

H. Council Trenholm State Community College

POLICY NAME:	Institutional Review Board (IRB)
EFFECTIVE:	September 2016
REVISED:	
APPROVED BY POLICY COMMITTEE:	Yes – 9/8/2016
APPROVED BY PRESIDENT’S CABINET:	

What is an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is part of a review process to ensure ethical research standards in conducting research that involves human subjects and when such projects and presentations become public (i.e., presentations at professional conferences, publications, etc.)

The purpose of the IRB is to review a proposed research project to determine whether participants in the study will be placed at physical or mental risk and, if risk is involved, to certify that the following conditions have been met: (a) risks to participants are minimized; (b) participants in the study (and their guardians) are fully aware of the risks and that the individuals may withdraw from the study at any time without any form of penalty; (c) risks to the participants are so outweighed by the sum of benefits to the participants and the importance of the knowledge to be gained as to warrant a decision to allow the participants to voluntarily accept these risks; (d) rights and welfare of any such participants will be adequately protected; (e) legally effective, informed consent will be obtained by adequate and appropriate methods in accordance with the provisions delineated in Title 45 of the Code of Federal Regulations; and (f) conduct of the activity will be reviewed at intervals determined by the IRB, but not less than annually (Lincoln, 2005).

Composition and Functioning of IRB

The membership of the IRB will consist of at minimum five members, with varying backgrounds, who review research activities commonly conducted by researchers at the institution or external researchers. The IRB shall be sufficiently qualified, through the experience, expertise, and diversity of the members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

In general, the IRB is self-governing. No other group or individual should be able to interfere with its decision-making process or overrule its decisions. The chair and members of the IRB will be appointed by the President of Trenholm State Community College. The chair of the IRB will conduct the meetings, assign certification authority to the members, maintain a record of the proceedings of the IRB meetings, including agendas, actions of the IRB and the certification logs

of the members, maintain a record of all IRB members, including current curriculum vitae or resumes of each member and invite new board members.

The IRB reviews all research projects to determine compliance with Federal and State laws.

The Three Categories for IRB Review

There are three categories for IRB review: Exempt (Level 1), Expedited (Level 2), and Full (Level 3). These levels are based on an assessment of the risk/benefit ratio to the participants. The investigator must assess the level of risk, or exposure to sensitive or harmful experiences, due to participation in the study and assign a category status to an IRB application (IRB applications can also be developed by faculty in consultation with the college/district researcher).

Exempt Review (Level 1) is performed for research projects using archived data and research projects for which there is no human participant interaction. Research projects on sensitive topics and vulnerable populations, such as children or minors, pregnant women and prisoners, do not qualify for exempt review. International studies also do not qualify for exempt review. The IRB makes the final determination about whether a proposal qualifies for exempt review.

Expedited Review (Level 2) is applicable to certain categories of research involving no more than moderate risk to human participants. Any research in which human participant interaction is anticipated falls in this category unless the risk to participants is considered more than moderate. Most projects and studies fall into this category. In addition to meeting the general eligibility criteria for Level 2, the research must also meet the certification criteria that assure (a) risks to participants for participating in the research are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be gained; (b) participant selection must be fair; (c) informed consent is sought and documented unless a waiver of consent and/or documentation of consent have met the waiver criteria; (d) the plan to collect and monitor data assures participant safety; (e) procedures provide for the privacy of participants and for maintenance and disposal of confidential data; and (f) where necessary, additional safeguards are included to protect vulnerable participants.

Finally, research projects requiring a Full IRB Review (Level 3) entail sensitive or risky research topics or methodologies. The application for a Level 3 project must contain extensive details describing procedures designed to protect vulnerable participants.

For any application, a majority of IRB members must approve the proposal and sign the cover page of the research proposal. The investigator must obtain this certification of compliance before any data is gathered or else he/she opens the college up to liability under federal law.

Sources

Lincoln, Y. S. (2005). Institutional review boards and conservatism: The challenge to and from phenomenological paradigms. In N. K. Denzin & Y. S. Lincoln (Eds.), *The sage handbook of qualitative research* (pp. 165-181)

O'Brien, R. (2001). *An overview of the methodological approach of action research*. Retrieved February 18, 2008 from:http://www.web.net/~robrien/papers/arfinal.html#_edn11

Stringer, E.T. (2007). *Action research* (3rd Ed.). Los Angeles: SAGE Publications