**Institutional Research Board (IRB) Review Policy**

**Intent:**

Eastern Nazarene College will maintain an Institutional Review Board in order to protect human research participants in all research projects conducted at the college. The human subjects review process arose as a response to some notorious abuses of human subjects, such as the Tuskegee Experiment and the Milgram Experiment. It is meant to ensure the ethical treatment of people and animals who participate in research

**Background:**

In the U.S., across college/university campuses and at hospitals and private institutions, *the protection of human subjects is not by the whim of a particular set of committee members or chairpersons. It is mandated by federal law.*

When the **Belmont Report** was issued by the Dept. of Health, Education, & Welfare in 1979, it set human research standards of *beneficence, justice,* and *respect for persons* (e.g., individual autonomy and protections for those with reduced autonomy) in human research in the United States.

Under the Federal Code, Title 45, Part 46 (called the "Common Rule"; Revised June 18, 1991) the Office for Protection from Research Risks described how it is that human research committees should conduct themselves. Today, the Office of Human Research Protections of the Dept. of Health & Human Services oversees human research protections that were established in the **45 CFR 46 guidelines**.

**Policy:**

1. All ENC personnel conducting research that includes human subjects, including those instructing courses with a requirement for student research, must complete the National Institutes of Health on-line course titled, “Protecting Human Research Participants” found at http://phrp.nihtraining.com.
2. A certificate of completion must be on file with the IRB Coordinator. Once completed, the certification is valid for two years
3. The IRB review and approval must be achieved prior to the initiation of any data collection.
4. For an IRB application to be considered by the Board, the primary researcher needs to submit an application to the IRB for approval prior the initiation of the project and include the following:
	1. The Institutional Review Board Application found on the ENC IRB webpage
	2. Conflict of Interest Form
	3. Informed Consent. A parental consent form will be required for research involving subjects who are children or minors. Informed Consent forms must be on ENC letterhead
	4. Copies of all research instruments that will be used. (Survey, Questionnaire etc.)
	5. Letter of agency approval if data collection involves working with an agency/institution other than Eastern Nazarene College.
	6. Authorization for Use of Private Health Information if medical records are used
	7. Experimental Subject’s Bill of Rights if research involving clinical treatment
5. **Conflict of Interest:** AConflict of Interest letter must be submitted with every IRB application.
	1. Faculty assuming the responsibility for the design, conduct or reporting of clinical trials have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Any possible conflict of interest relating to human subjects must be formally disclosed to the Institutional Review Board as part of the normal obligation for approval by the IRB for any clinical study.
	2. Eastern Nazarene College’s Conflict of Interest Policy related to Faculty Research is intended to be consistent with federal requirements for grantee institutions, including regulations adopted by the Public Health Service at the Department of Health and Human Services and the National Science Foundation.
	3. For research with external funding: Prior to the submission of a proposal to obtain funding for research, members of the faculty and staff are required to disclose to the Provost and the IRB any significant financial interests in an entity whose financial interest would reasonably appear to be directly or significantly affected by the external funding. Members are required to update disclosures of significant financial interest annually or as significant financial interests change during the period of the sponsored project.
6. Research falls under one of three categories:
	1. **Full Board review:** Research that involves (a) more than minimal risk, or (b) involves vulnerable populations or (c) includes sensitive topics requires full board review. Specific criteria can be found in the document ***Criteria for a Full Board Review***
	2. **Expedited Review:** Expedited review refers to research that does not involve vulnerable populations, sensitive topics and involves no more than minimal risk to human subjects. For a list of criteria and categories that fall under expedited review see the document ***Criteria for Expedited Review.***
	3. **Exempt Review:** Some studies on human subjects may be exempt from the need for full or expedited review by the Institutional Review Board. Many educational, behavioral, and social science studies present little or no risk to subjects and can be exempt from IRB review. For a list of criteria and categories that fall under expedited review see the document ***Criteria for Exempt Review.*** An exempt research project must still complete application and file it with the Institutional Review Board for official acknowledgment as **Exempt**.
		1. Decisions about whether studies are exempt from the requirements of the Common Rule must be made by the Institutional Review Board or by an ENC faculty member holding a certificate of completion for Human Participant Protections Education for Research Teams that was completed within the last two years. The decision regarding an exempt study involving human subjects may not be made by the investigator or faculty affiliated with the research (Steneck, 2004, p. 41).
		2. Research that cannot qualify for exempt status includes:
* Research involving interaction with children
* Research involving prisoners
* Research that involves deception or withholding of information from subjects
* Research that involves intense physical exercise
* Research that may cause emotional distress or discomfort greater that what would be expected in daily life
1. **Research Connected with Courses.** Research conducted within the confines of an academic course may be classified as **Excluded Research** if:
	* 1. the results of the research are solely reported to students enrolled in the course. Projects in this category are confined to the specific class and end at the termination of the class.
		2. the instructors determines that the student research project properly protects human subjects by reviewing and documenting that the student projects meet the criteria for protection of human subjects outlined in the document ***Criteria for Excluded Research***
		3. If it is anticipated that the student research might be presented at forums outside the department or college such as at professional conferences or in journals, the student and instructor must seek IRB review under categories labeled Exempt, Expedited or Full Board.

