**`Eastern Nazarene College**

**Research Application for Review of Faculty, Staff, or Student Research Projects**

## Involving Human Subjects

All faculty, staff, and student research projects involving human subjects must undergo a review process for the protection of human subjects In order to make this review possible, please complete this application and send it with any additional materials. Proposals should be submitted via campus mail or US Mail to: Provost and Dean of the College, Eastern Nazarene College, 23 East Elm Avenue, Quincy, MA 02170 or electronically to irb@enc.edu

**IRB OFFICE USE ONLY**

Project #

Date Received:

Actions:

Date Approved:

If you have any questions, please feel free to contact the Administrative Assistant to the Provost and Dean of the College, Janice Fletcher, at irb@enc.edu or (617) 745- 3706.

# Section A: Applicant Information

\* ***Instructions:*** Please complete the following. For the purposes of IRB review: "Researchers" are all persons who will have direct contact with research participants, with research records that list participants' identities, and/or with research data during analysis and writing of research reports. All fields of this table (below) must be completed.

|  |  |
| --- | --- |
| \*Researcher Name(s) |  |
| Title of Proposed Research |  |
| Anticipated Start Date of Project |  | Anticipated End Date of Project |  |
| Primary contact: |  | Address orBox # |  | Phone #and Email |  |
| \*Faculty/Staff Supervisor (write N/A, if not applicable) |  | Faculty Phone # and Email |  |
| Course # and Name (if applicable) |  |

Researcher(s): \_\_\_\_

 Signature(s) Date

* **Please, go on to the next page...**
* **Section B: Criteria for Determination of Review Level**

***Instructions*:** Please answer ALL questions. Circle the appropriate answer: Yes, No, or NA (not applicable)

1. Does application involve human subjects participating in biomedical procedures? YES NO

2. Does this project involve the use or collection of human tissue, human blood,

 and/or other human body fluids?. YES NO

3. Does this study involve giving false or misleading information to

 subjects or withholding information from them such that their

 “informed” consent is in question? YES NO

4. Are the procedures to be used new or innovative (not established and

 accepted)? YES NO

5. Will the procedures:

 a. cause any degree of discomfort, harassment, invasion of privacy,

 risk of physical injury, or threat to the dignity of subjects,

 or be otherwise potentially harmful to subjects? YES NO

 b. if answer to 5a is yes, have specific provisions been made to

 correct any harmful or adverse conditions that may arise? YES NA NO

 (Give details in Section C.)

6. Will any type of electrical equipment be used that will be connected to subjects?

 (If the answer is yes, provide with Section C the name and qualifications of the

 individual who will check for electrical safety and attach a signed letter

 from that person which indicates his/her level of involvement with the project.) YES NO

7. Will subjects receive any payment for participating (money, course credit, etc.)?

 (If answer is yes, give details in Section C.) YES NO

8. Will the targeted subject population be:

 minors (less than 18 years of age)? YES NO

 pregnant women? YES NO

 prisoners? YES NO

 mentally retarded? YES NO

 mentally disabled (e.g., brain-damaged, psychiatric patients, etc.)? YES NO

 physically challenged (e.g., uses wheelchair, walker, etc.)? YES NO

 institutionalized? YES NO

 members of specific ethnic or cultural groups? YES NO

 citizens of other countries? YES NO

* **Please, go on to the next page...**
* Section B: Criteria for Determination of Review Level (continued)

9. Will the targeted subject population be Eastern Nazarene College students? YES NO

 a. If yes and course credit is offered, does Section C (below) address an alternate means

 of earning the extra credit? YES NO

10. Do procedures include obtaining parental/guardian consent and/or

 institutional authorization for access to subjects if minor,

 mentally retarded/disabled, or institutionalized subjects are

 involved? YES NA NO

11. Are procedures for maintaining confidentiality of all subjects’

 data fully described in Section C (below)? YES NO

12. Are procedures for obtaining informed consent fully described in Section C (below)? YES NO

13. Will a copy of the informed consent document be provided to each subject? YES NO

14. If applicable, have copies of the following documents been submitted with

 Sections A, B, & C?

