Nyack College and Seminary

Human Participants in Research

Request for Institutional Review Board Approval (2020-2021)

INSTRUCTIONS:

1. Please answer all questions in the space beneath them.
2. Submit to the IRB: (1) Application (2) Informed consent (3) append Assent for minors, interview scripts, measurements/tools and/or recruitment materials and permission letters as appropriate; (4) If required by your program completed chapters 1 and 3 or equivalent. (Introduction and Method)
3. Human Participants Protections Training Requirement -- All applicants must provide a certificate of training or training verification from the appropriate school.
4. IRB documents will be submitted electronically by department dean/chair IRB Committee

SECTION I: INVESTIGATOR:

Check one: [ ] Student [ ] Faculty [ ] Staff [ ] Other _____

Principal Investigator's Name: (Last) _____ (First) _____

School : _____ Program _____

(Students: Faculty Advisor Name): _____

Student Contact Information for IRB responses

Address: _____

_____

_____

Telephone #s: Home: _____ Cell: _____

E-mail: _____

SECTION II: PROJECT/STUDY INFORMATION

Title:

_____

_____

- Anticipated Start & End Dates for Data Collection Research: _____/_____/_____ - _____/_____/_____

Please note: No work with participants may begin prior to approval by the IRB

SECTION III: PARTICIPANT POPULATION

Indicate the specific participant population(s) that will be involved in the research project.

[ ]Adults (competent to consent)
[ ]Adults (not competent to consent)
[ ]Minors (under 18 years old)
[ ]Prisoners
[ ]Pregnant Women
[ ]Developmentally Disabled – if so please specify the specific population _____
[ ]Non-English speaking

SECTION IV: FUNDED PROJECTS

Has this project been submitted for external funding? [ ] Yes [ ] No -- If yes, complete below:

What kind of funding will this project receive? [ ] None [ ] Grant/Contract [ ] Fellowship

Principal Investigator on Project: _____ Ext._____

Funding source: _____TC Index # if applicable:_____

Project Title: _____

Are the contents of this protocol identical to those described in the funded proposal application? [ ] Yes [ ] No

SECTION V: REQUEST FOR PROTOCOL REVIEW

Please see the attached Review Categories page and indicate the type of review you are requesting: Exempt, Expedited or Standard. If you select either Exempt or Expedited, circle the number of the review category that best fits your research. Final decisions about the appropriate level of review rest with the IRB.

____ I am requesting an EXEMPT REVIEW under category: 1 2 3 4 5 6

____ I am requesting an EXPEDITED REVIEW under category: 4 5 6 7 8 9

____ I am requesting a FULL COMMITTEE REVIEW because my research does not precisely apply to any of the categories specified in the EXEMPT or EXPEDITED review categories.

SECTION VI: SIGNATURES

INVESTIGATOR: I accept responsibility for the research protocol described herein. I am aware of all the procedures to be followed & I will monitor the research & notify the IRB of any CHANGES or significant problems. Further, I certify that I have undergone training in basic human participants protections.

Principal Investigator's Signature: _____ Date: _____/_____/_____

I have completed the required training in Human participants research: ____on-line ____workshop ____other

Verification Signature: _____ Position: _____

Proof of completion must be attached to application or signature above by trainer.

FACULTY ADVISOR (Required for student research): I accept responsibility for the research protocol described herein by the student/investigator working under my direction. I further attest that I am aware of all procedures to be followed, will monitor research & will notify the IRB of any CHANGES or significant problems. I certify that I have undergone training in basic human participants protections.

Faculty Advisor's Signature: _____ Date: _____/_____/_____

Print Faculty Advisor's Name: _____

DEPARTMENT CHAIR or PROGRAM DIRECTOR (Required for all research): I have reviewed the research protocol described herein and am aware of the procedures to be followed.

Signature: _____ Date: _____/_____/_____

Print Name: _____

SECTION VII: ADDITIONAL INVESTIGATORS AND KEY PERSONNEL

Fill out this section if additional investigators or research assistants will work on this project. Attach additional pages if necessary.

