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| Title: Human Subjects Review Committee: Policy & Procedure | |
| Written by: Human Subjects Review Committee | |
| Date Initiated: 4/2010 | Date Revised: 4/2014 |
| Approved by:  _____ Chancellor | Governing Board Approval: _____ Date |
| _____ 1/12/2016 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 study subjects and/or faculty and/or students.

It is the policy of Trinity College that any research or clinical project conducted with, on, or by students, faculty, or employees of the College which involves human subjects, shall be approved and monitored by the Trinity College Human Subjects Review Committee (further referenced as the Committee).

No potential subjects should be approached, nor any data collected before written Committee approval is received by the principal investigator (PI). A formal contractual relationship must be implemented between the PI and the research subjects.

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. Excluded from this definition are records and statistical data maintained as part of the College’s Systematic Evaluation Plan.

Philosophical Statement on Research Use of Human Subjects:

The faculty of Trinity College 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 educational improvement goals will be given priority.

PROCEDURE:

Function:

To fulfill these purposes, the Committee 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, as necessary, to faculty common and persistent human subjects' protection problems, improvement in proposals that are reviewed, national trends in approaches to review, ethics, and violations of human subject procedures.

Committee Structure:

1. Membership: there shall be a minimum of 5 individuals on the committee. The College of Nursing & Health Sciences shall be represented by a minimum of three faculty; two nursing faculty, and one non-nursing faculty, if available. Two community individuals will serve on the committee. All members will have a minimum of a master's degree.
2. Terms and Appointment: members shall be appointed and reviewed yearly by the Dean of Nursing & Health Sciences. Members may serve consecutive 2 year terms on the Committee. One member must hold a research doctorate degree. Completion of IRB training is required to be a committee member.
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. The Committee will review and update the packet as needed.
 - a. Following approval of the first three chapters of the student's proposal, the Chair will have the graduate student prepare the 'Application for Initial Research Protocol' to be submitted to the Trinity College Human Subjects Review Committee by the Chair. The Trinity College Human Subjects Review Committee will determine the status of the proposal (exempt, expedited, full). The Human Subjects Chair will sign-off on all exempt requests. For expedited requests, independent reviews by the Committee members may take place via e-mail within 1-2 weeks of the request. For a full review, the proposal will be independently reviewed by all committee members followed by a meeting of the Committee to determine if the study/project is approved, disapproved, or tabled for information.
 - b. The Human Subjects Review Committee Chair will notify the graduate student and his/her Chair of the Committee action and provide the signed approval form.
 - c. Study/project procedures may not be initiated until receipt of signed Human Subjects Request/Approval Form. Failure of Trinity College faculty/staff/students to obtain Human Subjects Review Committee approval before initiation of research will result in possible disciplinary outcome.