




Title: Human Subjects Review Committee: Policy & Procedure	
Written by: Human Subjects Review Committee	
Date Initiated: 4/2010	Date Revised: 4/2014, 3/2024
Approved by:  _____ Chancellor	Governing Board Approval: _____ Date
_____ Date	

PURPOSE

The purpose of the Human Subjects Review Committee is to safeguard subjects of faculty and student investigators, and to safeguard faculty and students as subjects of investigators external to the College who petition to include faculty and/or students in proposed study.

It is the policy of Trinity College of Nursing and Health Sciences (TCONHS) that any research or clinical project conducted with, on, or by students, faculty, or employees of TCONHS involving human subjects, shall be approved and monitored by the TCONHS Human Subjects Review Committee (HSRC).

No potential subjects should be approached, nor any data collected before written HSRC approval is issued. A Memorandum of Agreement (MOA) must be implemented between the Principle Investigator and a designated partner facility. Research participants must be offered a Confidentiality and Privacy Permission to Participate in Research Agreement.

Definition of Human Subjects

Human subjects are individuals who participate in research development, as subjects of a research study, or related activities. This includes record review for the purpose of research after permission to access records is signed by an authorized individual.

Philosophical Statement on Research Use of Human Subjects:

The faculty of TCONHS subscribe to the principles of the Belmont Report of 1979. It is our position that research directed at theory development, and at diagnostic, therapeutic, and clinical education improvement goals will be given priority.

PROCEDURE:

Function:

To fulfill these purposes, the HSRC has the following functions:

1. To develop and implement Human Subjects Protection policies and guidelines.
2. To ensure the guidelines as approved by faculty for protection of human subjects are followed.
3. To develop and revise procedures and methods for review of research proposals and monitoring of ongoing research in terms of protection of human subjects.
4. To report to faculty the common and persistent human subject protection problems, needed improvement in proposal reviews, national trends in research review, ethical issues encountered, and violations of human subject procedures.

Committee Structure:

1. Membership: there shall be a minimum of 5 individuals on the committee. TCONHS shall be represented by a minimum of three faculty; two nursing faculty, and one non-nursing faculty, if available. Two community individuals are invited to serve on the committee. All faculty and community members will have achieved a minimum of a master's degree. One TCONHS MSN student may be invited to join HSRC.
2. Terms and Appointment: members shall be appointed and reviewed yearly by the Dean of Nursing & Health Sciences. Faculty members may serve consecutive 2 year terms on the Committee. The HSRC Chair must hold a research doctorate degree. Completion of IRB training is required to be a committee member upon joining and at least every three years thereafter.
3. Officers: there shall be a Chair, appointed by the Dean of Nursing & Health Sciences, who will set the agenda and preside over the meetings and keep records. The meeting record and committee correspondence shall be assigned as needed by the Chair.
4. Guidelines for review of research proposals are contained in the Trinity College Human Subjects Review Procedures and Applications Packet. HSRC will review and update the packet as needed.
 - a. Following the Thesis Facilitator's approval of the first three chapters of the student's proposal, the graduate student will submit the 'Application for Initial Research Protocol' to the Chair of the HSRC. The HSRC will determine the status of the proposal (exempt, expedited, or full review). Independent reviews by all members of the HSRC members may take place via e-mail or at a called or regular HSRC meeting within 3 weeks of the request. The HSRC determines if the study/project is approved, disapproved, or tabled for information.
 - b. The HSRC Chair will notify the graduate student and his/her Faculty Facilitator of the HSRC decision in writing.
 - c. Study/project procedures may not be initiated until A) a permission of subjects agreement is approved and B) receipt of HSRC Chair's signature on the submitted Human Subjects Request/Approval Form is shared. Failure of TCONHS faculty/staff/students to obtain HSRC approval before initiation of research will result in possible disciplinary outcomes.