1. ADDITIONAL INVESTIGATOR Check one:

[ ] Student [ ] Faculty [ ] Staff [ ] Other _____

Name: (Last) _____ (First) _____

Department: _____

Telephone#: _____ E-mail: _____

Signature_____ Date: _____/_____/_____

By signing above, I certify that I have undergone training in basic human subjects protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Add additional investigators as needed below.

SECTION VIII: Protocol Description

Please answer each question in the space below it

Participants

1. Who will your potential participants be? Please check the participant population(s) that will be involved in the research project:

[ ]Adults (competent to consent) [ ]Adults (not competent to consent)

[ ]Minors (under 18 years old) [ ]Prisoners [ ]Pregnant Women

[ ]Developmentally Disabled [ ]Non-English speaking

2. Please describe their anticipated age range, gender, race/ethnicity (if applicable) and/or any important characteristics.

3. Please describe the purpose of your research. Provide relevant background information and scientific justification for your study. You may provide citations as necessary.

4. Federal guidelines state that research cannot exclude any classes of subjects without scientific justification. Will your study be purposely excluding any classes of subjects? (e.g. children 17 and under, by gender, class, race) If so, please justify this.

5. Please state your research question and hypotheses

6. What specific data will you collect and how will the participants you choose help to answer your research question? Define your variables operationally by indicating how you will collect data for each variable.

7. Briefly describe how you will analyze the data collected. In the case of multiple hypotheses list the analysis method for each hypothesis.

DESCRIPTION OF RECRUITMENT AND PROCEDURES

8. Please describe your recruitment methods for your participants. How and where will they be recruited (flyers, general announcement, word-of-mouth, snowballing, etc.)?

9. Are you are recruiting participants from institutions of higher education other than Nyack College? If so, documentation of permission or pending IRB approval from that institution is required with this submission. State date of approval , name and title from the institution

10. How many participants are you planning to recruit?

11. Where will your research take place specifically? (classroom, outside of classroom, waiting room,church office, other location)

12. Will participants be remunerated for their participation? If, so please describe.

13. Will deception be used? If so, please provide a rationale for its use. How will subjects be debriefed afterward? Submit debriefing script. Scripts should include a statement that gives your subjects the opportunity to withdraw his/her participation at that time.

14. Will you have a control group?

15. Will you be videotaping your subjects? If so, please describe in detail. Please note that the IRB will only approve videotaping when there is adequate scientific and ethical justification. If you will be audio/videotaping, please state how you will ensure that all participants have consented to be recorded? (This must also be clearly stated in consent form)

CONFIDENTIALITY PROCEDURES

16. How will you ensure the participants confidentiality? Describe in detail your plans for ensuring confidentiality of data regarding subjects.

17. Will data be collected anonymously? Will you be able to link the data? If not, how will participants' identity/information be protected? (e.g. codes or pseudonyms, etc.)?

18. Where will coding and data material be stored, such as "in a locked file cabinet?"

19. If bilingual interpreters or interviewers will be used, what will you do to ensure confidentiality of the subjects? What are your procedures for recruiting interpreters/interviewers? Indicate the name of the interpreter/interviewer and for whom he/she works. Submit copies of all questionnaires or interview questions for each subject population.

DESCRIPTION OF RESEARCH RISKS & BENEFITS

20. What are the potential risks, if any, (physical, psychological, social, legal, or other) to your subjects? What is the likelihood of these risks occurring, and/or their seriousness? How will you work to minimize them?

21. What are the potential benefits of this study to the subjects? If there are direct benefits, please state so. If there are no direct benefits, please simply state the benefits that *may be possible* from your research. You cannot *promise* a result of your study as being a benefit. It is also important to note that remuneration or any reward for participation is not considered a benefit.

INFORMED CONSENT PROCEDURES

Informed consent is a process, not a form.

22. What are your procedures for obtaining participants informed consent to participate in the research?

23. How will you describe your research to potential participants ? *(A script is preferred).*

24. What will you do to ensure their understanding of the study and what it involves?

25. If you are recruiting students from a classroom during normal school hours, what will the alternative activities for those who wish not to participate?

