Ivy Tech Community College of Indiana

POLICY TITLE
Research Involving Human Subjects

POLICY NUMBER
9.5 (Formerly APPM 7.12)

PRIMARY RESPONSIBILITY
Office of Institutional Research
Academic Affairs

CREATION / REVISION / EFFECTIVE DATES
Created January 2004/Effective January 2004

PURPOSE
Educational researchers come from many disciplines, embrace several competing theoretical frameworks, and use a variety of research methodologies. As such, it is important for the college to ensure that the faculty, staff, and students follow relevant professional guidelines concerning the protection of human subjects, such as those defined in the uniform Federal Policy for the Protection of Human Subjects.

ORGANIZATIONAL SCOPE OR AUDIENCE
Faculty, students

DEFINITIONS
Human subjects: Living individuals about whom a researcher obtains data through intervention or interaction with the individual, or identifiable private information.

POLICY
To ensure that the rights and welfare of human subjects involved in research are protected, researchers are required to obtain clearance from the Office of Institutional Research (OIR) before research begins. All research involving human subjects, which includes research by faculty, staff, and students, is subject to review by the OIR. Research covered by this policy includes theses, dissertation, publication, or coursework outside of instructional or administrative College purposes.

PROCEDURE
The OIR can grant approval at three different levels:
1. Exempted research requiring OIR approval;
2. Research which may be reviewed through expedited review procedures, requiring OIR and Human Subjects Review Board (HSRB) subgroup approval;
3. Research that requires College HSRB approval.
The OIR may, at their discretion, submit any research proposal to the HSRB for its advice and evaluation.

Any decisions, modifications, or requirements by the OIR and HSRB are final. In addition, projects that are ongoing will require an annual review by the OIR and HSRB. In such a review, the researcher will provide assurances that the research is being conducted in accordance with the OIR and HSRB approval, as well as a status report concerning the progress of the research. The OIR and HSRB may also suspend or terminate the approval of research that is not being conducted in accordance with the OIR’s and HSRB’s requirements or that has been associated with unexpected harm to subjects. Procedures define the steps to successful implementation.

Exempted Research
Some categories of research are exempt. Such research could include that conducted in established or commonly accepted educational settings, or involve the collection or study of existing data, documents, or records that are publicly available. For a complete list the researcher should refer to The Code of Federal Regulations, Title 45, Part 46, Section 46.101.

To initiate the exempted review process in the School, the researcher should submit the Application for Project Approval to the OIR. In addition the researcher should attach a memo specifying the reason(s) that the research qualifies for an exemption.

Expedited Review
Some categories of research involving no more than minimal risk can be reviewed through the college’s expedited review process, which involves approval by the Executive Director of the OIR and a subgroup of the College’s HSRB. Minimal risk is that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In determining if the research meets the guidelines for expedited review, the researcher should refer to the Code of Federal Regulations, Title 45, Part 46, Section 46.110.

To initiate the expedited review process in the college, the researcher should submit the Application for Project Approval to the OIR. In addition, the research should attach a memo specifying the reason(s) that the research qualifies for an exemption.

College Human Subjects Board Review
All research that neither qualifies for an exemption nor an expedited review must be submitted to the College’s HSRB. The HSRB is comprised of the Executive Director of the OIR, one member appointed by College Legal Counsel, and three members appointed by the Vice President of Academic Affairs. In addition, the HSRB may include additional individuals who are knowledgeable about and experienced in working with the human subject group to be studied.

To initiate the process in the college, the researcher should submit the Application for Project Approval (see References) to the OIR. If the research involves the approval of other colleges,
universities, agencies, governmental entities, or other related organizations as well as their ethics or human subjects review committees, that information and related approval must be attached to the Application for Project Approval.

REFERENCES
Federal Policy for the Protection of Human Subjects  
Code of Federal Regulations, Title 45, Part 46, Section 46.110  
Application for Project Approval

RESOURCE PERSON
Vice Chancellor for Academic Affairs; Executive Director – Office of Institutional Research