**Not Human-Subject Research Request Form**

**Please delete instructions and checklist before the 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. 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.

This checklist will help you determine whether a proposed project is a quality improvement (“QI”) project or potentially human subjects research. If all of the check marks are inside the shaded gray boxes, then the project is very likely QI and not human subjects research.

|  |  |  |  |
| --- | --- | --- | --- |
| Consideration | Question  | Yes | No |
| PURPOSE  | Is the primary aim or motive of the project either to improve a specific program, operations, or efficiency?  |  |  |
| RATIONALE  | Is there sufficient acceptance of this mode or approach to support implementing this activity or to create change? |  |  |
| METHODS 1  | Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?  |  |  |
| METHODS 2  | Do the methods include any of the following? * Control group
* Randomization
* Fixed protocol
 |  |  |
| RISK | Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?  |  |  |
| PARTICIPANTS | Will the activity only involve participants (faculty, staff, students, patients, etc.) who ordinarily work in or are seen or care for in the setting where the activity will take place?  |  |  |
| FUNDING  | Is the project funded by any of the following? * An outside organization with an interest in the results
* A manufacturer with an interest in the outcome of the project relevant to its products
* A non-profit foundation that typically funds research, or by internal research accounts
 |  |  |

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.]

[ ]  **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.