26. Are you a teacher, administrator, counselor, case worker or in any other way affiliated with the research site? If so, how will you insure voluntary participation and minimize the appearance of coercion in your study?

Submit all consent forms/scripts. Each consent form must be a separate document and titled for its respective subject population (e.g. teachers, parents, etc.). All consent documents must be in English, even though you may translate them. If your research project requires using documents that are translated into other languages, please submit both the translated English version AND the translated document with your application.

RESEARCH SITE(S)

27. Where will research be conducted? If you are conducting research or any part of your study, or recruiting participants from schools or other institutions, approval must be obtained from the appropriate administrator, IRB, or representative of that institution. Submit the letter(s) of approval or letter(s) indicating that approval has been granted "pending the receipt of Nyack College IRB approval".

NOTE: IF YOU ARE CONDUCTING ANY PART OF YOUR RESEARCH WITHIN NYC BOARD OF EDUCATION SCHOOLS: It is required that you receive approval from Nyack College prior to submitting to the NYC Board of Education's Division of Assessment and Accountability.

Please attach:

1. Informed Consent Signature page
2. Participants' Rights and Assent for Minors
3. Recruiting materials, survey materials, etc as appropriate

Categories of IRB Review

EXEMPT RESEARCH - Constitutes no more than minimal risk AND only involves human participants in one or more of the following categories:

1. Research conducted in established educational settings, involving normal educational practices, such as: (i) research on education instructional strategies or (ii) research on the effectiveness of or comparison among instruction techniques, curricula, or classroom management methods.

2. Research involving the use of (a) educational tests (cognitive, diagnostic, aptitude, achievement); (b) surveys, interviews, or observation of public behavior* UNLESS (i) information is recorded with identifiers linked to subjects and (ii) subjects' responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation).
*No exemptions are allowed under (b) when children are involved in survey/interview procedures, or observations when investigator participates in activities being observed.

3. Research involving educational tests, surveys, interviews, or observation of pubic behavior is exempt if: (I) the subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute requires confidentiality of identifiable information to be maintained permanently.

4. Research involving the collection or study of existing data, document, or records. Sources must either be publicly available or information must be recorded without identifiers linked to subjects.

5. Research conducted by or subject to the approval of federal department or agency heads and designated to evaluate possible changes in or alternatives to those programs or changes in methods of payment for benefits under those programs.

6. Taste or food quality evaluation involving wholesome/safe foods.
Note: Federal regulations indicate that certain research is exempt from review. However, a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status. Exemptions do not apply to research conducted on pregnant women, prisoners, or vulnerable populations.

EXPEDITED RESEARCH-- Constitutes no more than minimal risk AND only involves human participants in one or more of the following categories:

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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of

subjects; or
(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Note: Expedited review categories 1-3 apply to biomedical research not typically conducted at Nyack College, and consequently do not appear on this list.

STANDARD REVIEW OF RESEARCH:

If your project does not precisely fit under any of the categories under either the EXEMPT or EXPEDITED review sections listed above, then it must be submitted under STANDARD review procedures. Standard Review is used for all projects involving vulnerable populations, except some minimal risk research involving children. Research involving deception and any research that entails more than minimal risk to the subject, even if it otherwise appears to fall into one of the exempt or expedited categories, must be submitted under standard review procedures.

Signature Page

Thesis Title_____

The signatures below indicate that the information contained in the document and/or proposal has been reviewed and is in compliance with the standards set by the academic department , IRB and Nyack College. If this project involves student research, the signature of faculty and site supervisory indicates acceptance of oversight responsibility for the student.

_____
Name of principal investigator (student) and date

I have received Human Participants Training

_____
Signature of principal investigator (student) and date of Human Participants Training

_____
Signature of organizational site supervisor, title, organization and date

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APPROVED BY THE IRB COMMITTEE ON THE USE OF HUMAN PARTICIPANTS IN RESEARCH

_____ _____
Signature of faculty supervising research and date

_____
Signature of Department Chair or Dean and date

_____
Signature of IRB Chair and date