**Not Human-Subject Research Request Form**

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. Some research projects may not meet the definition of human subject research as described in the 45 CFR 46 and thus, IRB approval is not required. However, the TCU IRB will review these projects and offer a determination letter if the project is deemed Not Human Subject Research.

Please note that this form should not be used to describe projects that have both a quality improvement and research component. Projects that involve research do not qualify as QI or NHSR.

1. **Date:**
2. **Study Title:**
3. **Principal Investigator (must be a TCU faculty or staff):**
4. **Department:**
5. **Other Investigators: List all faculty, staff, and students conducting the study including those not affiliated with TCU.**

1. **Project Period (mm/yyyy - mm/yyyy):**

**7. Please select the appropriate activity for your research:**

Routine **Quality Improvement (QI)** means systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of education or processes in a particular settings. QI involves deliberate actions to improve processes, guided by data reflecting the effects (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the organizational level to identify a process or management change that can be expected to improvements).

\*For QI – answers to the following questions should be YES:

Are participants who receive the project intervention expected to benefit?

Will all groups in the project receive, at the minimum, usual treatment at this institution?

Is the purpose to measure the performance of or to determine the effect of a process change intended to improve an established process or procedure?

Will the results be used to inform and implement improvements at the institution the process is being implemented?

**Program evaluation.** This refers to assessments of the success of established programs in achieving objectives when the assessments are for the use of program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. [Note: Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge not otherwise known.]

□ **Secondary Data Analysis.** This refers to the analysis of data that was collected by someone else for another primary purpose. The aggregate data should not contain any identifiers (de-identified), meaning the dataset has been stripped of all identifying information and there is no way it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by other means), its subsequent use by the Principal Investigator or by another researcher would not constitute human subjects research, since the data is no longer identifiable.

**Customer satisfaction surveys**. This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation.

**Academic Projects**: academic projects or student assignments involving collection of data from human subjects when the data is used solely for the purpose of learning research methods and not intended to be used to develop or contribute to generalizable knowledge. ***Please note: If you believe there is the possibility that the data you collect from this project \*may\* be submitted to a conference or academic journal(i.e., will contribute to generalizable knowledge), please do not use this form. Submit your protocol as either exempt or expedited.***

**Case Reports**: use information collected from a clinical or educational activity rather than a research activity and presented on no more than three (3) participants. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI.

**Other**: Describe here **⭢**

**8. Summary of the Activity:** Please provide a summary of the proposed activity. Provide sufficient detail for the reviewer to verify whether or not the activity is research and if research, whether or not it is “human research” requiring IRB approval as you have indicated above. If a separate activity description/written plan is available, attach it to this document.