

IRB REQUEST FOR REVIEW

NEW ENGLAND COLLEGE

Institutional Review Board for the Protection of Human Research Subjects

PLEASE NOTE: NEC's assurance for the protection of human subjects prohibits the start of any research activity (including recruitment of subjects) that has not been reviewed and approved by the IRB.

NOTE: Review of IRB proposals normally takes at least two weeks. Approval or areas for revisions will be returned to the Director of the Program who submitted the Proposal who will share the information with the faculty instructor and/or student. Remember, research including meeting participants, obtaining participant consent, collecting data, etc. may not be done until you have received IRB approval.

To be completed by student:

Today's Date _____

Name _____

Department: _____

Mailing Address: _____

Email Address: _____ Phone Number: _____

Title of Research Project _____

Anticipated Start Date * _____ Anticipated End Date _____

Project Status Information (To be completed by student: Check One):

- _____ New Project
- _____ Continuation of Previously Approved Project
- _____ Modification to Previously Approved Project

Project Review Recommendation (To be completed by the faculty instructor after review of documents – see levels of review on the last page – check one):

- _____ Exempt Status
- _____ Expedited Review
- _____ Full Review

Faculty Signature (May be electronic): _____

Project Funding Information for sponsored projects (if applicable) (To be completed by student in consultation with faculty instructor):

Funding Agency _____

Is human subjects certification required by sponsor? YES _____ NO _____

If yes, notification of deadline _____

IRB Review by Other Institutions (if applicable) (To be completed by student in consultation with faculty instructor):

If this proposal has been submitted to a review board at another institution, provide the date of review and the board's recommendations. *Please attach relevant correspondence.*

Name of Institution _____

Date of Review _____

FOR IRB USE – completed by chair of IRB committee:

PROTOCOL # _____

DATE REC'D _____

PROJECT AND SUBJECT INFORMATION (to be completed by student and reviewed by faculty instructor before sending to IRB committee) – please be brief but specific and include all required information:

1. Title of Project
2. Project Description
3. Research Question(s)
4. Time frame for data collection (**remember, you cannot conduct any research without IRB approval**)
5. Site of Research
6. Describe your proposed participants. Be sure to include how many participants will be involved, their age(s), sex, location, and any other important distinguishing demographic information.
7. Time Commitment for Each Participant
8. Compensation – Indicate, if applicable, the amount and form of compensations (i.e. cash, course requirement, mileage, etc.)
9. Informed Consent – describe how informed consent is to be obtained from the subjects as well as from the administration in the site under consideration for this study.
10. Provide a copy of the informed consent documents (participants and administration consent forms) you will use in your research. Attach to the end of this proposal.
11. Provide copies of ALL data collection tools (surveys, interview questions, observation protocols, etc.) that you propose to use in your study. Attach to the end of this proposal.
12. Describe how confidentiality of participant data will be assured as it is collected, and, if it is retained, over the length of time it is to be retained and where. (Standard is 5 years in a secure, locked cabinet maintained by the researcher. All data is destroyed five years after the conclusion of the project.)
13. Describe foreseeable risks which may be encountered by the subjects and the justification for the project in terms of benefits to be realized which may outweigh the risks and steps you will take to reduce any potential risks. Be careful to explain how you will manage the risks, what steps will you take.

Signatures:

The undersigned accepts responsibility for the study, including adherence to policies relative to the protection of the rights and welfare of patients/subjects participating in this study. If the researcher is not a faculty member, then s/he must obtain the signature of his/her research instructor below. In the case of non-faculty protocols, both the Faculty Sponsor and the researcher share responsibility for adherence.

Signature of Researcher (may be electronic)
_____ Faculty _____ Undergraduate Student _____ Graduate Student _____ Staff

Signature of Faculty Member (may be electronic)

Return this form to the Chair of the Institutional Review Board Committee.

IRB #: _____

<p><u>PROTOCOL REVIEW FORM</u></p> <h1>NEW ENGLAND COLLEGE</h1>
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Institutional Review Board for the Protection of Human Research Subjects

To be completed by student:

Researcher(s):

Department: _____

Research Project Title:

Date Submitted:

To be completed by faculty sponsor (see descriptions at end of this proposal form):

Proposal meets eligibility for:

- _____ exempt status (Add you reason for this request)
- _____ expedited review
- _____ full review

Faculty Sponsor Signature (May be electronic):

To be completed by IRB Committee:

IRB Decision:

_____ Exempt status is granted.

_____ Expedited Review is granted.

_____ Protocol is approved.

_____ Protocol is conditionally approved. The following conditions must be met before data collection begins:

Protocol is not approved for the following reasons

Full Review is required.

Protocol is approved.

Protocol is conditionally approved. The following conditions must be met before data collection begins:

Protocol is not approved for the following reasons:

Signature of IRB reviewer (Chair) (may be electronic)

Date

Reviewers: _____ (print)

Reviewer: Please add additional comments, if necessary, to this form.

IV. Levels of Review

Exempt Status: Research activities in which the only involvement of human subjects will be in one of the following categories of research are normally exempt from full IRB review protocols, but must be reported to the IRB to determine if the activity is exempt.

1. Research conducted in established or commonly established educational settings, involving normal educational practices. This includes research on regular and special education instructional strategies or research on the effectiveness of instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior. This exemption does not apply if information is obtained in such a manner that human subjects can be identified or if any disclosure of the human subjects' responses could reasonably place the subject at risk of criminal or civil liability, or damage financial standing, employability or reputation.

3. Research involving existing data or documents that are publicly available or if the investigator records the information in a manner that human subjects cannot be directly identified or through identifiers linked to the subjects.

Expedited Status: Research activities that present no more than a minimal risk to human subjects and involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure. The expedited review procedure may not be used if the identification of subjects and/or their responses would reasonably put the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing.

These are the categories that qualify for expedited reviews:

1. Clinical studies of drug and medical devices only when either research on drugs for which an investigational new drug application (21 CFR Part 312) is not required or research on medical devices for which an investigational device exemption is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week from subjects 18 years of age or older and who are in good health and not pregnant or known to be pregnant.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or simulated by chewing gumbase or wax by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subjects' privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography and electroretinography.

5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior, such as studies of perception, cognition, game theory or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to the subjects.

Full Review: All research activities that do not qualify for exempt or expedited status will be presented to the IRB for full review.