

Appendix D
STATE UNIVERSITY OF NEW YORK AT NEW PALTZ
Institutional Review Board

Protocol #
Approval Date:

Application for Research Proposal Review

Note: Incomplete applications will be returned. Refer to IRB guidelines & policies available on the web at www.newpaltz.edu/sponsored_programs/humansubs.html

Allow a minimum of 15 days for processing of your application (if it is delivered to the Office of Sponsored Programs by noon Monday through Thursday. Allow more time if delivered on Thursday p.m. or Friday.) You will receive e-mail notification of approval or of modifications required.

For proposals falling under the categories of Expedited and Exempt, two (2) hard copies and one electronic copy via e-mail attachment must be submitted to the IRB secretary. Please submit the hard copies to: Institutional Review Board, c/o Office of Sponsored Programs, HAB 805 and the electronic copies to: irbsecretary@newpaltz.edu. The hard copies must include the signed cover sheets and all relevant materials, i.e., consent form(s), questionnaire(s), advertisements, etc. The protocol submitted as an electronic attachment should include the unsigned cover sheets and the same relevant materials as a single file in MS Word or PDF format. After the signed hard copies are received by the IRB secretary, the secretary will then forward the electronic proposal to the IRB Chair and one IRB member for review. For Full Board Review applications, submit 12 hard copies of your application to the IRB secretary. Applications will be distributed for review at convened meetings. For all proposals submit two copies of grant/contract proposals, if any.

Full
(all international studies)
(see Appendix H of the IRB Manual)

Expedited Category _____
(see appendix B of the IRB Manual)

Exempt 45 CFR 46.101 _____
(see appendix A of the IRB Manual)

Note: If this study qualifies as an Exempt Survey (see appendix A of the IRB Manual) please use the abbreviated Survey Research Application instead.

Title of Study: _____

Date of Submission:

Principal Investigator Name:

Specify: Faculty/Staff Graduate Student Undergraduate Student Other

Local Mailing Address:

Department: Division: Phone: email:

If PI is a Student

Name of Faculty Sponsor: Department: Phone: email:

Co-Investigator's Names:

Specify: Faculty/Staff Graduate Student Undergraduate Student Other

Institutional Affiliation (if not SUNY at New Paltz):

To complete the required CITI human subjects training program, go to www.miami.edu/citireg. This training must be completed prior to submission of application. Please note that if your research involves any of the issues below, you are required to take the corresponding CITI modules. Please check all that apply: International Research Vulnerable Subjects – Women, Fetuses Vulnerable Subjects – Groups/Communities Res. using internet Records Based Research Genetics Research VA Research HIPAA

Principal Investigator

CITI completed? Yes No

Study Team: List all individuals who assist the PI in the design or conduct of the study. Attach additional pages as needed.

Name: Department: CITI completed? Yes No
Name: Department: CITI completed? Yes No

Name:

Department:

CITI completed? Yes No

Rates of Pay to Subjects, if applicable:

Funding Source(s) and Application Deadline(s) (if applicable):

Agency/Organization: _____

Application Date: _____

Is this project expected to continue for more than one year? Yes No Anticipated completion date _____

Approval for projects is valid for one year only. Investigators must request a continuation of the approval yearly if the activity is ongoing for more than one year. The *Application for Continued Approval/Final Report* in Appendix G of the Institutional Review Board Manual is to be used for this purpose. The same form is to be used for your final report upon completion of the project.

Signature of Principal Investigator (PI)

Signature certifies that the information in this application is correct and that the research will be conducted in full compliance with SUNY New Paltz policies and federal regulations. The period of approval is determined by the IRB and continuing review is required in order to maintain approval status. The PI must submit progress reports for this review. Adverse events must be reported to the IRB according to the guidelines and changes in the study must be approved by the IRB prior to implementation.

Signature of Principal Investigator

Date

Statement of Assurance for Investigators Applying for Full or Expedited Review

Disclosure of Financial Relationships and Interests in Research

Do you, your spouse, or dependent child(ren) have any financial relationships that may create financial interests in research studies that may bias the design, conduct, or reporting of the research or that may adversely affect the rights and welfare of subjects?

