NEW YORK INSTITUTE OF TECHNOLOGY
Institutional Review Board for the Protection of Human Participants
Northern Blvd, Old Westbury, NY 11568
516-686-7488♦ https://www.nyit.edu/ospar/institutional_review_board

Request for Exemption

Instructions

Certain categories of research are exempt from Federal regulations requiring IRB review. These categories can be found on the attached or at:
https://web.nyit.edu/files/academic_affairs/AA_OSPAR_IRB_ReviewExemptionCategories.pdf

Only the IRB can determine if a protocol is exempt. To request an exemption, complete the *Request for Exemption* form and submit it to the IRB office shown below. Requests for exemption are reviewed on a rolling basis and can be submitted at any time.

If the IRB determines that the proposed project qualifies for exemption, you will receive a letter to this effect. No further action will be required.

Please read these instructions carefully. The most common reason for delay in review of protocols is that the IRB does not have enough information about the project.

Submitting your protocol for review

What to submit:

Submit one copy of the original in PDF format:

- ☐ The signed Request for Exemption form
- ☐ Protocol description
- ☐ Copies of surveys, interview questions, tests or other instruments
- ☐ Certificate of completion of the CITI training program
- ☐ COI Form (OSPAR will initiate to all researchers via Adobe Sign, just submit email addresses)
- ☐ Letters of permission from study sites (if applicable)

Protocols **WILL NOT** be reviewed without:

- Phone and email address for the Principal Investigator (PI) or Instructor
- Phone and email address for the Student Investigator
- Signatures of the PI/Instructor (Instructor should sign as both PI and Instructor)
- Signature of Student Investigator

Where:

Requests for Exemption should be emailed to grants@nyit.edu

When:

Requests for exemption can be submitted at any time. There are no deadlines. Please allow a minimum of 2 weeks for review.

If you have questions, please call 516.686.7488 or e-mail grants@nyit.edu

More information can be found at https://www.nyit.edu/ospar/institutional_review_board.

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Request for Exemption

Complete and sign this page and respond to the attached questions on a separate sheet.

Principal Investigator (PI)/Instructor Name: _____

Phone Number: _____ **Email Address:** _____

Address (to which correspondence should be sent)**:** _____

Student Investigator Name: _____

Student Email Address; _____ **Student Phone Number:** _____

NYIT ID Number: _____ **Course Number:** _____

Project Title: _____

Study Location(1) **:** _____

Start Date: ____/____/____ **End Date:** ____/____/____

Exemption Category: Review the categories for exemption carefully. If your protocol does not fit precisely into one or more of these categories, it cannot be considered for exemption. If your protocol does not fit the exemption categories, refer to the guidelines for expedited or full review.

Category ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

Human Protections training completed?(2) ☐ Yes Completion Date: ____/____/____

Principal Investigators:

I certify that to the best of my understanding I am in compliance with the policies of NYIT regarding human protections and will perform my research consistent with the description above. I have completed the required training in human subjects' research and ☐ a copy is on file with OSPAR or ☐ I have attached a copy of the certificate of completion.

PI Signature: _____ **Date:** _____

Department Chair: _____ **Date:** _____

Instructors:

I certify that I have instructed this student in research techniques, have reviewed his/her complete research proposal and have found it to be consistent with the attached description and in compliance with NYIT Human Protections Policies.

Instructor Signature: _____ **Date:** ____/____/____

Students:

I certify that to the best of my understanding I am in compliance with the policies of NYIT regarding human protections and will perform my research consistent with the description above. I have completed the required training in human subjects' research and ☐ a copy is on file or ☐ I have attached a copy of the certificate of completion.

Student signature: _____ **Date:** ____/____/____

Add additional sheet of paper if multiple students;

Please respond to the questions on the following page on separate sheet of paper.

(1) Letter(s) of permission from the study site(s) must be attached.
(2) Protocols will not be reviewed without the certificate of completion of the required training program.

Project Description:

Please respond to the following questions one by one on a separate page. Refer to *Describing your research to the IRB* for additional guidance.

1. What is the purpose of the proposed study? Describe the purpose of the study and your hypothesis. State the type of research design.
2. How will subjects be recruited and selected? Describe how you will advertise the study, compensation or incentives you will give to subjects, inclusion and exclusion criteria, and the number of subjects you hope to recruit.
3. Describe the study procedures (what the subjects will be asked to do). You should attach copies of the surveys, interview questions, or other instruments that you plan to use. You may want to include a timeline or diagram to show how the subjects will be involved.
4. Discuss the potential harms and benefits to the subjects.
5. Describe how you plan to preserve the subjects' anonymity or protect their confidentiality. Where will the data be stored? Who will have access to it? What will happen to it after the study is completed?
6. Provide a consent and/or assent form if needed. If the study qualifies for exemption, it will generally be exempt from the requirement for a consent form.
7. If the study includes a survey, include the email recruitment with: title of study, purpose of study, how the data will be used and how the data will appear in publication, the group selected to participate and why this group, whether the data collected is anonymous or de identified, whom to contact with questions and contact information (Principal Investigator and Institutional Review Board), if you agree to participate in this study please check the link below.
8. If the study includes a survey utilizing an online platform and/or proprietary software, please include the following language, or a variant thereof, in the survey instructions to prospective subjects, and in the consent form (if any);

If using REDCap survey use this disclaimer:

Confidentiality:

Research records and data will be stored and maintained by New York Institute of Technology (NYIT) using Research Electronic Data Capture (REDCap) software under license from Vanderbilt University. REDCap is a secure web application for building and managing online surveys and databases. At NYIT, REDCap is installed on-premises on a web server located behind a firewall augmented by an Intrusion Preventions System (IPS). The Institute's REDCap database is stored and maintained on a different server with additional firewall protections. Access to the web and database servers is restricted to the NYIT Information Technology Department System Administration staff and to select members of the support staff of NYIT's College of Osteopathic Medicine. All reasonable efforts have been and will be made to keep your personal information confidential. However, total confidentiality cannot be guaranteed.

If using Qualtrics survey use this disclaimer:

Confidentiality:

Participants may complete the online survey without explicitly identifying themselves. Also investigators using Qualtrics are advised how to use an anonymous setting such that responses do not include identifying information such as IP address or location information. However, by agreeing to continue, participants acknowledge that New York Tech cannot guarantee anonymity for these survey responses with 100% certainty.

Exempt Categories [Revised Common Rule, 45 CFR 46.104(d), effective January 21, 2019]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § ____.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § ____.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or
(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § ____.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § ____.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § ____.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § ____.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.