 •Instrument(s) (e.g., surveys, interview outlines, etc.) YES NA NO

 •Consent document YES NA NO

 •Debriefing statement YES NA NO

 •Letter of agreement from cooperating institution(s) YES NA NO

 •Letter(s) from cooperating individuals (e.g., secondary data, individual responsible

 for electrical safety, physicians, etc.) YES NA NO

 •Emergency Procedures YES NA NO

15. Will this research be funded in any way? YES NO

* If yes, how will this research be funded?

16. What are the possible uses of the study results (check all that apply):

 \_\_\_\_\_ Degree program only

 \_\_\_\_\_ Professional journal articles

 \_\_\_\_\_ Trade publications

 \_\_\_\_\_ Public presentations

 \_\_\_\_\_ Other (please specify):

17. Fill in the number of estimates:

 Average amount of time required for subject’s participation (in hours)

 How many different questionnaires, tests, surveys, etc., per subject, are to be involved?

 Number of subjects to be involved in this study

18. Earliest possible date when research subjects will first be involved. / /

 (This date must **not** be prior to the date of approval by the IRB)

19. Approximate ending date of involvement of research subjects. / /

20. Animals will be used in this research project. (If yes, please add addendum detailing compliance with Federal and State regulations for care and use of animals in research.) YES NO

* **Please, go on to the next page...**
* **Section C: Explanation of the Proposed Research Project**

***Instructions:*** Section C might be waived by the IRB, if there is sufficient information in other submitted documents (e.g., a written research proposal for an ENC course, copies of survey instructions and materials) to warrant a waiver of it. Please, check with the current chair of the Institutional Review Board at Eastern Nazarene College in order to discover whether Section C can be waived for your project.

If Section C *is not waived*, please, respond to EACH of the following items or questions. Provide enough detail so that the IRB will be able to judge how well your study protects human subjects. Please type your responses to Section C or print clearly, and number them to correspond to the items on this form (if a separate page is used). NOTE: Write NA whenever an item is not applicable to your study.

1. Provide a brief description of the issue under investigation in the study.

2. What are the requirements for and characteristics of the participants? (e.g., what gender, age range, health or medical status, prisoners, institutionalized, mentally handicapped)

3. How will people be sampled, recruited, or otherwise enlisted as participants in the study (e.g., at random, via particular classes, by convenience as they wander out of the Library, etc.)?

4. Describe, in detail, the methodology of your study. (e.g., How will the study be conducted from start to finish, as far as human subjects are concerned? Be specific about the methods, instrumentation, types of data collected, etc.) Any parts of the study which are not yet fully developed should be outlined. Revisions/final methods should be submitted upon completion with a “letter of modification.

* **Please, go on to the next page...**
* **Section C: Explanation of the Proposed Research Project (continued)**

5. Identify all personnel involved in the study including their roles, qualifications, and access to confidential data.

 PROVIDE A LETTER OF AGREEMENT FROM ALL COOPERATING INSTITUTIONS.

6. If you are not using a written informed consent form, describe the procedure for obtaining informed consent from the participants (e.g., how, when, and where the study will be explained to participants). How will participants indicate their consent? (If you are using a written informed consent form, simply include it with your proposal.)

7. What are the potential risks to the participants, and what is the likelihood and seriousness of these risks? (Risks could be physical, psychological, social, legal, etc. Risks may result from your experimental procedures or from your methods of obtaining, handling, or reporting data.). As applicable, describe how you will minimize or protect against potential risks to participants throughout the study. (Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, etc.)

8. What are the potential benefits to the individual participants and/or society of the proposed research?

* **Please, go on to the next page...**
* **Section C: Explanation of the Proposed Research Project (continued)**

9. If you are not using a written debriefing statement, please describe how participants will be debriefed? What will they be told? For either a written or oral debriefing, will participants be given an opportunity to ask questions about the study?

10. Please, describe the steps that will be taken to minimize risk to research participants. (If your study is “minimal risk” in nature, your response may be that this review embodies the steps taken to ensure appropriate risk minimization is in place.)

\_ \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date:

**PI Name**

**Address**

**Phone**

**Email**

* **End of Research Forms.**

Reviewer Comments: For Use by the Human Research Committee only

Name of Reviewer (print)

Signature of Reviewer

Date Phone Box #

Reviewer Comments and Recommendations:

# IRB Office Use Only

 This research project **is exempt** from IRB review based on 45 CFR 46.101(b)

 This project **is approved** as submitted.

 This project **is approved contingent** on the changes listed below.

 A **waiver** of written informed consent is granted.

Other: