IRB#\_\_\_\_\_ (TCU Cayuse issued) *Study Title*

**Primary Investigator and Institution:**

**Other Investigators and Institution(s):**

## Study Purpose (research aims):

## Please describe the objectives, aims, or hypotheses of the study and what you expect to learn or demonstrate.

## Research Objectives:

## The objectives related to parameters or tools used to achieve the study purpose.

1. Hypotheses

Statement that introduces a research question and proposes an expected result.

## Outcomes

Describe the anticipated outcomes of the study.

## Background

## Describe the theory, prior research, or data supporting the study's objectives and include a bibliography of key references as applicable.

## References:

## Participant Population and Recruitment

Describe the desired population(s) for this study

**Study Site Location:**

**Number of Participants:** List the **total** number of participants expected to enroll in the study. **Note:***You may also include a breakdown if you have multiple populations you plan to enroll. (How many children, parents, various student populations, etc.)*

## Inclusion Criteria

Define specific conditions or characteristics that make it appropriate to enroll a person into a study.  
  
*Please***describe and provide justification***for the criteria not already addressed above.*.

## Exclusion Criteria

Define conditions or characteristics that would make it inappropriate for a person to be enrolled.  
  
Please ***describe and provide justification***for the exclusion criteria.

**Recruitment**

Please provide:

* A complete description of all recruitment procedures.
* Include methods of how and where the potential participants will be approached and specify by whom.
* Describe who and how recruitment material(s) will be distributed?

## Incentives:

Describe any incentives for participating in this study.

**Study Procedures**

Provide a chronological description in lay terms of the procedures, tests, and interventions that will be implemented during the course of the study.  
  
***Be sure to include:***

* The number of study visits
* Describe the frequency and duration of each visit & the time it would take to undergo the various test, procedures, and interventions
* Describe if there will be any stopping criteria due to any potential safety concerns for participants or members of the study team

## Potential Risks and Mechanisms to Reduce Risk

|  |
| --- |
| 1. 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. 2. Also, describe what measures have been or will be taken to prevent and minimize each of the risks identified. 3. If any deception is to be used, explain if the 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. 4. **Explain how this risk will be minimized during the experiment and after the experiment is complete (i.e. full debriefing attached in the previous study procedure section).**   **Potential Benefits**   1. 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)**. 2. If using deception describes how the potential benefits of the research justify the deception.   **Informed Consent Process**  Will you or members of the study team collect informed consent as a part of this study?  *In addition, if you think your study is going to be Exempt, please select "Yes" and upload the*[Research Information sheet](https://research.tcu.edu/wp-content/uploads/2021/01/Research-Information-Sheet-for-exempt-studies-only.docx)*in the attachment point that follows.* |

1. Describe the consenting procedure in detail, when and where consenting will take place, indicate if potential participants will be given time to decide if they want to participate and ask questions; whether participation is completely voluntary.
2. If students are used as participants, indicate there will be an alternative in lieu of participation if course credit is provided for participation.
3. If a vulnerable population is recruited, describe the measures that will be taken to obtain surrogate/LAR (Legally Authorized Representative) consent (e.g., cognitively impaired participants) or assent from minors and permission from parents of minors.

## Participant withdrawal procedures

1. Describe the procedures for withdrawing from the study.
2. Include if participant withdraws their consent will they also be able to request their data (information or samples)  be withdrawn as well or will the study keep data for analysis or future research?

**Note:** ***Please make sure this process is explicitly clear in the informed consent document.***

## Privacy, Confidentiality, Data Analysis, & Data Monitoring

## Data Analysis

Describe your plan for analysis and include information on power analysis and sampling (if applicable).

## Demographics

Describe any demographic data you will collect and how you will ensure protection of participant anonymity.

## Data Safety Monitoring

Describe your data safety plan, response for breaches.

***Note:****The PI is responsible for reporting any reasons outside the planned study design such as in compliance with the protocol or if there is any delay in the initiation of the study due to administrative reasons. This section****must be answered for clinical studies or greater than minimal risk studies.***

**Please include copies of the following at the end of the proposal for review:**

Research Proposal IRB:

* 1. Informed Consent (IRB)
  2. All recruitment materials to be used in the study
  3. Research Instruments

Grant Proposal:

1. Call for Proposals