Application for Research Proposal Review

Note: Incomplete applications will be returned. Refer to HREB 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, the original, one hard copy and one electronic copy via e-mail attachment must be submitted to the HREB secretary. Please submit the hard copies to: Human Research Ethics Board, c/o Office of Sponsored Programs, HAB 604 and the electronic copies to: hrebsecretary@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 HREB secretary, the secretary will then forward the electronic proposal to the HREB Chair and one HREB member for review. For Full Board Review applications, submit 12 hard copies of your application to the HREB secretary. Applications will be distributed for review at convened meetings. For all proposals submit two copies of grant/contract proposals, if any.

☐ Full Expedited Category      ☐ Exempt Category

Note: If this study qualifies as an Exempt Interview or Exempt Survey use those appropriate abbreviated Applications instead.

Title of Study: __________________________ Date of Submission: __________

Principal Investigator Name: __________________________ CITI Completed? Yes ☐ No ☐
Specify: ☐ Faculty/Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other

Co-Principal Investigator Name: (if applicable) __________________________ CITI Completed? Yes ☐ No ☐
Specify: ☐ Faculty/Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Other

Local Mailing Address: ______
Department: ______ Phone: ______ E-mail: ______

If PI is a Student (Please attach the Faculty Advisor Assurances Addendum)

Name of Faculty Sponsor: ______ Department: ______ Phone: ______ E-mail: ______ CITI Completed? Yes ☐ No ☐

External Researchers (if not SUNY at New Paltz):
Institutional Affiliation: __________________________

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 ☐

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 Expedited 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 located on the HREB website is to be used for this purpose.

For completed studies: A research project no longer involves human participants once the investigators have finished obtaining data through interaction or intervention with participants or obtaining identifiable private information about the participants, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the HREB-approved protocol are finished, the research project no longer needs to undergo continuing review. If this is the case, e-mail the HREB Chair (hrebchair@newpaltz.edu) copying the HREB Secretary (hrebsecretary@newpaltz.edu) stating that your study is complete. Be sure to include the title of your study and protocol number in your e-mail.

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 HREB 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 HREB according to the guidelines and changes in the study must be approved by the HREB prior to implementation.

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 participants?

☐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 Requests for Certification of Exempt Status.

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

I (We) understand the SUNY New Paltz policy concerning research involving human participants 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 New Paltz educational requirements for human subject research prior to assuming duties;
4. Use only an HREB approved and stamped copy of the consent form;
5. Maintain research data and consent documents under appropriately secure conditions in order to protect subject confidentiality;
6. Report promptly to the HREB any injuries to human participants or any problems which involve risks to the human participants or others, which become apparent during the course of or as a result of experimentation and any actions taken;
7. Report promptly, both to participants and the HREB, significant new findings developed during the course of the research which may relate to the participants’ willingness to continue participation;
8. Comply with all HREB decisions, conditions and requirements;
9. Report to the HREB any serious or continuing noncompliance with the requirements of the SUNY New Paltz human participants policy or determinations of the HREB;
10. 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
Principal Investigator(s) and Faculty Sponsor (if a student investigator) must sign the following Statement of Assurance, for above statements 1-10 and the following statements 14-16, if the research proposal is being submitted for Full or Expedited Review Procedures.

14. Obtain prior approval from the HREB 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;
15. Cooperate with the HREB with the continuing review of this project including submission of the Application for Continued Approval;
16. Obtain informed consent of all participants, provide participants with copies of consent forms and maintain consent forms for the required three years, unless these procedures are waived by the HREB. (Faculty sponsors will keep consent forms on file for student investigators below the thesis level.)

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**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 HREB 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 Participants/Participants**

Question 4: State the source of the participant population.

Question 5: State the approximate number of participants.

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 participants or participants 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 participants in the study or excluding them from the study.

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

Question 10: Describe how you will recruit participants 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: Describe any compensation given to participants to participate in the study. (i.e. payments, gift cards, course credit, psychology subject pool credit, enter into a raffle, etc.)

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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 to be submitted directly to the H.R.E.B. Office either on letterhead or their workplace email; after final approval of proposal)

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: Under certain conditions you can request for a waiver of documentation of the informed consent process by meeting both criteria - minimal risk or if the only link to the participant is their signature. Each participant will be asked whether the participant wants documentation linking the subject with the research and the participant’s wishes will govern.

Question 32: Give a full justification for a request for waiver of the informed consent process.

Category G: Privacy and Confidentiality Procedures

Question 33: Describe the method(s) used to protect the identity of individual participants.

Question 34: Describe your plans for maintaining data after the study is complete.

Question 35: 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 36: 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 37: Discuss any other aspects of confidentiality.

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

Question 38: Give a full justification for an exemption or expedited review request.

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