IRB Quick Reference and Frequently Asked Questions

(1) Do I need special certification to conduct or approve research involving human subjects at Eastern Nazarene College?
Yes. All those who conduct research, review the applications of researchers, or teach a course with a requirement for student research must complete the *Protecting Human Research Participants certificate*. The National Institutes of Health (NIH) provides this special certification. You can obtain this certification at http://phrp.nihtraining.com. Once completed, the certification is valid for two years. Evidence of certification must be attached to all IRB applications.

(2) Is my project "research" with "human subjects" that must be reviewed by the Institutional Review Board (IRB)?
Here are the Federal definitions of "**research**" and "**human subjects**":

Research:
Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (§ 45 CFR. 46.102 [d]). (For the current Code of Federal Regulations, please see: http://www.hhs.gov/ohrp/ A project or study is research if it: a) is conducted with the intention of drawing conclusions that have some general applicability, and b) uses a commonly accepted qualitative or quantitative method. (Opportunity samples are subject to IRB review.)

Human Subjects:
Human Subjects are "living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (§ 45 CFR 46.101[f]). If an auditor could reasonably conclude that your project meets both of these criteria, your project must have some level of review from the IRB.

If the project does not meet the Federal definition of "research" with "human subjects", you can proceed with data collection and publish findings. Research with public databases does not include identifiable private information and does not require review by the IRB. Studies initiated with the primary intent of improving institutional practice (sometimes labeled outcome studies or program assessment) are considered "quality improvement" activities and are not classified as research. This latter type of study should not be labeled as research in publications.

(3) What level of IRB review is appropriate for my research project?
There are four categories of review:
a. **Excluded**
b. **Exempt**
c. **Expedited**
d. **Full Board Review**
(The category labels are not descriptive). The difference between the review categories is degree of scrutiny, which depends on level of risk to human subjects.

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a. Excluded research
Excluded research is typically conducted in research methods classes and is very low risk. The class instructor determines that the student research projects meet criteria for protection of human subjects. The criteria for Excluded Review are listed on ENC IRB webpage. Projects in this category are confined to the specific class and end at the termination of the class.

The instructor collects IRB Classroom Research form (see ENC IRB webpage) from students to document student plans for research procedures. The instructor certifies that projects meet criteria for protection of human subjects. The forms are not submitted to the IRB. The forms are filed with the instructor's class records. If students wish to publish or present their research outside ENC, they should prepare the Institutional Review Board application for standard review by the IRB.

If it is anticipated that the student research might be presented at forums outside the class, department or school, the student should seek IRB review under categories labeled Exempt, Expedited or Full Board. The IRB must conduct some level of review of research projects that instructors or students anticipate might be presented to professional conferences or journals. The IRB review must be conducted prior to data collection.

It is ENC policy that all persons 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

The course is free and takes about 2 hours. Faculty members must file their NIH certificate of completion with the IRB Coordinator before assigning research projects to students. ENC expects instructors to inform students regarding NIH standards for protecting human subjects in research projects.

b. Exempt Research
Exempt research proposals are reviewed for protection of human subjects by a member of your department who is not associated with the research and who holds current NIH certification. See the HHS Human Subject Regulations Decision Charts on ENC IRB webpage.

ENC policy provides guidance in determining whether your project is eligible for exempt review.

The Principal Investigator will prepare the Institutional Review Board application and submit to certified faculty for approval. The forms are submitted electronically irb@enc.edu

c. Expedited Research
Expedited research proposals are reviewed for protection of human subjects by the Chair of the IRB. See the HHS Human Subject Regulations Decision Charts on ENC IRB webpage.

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d. Full Board Review
The Full Board in convened session reviews all projects that include any of the following:
1) Vulnerable populations
2) Sensitive topics
3) More than minimal risk
4) Invasive procedures

(4) What are some esoteric issues the IRB considers when reviewing a project for protection of human subjects?

Benefit
Federal regulations charge the IRB with determining that research benefits outweigh research risks. Benefit can be defined as value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.

Risk
Risk can be defined as the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring. For purposes of protecting human subjects in research projects, risk includes:
a. Violation of privacy
b. Violation of confidentiality
c. Questions that the participant may consider sensitive
d. Possible emotional distress or physical injury
e. Invasive procedures

Minimal Risk
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.

Benefit vs. Risk
The Common Rule instructs Institutional Review Boards to ensure that "risks to subjects are minimized" and "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result".

Vulnerable populations
Vulnerable populations are individuals or groups who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Neither the Federal regulations nor ethical codes . . . proscribe inclusion of vulnerable person as research subjects. However, the Department of Health and Human Services regulations mandate special justification for research involving fetuses, pregnant women, and human in vitro fertilization; prisoners; and children.

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Sensitive topics
Any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential is considered sensitive topic research. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive (See information below for examples of some sensitive topics).

Examples of Sensitive Topics that May Require Full Board Review

1. Sexual orientation, attitudes, preferences, or practices
2. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
3. Information that could damage an individual's financial standing, employability, or reputation
4. Information (usually in medical records) that could lead to social stigmatization or discrimination
5. Psychological well-being or mental health, including physical or mental abuse
6. Incest, rape, date rape, or sexual molestation
7. Genetic information
8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at ENC. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.
9. Veteran or wartime experiences
10. Topics relevant to diversity and possible discrimination such as race/ethnicity, age, disability, gender and socio-economic status.
11. Immigration status

Please note: The sensitive subjects listed above are examples and not an exclusive list.

Privacy
Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Threats to privacy are mitigated by participant's informed consent for participation in the research.

Confidentiality
Confidentiality pertains to treatment of information that an individual discloses in a relationship of trust with the expectation that it will not be divulged to others without permission.

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Confidentiality is often protected by anonymous responses or by de-identifying data by replacing names with codes.

Principal Investigator
The scientist or scholar with primary responsibility for the design and conduct of a research project, including preparation of the research protocol

(5) When does the IRB meet?
The Full IRB Board meets as needed. The deadline to submit an application for consideration by the full board is 10 working days before the meeting.

(6) Who are the members of the IRB?
The Provost appoints members in accordance with Federal guidelines. A majority of the members are faculty. For current members and alternates, contact ***irb@enc.edu***

(7) What needs to be submitted for an IRB application?
This depends on the type of review that you are requesting. For a full board review, expedited review, or exempt review, see ENC IRB webpage for more details of the criteria for each. Submit the completed application form, and the IRB Board will request additional supporting information as needed.
For any questions you may contact ***irb@enc.edu***

(8) What are special considerations for persons planning to survey members of the ENC community?
Persons planning to survey members of the ENC community must contact ***irb@enc.edu*** for approval and to provide scheduling of their data collection. This policy applies to electronic and paper surveys.

(9) Are studies of medical charts eligible for exempt review?
No, unless records are publicly available.

(10) Does a researcher from outside the APU community need to receive approval from ENC's Institutional Review Board to conduct research using APU faculty staff or student?
Persons from outside the ENC community wishing to conduct research at ENC should contact Janice Fletcher, Assistant to the Provost, at mailto: Janice.Fletcher@enc.edu, prior to proceeding.

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