

Note: This is the FIRST FORM (step one) to complete for your student research review process.

This document has two pages.

**TEXAS CHRISTIAN UNIVERSITY (TCU) - HARRIS COLLEGE OF NURSING AND HEALTH SCIENCES
HUMAN VERSUS NON- HUMAN SUBJECTS DECISION CHECKLIST**

Student Name:

Degree Program:

Faculty Project Advisor(s) Name(s):

Project Title:

The checklist below will assist you to determine whether a project requires review for approval only at the department review board level and by Dr. Emily Lund, Interim Associate Dean of Research-Harris College, or also by the TCU Institutional Review Board (IRB). **Note: The Department Review Board (DRB) is the department review board for all KINE, COSD, & SOWO programs. The DRB chair for each department will review all research proposals as a first step in the full review process. If considered non-human subjects, then Dr. Emily Lund will review the application for approval.**

Preliminary Questions:

1. Is the proposed project a systematic review?

____ Yes or ____ No

2. Is the proposed project a guideline or policy development/analysis only, with no implementation component?

____ Yes or ____ No

If either of these questions are answered “yes”, you may bypass the decision checklist, sign (initial) the form and move on to step two. If you answer “no” to both of the above questions, continue with the secondary checklist.

Secondary Checklist:

If you answer *False* to **ANY** of the below questions, a review at all levels is necessary (i.e. the department level, Dr. Emily Lund and the university level.) You must complete this checklist, sign it and submit it to the DRB with the **TCU Departmental Protocol Review document-student version (aka the university level IRB protocol document)**. **Final approval of your project will come from the TCU (university level) IRB.**

If you answer *True* to **ALL** of the below questions, you must complete this checklist, sign it and submit it with the **Non-Human Subjects Student Research Application Form** to the DRB. **Next, Dr. Lund will review the application. Final approval for your project will come from Dr. Lund.**

Decision Checklist		True	False
1	The purpose of the project is to describe standard care, determine best practice based upon the evidence or improve internal (local agency) processes, practices, costs, or productivity.		
2	You are measuring an existing practice that may or may not have been shown effective in the literature.		
3	There are no risks to human subjects such as disclosure of protected health information or risks from changes in usual care delivery.		
4	You will use a small sample size data set but large enough to observe the purpose of the project. There is no need for a power analysis to determine a sample size.		

5	There will be no participants data used outside your setting because another setting would not provide care the same way.		
6	The data will be analyzed using only descriptive statistics that demonstrate change or graphs that show trends only- NOT inferential statistics to test for significance.		
7	The project will NOT be described as research in public presentations, portfolios, or other representations.		
8	There is NO withholding of any aspect of a standard of care or NO testing of an intervention that is not standard of care (neither consensus-based or evidence-based.)		
9	The project DOES NOT involve grant/contract funding or sponsorship that requires IRB approval?		
10	The project DOES NOT involve a drug or device used outside of usual medical practice, including non-FDA approved agents or the use of any off-label uses of FDA approved drugs/devices.		

I have reviewed the decision checklist and believe my answers to represent the project titled above.

Student initials represent student signature.

I have reviewed the decision checklist with the student and the answers represent the project titled above.

Faculty initials represent faculty chair signature.

Note: Any forgery or intentional misinformation represented in this document can be considered grounds for termination from the University.