etc.) payments to subjects. Compensation cannot be random, if utilizing a raffle, you must describe how you will choose which participants (every 5th or 10th or 15th for example). Your consent document should clearly specify what form(s) and how compensation would be provided to participants in your study and the amount of payment. You must also include and describe if participants can still receive full or partial compensation should they either withdraw or are not able to complete the study procedures for any reason. For non-monetary items, please provide an approximate value.**

1. **Procedures to Maintain Confidentiality: Describe how the data will be collected, de-identified, stored, used, and disposed to protect confidentiality. If protected health information is to be re-identified at a later date, describe the procedure for doing so. All signed consents and hard data must be stored for a minimum of 3 years in a locked filing cabinet (and locked room) in the principal investigator’s office, lab, or storage closet at TCU. Your professional society may recommend keeping the materials for a longer period of time.**

1. **Data Analyses: Describe how you will analyze your data to answer the study question.** **Describe any procedures that will be used to ensure the accuracy and quality of collected data. If participants withdraw from the study, describe what options they will have in terms of their data being used or removed from the study. If collecting blood or other biospecimens please indicate what and where analysis (on campus or off campus) will take place. If transcribing data please indicate and the provide the name of the person or service/vendor that will conduct the transcription.**

1. **Check List for the Items That Need to be Submitted: Please submit protocol and consent documents separately in MS word, supplemental documents (interview guides, surveys, recruitment materials etc. can be submitted as separate pdfs) before submitting the materials electronically to the IRB. To prevent any delay in the approval of your protocol, use the most recent template for the protocol, consent document, and HIPAA form by downloading them from** <https://research.tcu.edu/research-compliance/irb/irb-forms-templates/> **each time you prepare your materials.**

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| 1. Protocol
 | [ ]  |
| 1. Consent document
 | [ ]  |
| 1. HIPAA form if applicable
 | [ ]  |
| 1. Protecting Human Research Participants Training certificate for each investigator
 | [ ]  |
| 1. Recruitment flyers, letters, ads, etc.
 | [ ]  |
| 1. Questionnaires or other documents utilized in screening and data collection
 | [ ]  |

**Principal Investigator Assurance**

1. **By signing below, I certify to the following:**

* The project described herein will be conducted in accordance with applicable TCU policies and procedures, as determined by the IRB of record. All Human Subject Research projects occurring at TCU must be conducted in compliance with the Office of Human Protection (“OHRP”) regulations at 45 CFR 46 and all other applicable federal and state laws and regulations (collectively “Applicable Law”)
* I have a working knowledge of Applicable Law
* All personnel who work with human participants under this protocol have received, or will receive, appropriate training in protocol procedures and protection of human subjects prior to working with humans.
* All experiments involving human participants will be performed only by the qualified individuals listed in this protocol and individuals not listed in this protocol will not participate in the protocol experiments.
* Procedures on experimental subjects described in this IRB protocol accurately reflect those described in the funding applications and awards, if externally supported.
* I and all personnel have read and will comply with any pertinent safety information, IRB requirements, and security procedures.
* I will maintain records of all human participants and the procedures carried out throughout the entire term of my project.
* As Principal Investigator, I am aware that I have the ultimate responsibility, on a day-to-day basis, for the proper care, treatment, and protection of the human participants.

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 Signature of Principal Investigator Date