-----Yes -----No

Signature

Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance if the research proposal is being submitted for Full or Expedited Review Procedures.

The proposed investigation involves the use of human subjects. I am (we are) submitting this form with a description of the project prepared in accordance with institutional policy for the protection of human subjects participating in research

_____ **I (We) understand the SUNY New Paltz policy concerning research involving human subjects and agree to:**

1. Accept responsibility for the scientific conduct of this project.
2. Assure that the information in this application is correct;
3. Obtain informed consent of all subjects, provide subjects with copies of consent forms and maintain consent forms for the required three years, unless these procedures are waived by the IRB. (Faculty sponsors will keep consent forms on file for student investigators below the thesis level.)
4. Assure that all key personnel have completed the SUNY New Paltz educational requirements for human subject research prior to assuming duties;
5. Use only an IRB approved and stamped copy of the consent form.
6. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form and utilize only the revised, stamped copy of the consent form.
7. Maintain research data and consent documents under appropriately secure conditions in order to protect subject confidentiality.
8. Report promptly to the IRB any injuries to human subjects or any problems which involve risks to the human subjects or others, which become apparent during the course of or as a result of experimentation and any actions taken.
9. Cooperate with the IRB with the continuing review of this project including submission of the Application for Continued

Approval/Final Report.

10. Report promptly, both to subjects and the IRB, significant new findings developed during the course of the research which may relate to the subjects' willingness to continue participation.
11. Comply with all IRB decisions, conditions and requirements.
12. Report to the IRB any serious or continuing noncompliance with the requirements of the SUNY New Paltz human subjects policy or determinations of the IRB.
13. Train and supervise study personnel who are obtaining consent.

Printed Name of Investigator	Signature of Investigator	Date
Printed Name of Faculty Sponsor	Signature/Approval of Faculty Sponsor	Date

Statement of Assurance for Requests for Certification of Exempt Status

Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance.

The proposed investigation involves the use of human subjects. I am (we are) submitting this form with a description of the project prepared in accordance with institutional policy for the protection of human subjects participating in research. **I have ensured that all items on the Research Proposal Checklist are included.**

_____ **I (We) understand the College's policy concerning research involving human subjects and agree to:**

1. Accept responsibility for the scientific conduct of this research;
2. Assure that the information in this application is correct
3. Assure that all key personnel have completed the SUNY at New Paltz educational requirements for human subject research prior to assuming any duties;
4. Obtain parental permission for all subjects (if required) and maintain permission forms for the required three years, unless these procedures are waived by the IRB. (Faculty Sponsors will keep permission forms on file for Student Investigators below the thesis level.).
5. Maintain research data and permission documents under appropriately secure conditions in order to protect subject confidentiality;
6. Report to the IRB any unanticipated effects on subjects which become apparent during the course or as a result of experimentation and any actions taken;
7. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form.
8. Comply with all IRB decisions, conditions and requirements.

Signature of Investigator	Date
Approval/Signature of Faculty Sponsor	Date

Completing the Application for Research Proposal Review

General Considerations:

There may be some questions on this form, which you consider do not apply to your application. For those questions, state, "Does not apply" if it is clear that it does not apply. If it might be subject to question, then give a rationale for why you do not believe this question pertains to your study. If you leave a question unanswered, the IRB will consider that you forgot to answer the question and will return your application with the request for further information. Refer to pages 2-12 for instructions pertaining to the questions below.

Category A: Brief Description of Proposed Research:

Question 1: State the purpose of your research.

Question 2: State the major hypotheses, research question and/or the aims of your study.

Question 3: Provide a brief review of literature including citations.

Category B: Description of Subjects/Participants

Question 4: State the source of the participant population. (For international or internet studies, refer to the IRB Manual, pp. 3 & 4.)

Question 5: State the approximate number of subjects.

Question 6: Discuss the characteristics of participants as individuals and as a pool (including age, gender, student status, disease conditions, behavioral abnormalities and affiliations or memberships).

Question 7: If your research involves non-English speaking subjects or subjects from a foreign culture, include contact information for someone who can act as a cultural consultant for your study, i.e., name, address, telephone number, and email. (The cultural consultant should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.)