For research connected with a course which falls under the *Excluded Research Category:*

* 1. The instructor must collect and review *Classroom Research Low Risk Project Application* from students for Excluded research before authorizing data collection.
	2. The instructor must file the approved forms with her/his class records to document student plans for research procedures. The forms are not submitted to the IRB.
	3. If students wish to publish or present their research outside ENC then the research is NOT considered Excluded Research. The student/faculty should prepare the Institutional Review Board Application for standard review by the IRB prior to the initiation of the research project.
	4. The syllabus for courses that include a student research component must include a section which informs students regarding NIH standards for protecting human subjects in research projects.
1. **Animal Research:**

Eastern Nazarene College adheres to and adopts the policies and expectations of the Federal and State regulations for animal use and care in research , as well as the APA guidelines for animal care and research.. As a result, we expect that all individuals responsible for any research project that employs animals of any kind, in any manner, to sign their acknowledgement of having reviewed the documents on the ENC IRB webpage.  Furthermore that individual should indicate in the application that animals are used in the research, and submit an addendum to the IRB application that details the following categories of information:

* 1. How the research adheres to or diverges from the Federal or State regulations
	2. How the animals will specifically be used in the research

**Procedure:**

**IRB Research Application Submission:**

1. To submit a project proposal, please use form: ENC IRB --Research Application. Sections A, B and C are *required* for all proposals. Submit a copy of your survey, consent forms, instructions to participants, and debriefing script (if applicable) along with Sections A, B and C. Be sure that *all* persons who will have contact with research participants have signed Section A of the forms. For IRB review, electronically submit your application and other documents as attachments to an email requesting IRB review to irb@enc.edu.

Add to your IRB forms: currently valid copies of your Human Subjects Protections Training Certificates (from NIH) for all those involved in oversight and implementation of the research project. These documents should be legibly scanned and attached along with your IRB forms to complete your IRB application email.

***This certificate is not needed if no human subjects are involved in the research, as with studies involving the use of secondary data.***

1. Faculty who are overseeing student research projects should assist students in preparing the IRB documents and communicating with the IRB.
2. If you are requesting renewals, reporting adverse events, or requesting renewals with changes to a previously approved study, please use the specific form for each category.
3. It is recommended that the primary researcher be as thorough as possible in completing the application. The most frequent reason that an IRB application is delayed is because there is not enough detail included for the IRB Chair to understand the exact nature, benefit and procedure of the study.
4. Once submitted, the IRB will
	* Verify that the certificate of completion for the National Institutes of Health on-line course is on file for all investigators
	* Review to determine if the research will be categorized for full review, expedited review or exempt
	* Will inform the researcher in writing of the IRB review decision

**History:**

 Reviewed by APC on 4-5-2012

 Reviewed by Faculty on 4-18-2012