Question 8: State criteria for including subjects in the study or excluding them from the study.

Question 9: Provide a rationale for the inclusion or exclusion of vulnerable subjects.

Question 10: Describe how you will recruit subjects for the study. Include all relevant materials, e.g., advertisements, fliers, scripts, translations, psychology pool sign-up sheets, etc. (Student researchers using the Psychology Pool are to include a blank copy of the sign-up sheet and departmental authorization for use of the pool.)

Question 11: Discuss other matters pertinent to human participants.

Category C: Procedures

Question 12: Specify the location of the study. (If this is an external agency or organization, a letter of cooperation is necessary.)

Question 13: List and briefly describe all variables to be studied.

Question 14: Describe Procedures including:

(a) Describe the methods of study administration in detail (Attach a complete copy of all instruments).

(b) Describe the methods of record-keeping

(c) Describe the methods you will use to analyze the collected data.

(d) Document authorization of use or permission to modify a copyrighted instrument, or document access in the public domain of non-copyrighted instruments.

Question 15: Describe all activities involving participants, including:

- (a) Frequency of each activity.
- (b) Duration of each activity.
- (c) Participant's total time commitment.
- (d) Instructional script for administration of the study.

Question 16: Describe all equipment used with participants, if any.

Question 17: Specify what factors will lead to cessation of procedures causing physical or emotional stress. Outline procedures for stopping or interrupting the protocol.

Question 18: Describe biological samples to be taken, the method for their handling and the qualifications of individuals taking samples.

Question 19: Provide debriefing method, rationale for deception (if applicable) and debriefing protocol.

Question 20: Discuss any other aspects of the procedures.

Category D: Risks to Participants

Question 21: Describe potential risks and assess the likelihood, severity, duration and effects of each. (Consider risks of physical injury, psychological trauma or stress, social/economic harm, legal risks and loss of confidentiality. Could any of the questions be more offensive than those encountered in a participant's everyday life? Note "no known risks" if none are anticipated.)

Question 22: Describe methods for minimizing risks. For example, document how potential psychological distress will be addressed, by whom, and with what credentials.

Question 23: Describe other methods, if any, that were considered alternatively and why they will not be used.

Question 24: State any other matters relative to risk to participants.

Category E: Anticipated Benefits to Participants

Question 25: Describe the anticipated direct benefits to these participants because of their participation.

Question 26: Describe the anticipated benefits accruing to the class of participants these individuals represent.

Question 27: Describe the anticipated benefits accruing to society-at-large or other.

Question 28: State any other aspects of anticipated benefits to participants.

Category F: Consent Procedures

Question 29: Describe how potential participants will be informed about the project activities.

Question 30: Attach consent form and assent form/script, if appropriate. (Use reading level and terminology understandable to participants. If participants are non-English speaking, include translations of all consent/assent documents and certification of the validity and reliability of the translation in relation to the English language documents See Question 7.)

Question 31: Discuss any other aspects of the consent process.

Category G: Privacy and Confidentiality Procedures

Question 32: Describe the method(s) used to protect the identity of individual participants.

Question 33: Describe your plans for maintaining data after the study is complete.

Question 34: Describe how the federal requirement for consent forms to be retained for three years following the conclusion of the project will be met. (If an institution/organization requires retention of consent forms on site, then the investigator may request a waiver of this requirement.)

Question 35: If you are audiotaping, videotaping or photographing, specify tape/film storage, use, and when and how disposition of the tapes/film will take place.

Question 36: Discuss any other aspects of confidentiality.

Category H: Justification of Request for Exempt or Expedited Review Processes

Question 37: Give a full justification for an exemption or expedited review request. (Refer to p. 13 in Manual.)

Include the category of exemption (Appendix A) or expedited review (Appendix B) you are requesting and discuss the relationship of your study to the criteria for the specified exemption/expedited review category.

Category I: Justification for Request for Waiver of Informed Consent Process and/or Documentation

Question 38: Give a full justification for a request for waiver of the informed consent process. (Refer to p. 13 in Manual)

Question 39: Give a full justification for a request for waiver of documentation of the informed consent process. (Refer to p. 13 in Manual)