

**STATE UNIVERSITY OF NEW YORK AT NEW PALTZ
HUMAN RESEARCH ETHICS BOARD
APPLICATION FOR CONTINUED APPROVAL**

- This application is to be used to apply for continued approval for research that has been approved as Expedited or Full Board.
- Continued approval is not required for research that has been certified as Exempt.
- A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, 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 email.

Principal Investigator Name: _____

Project Title: _____

Protocol Number: _____

SECTION 1: GENERAL INFORMATION

A. Investigators:

Principal Investigator:

Faculty Graduate* Undergrad* Staff

Campus Address:

Campus Phone:

Campus Fax:

E-mail Address:

Co-Investigator:

Faculty Graduate Undergrad Staff

Co-Investigator Faculty Graduate Undergrad

Staff

***Faculty Advisor (if PI is student):**

Department:

Co-Investigator:

Faculty Graduate Undergrad Staff

B. Source of Funding: (If title of grant differs from above, please provide)

Externally Funded

Sponsor (s):

Internally Funded

Seeking Funding

Sponsor(s):

Sponsor Deadline

Not Seeking Funding

SECTION 2: STATUS OF STUDY (Check one under A or B)

A. Active Projects with Human Subjects Accrued Since Last Approval:

- Check the appropriate box below.
- Submit a copy of the redacted consent/permission/assent form(s)
- Submit a copy of the current consent/permission /assent form(s) to be used during the upcoming approval period if new accrual of human subjects is expected.

Accrual and research intervention will continue

Accrual is complete, but research intervention continues with those enrolled

Accrual and research intervention are complete, but follow-up data collection continues

Accrual, research intervention, data collection are complete, but data analysis on data that contains individual identifiers continues

B. Active Projects with No Human Subjects Accrued Since Last Approval:

- Check the appropriate box below
- If appropriate, submit a copy of the current consent/permission/ assent form(s) to be used in the upcoming approval period
- Provide a reason for no accrual

- Accrual is complete, but research intervention continues with those enrolled
 Accrual and research intervention are complete, but follow-up data collection continues
 Accrual, research intervention, data collection are complete, but data analysis on data that contains individual identifiers continues
 No accrual to date, but recruitment is continuing

SECTION 3: PROGRESS REPORT

A. On-Site Subject Enrollment Since Date of Last HREB Approval and Total:

	Since Last Approval	Cumulative Total
Number of Males (18 years or older) enrolled:	_____	_____
Number of Males (17 years or younger) enrolled:	_____	_____
Number of Females (18 years or older) enrolled:	_____	_____
Number of Females (17 years or younger) enrolled:	_____	_____
Total:	_____	_____
Estimated percentage of this total that were minorities*	_____ %	_____ %

*including American Indians or Alaskan Native, Asian or Pacific Islander, Black (not of Hispanic origin), Hispanic

Note: If subjects have been enrolled since the last HREB approval, you must include a redacted copy of your informed consent form(s). A redacted copy is a copy of the actual informed consent form with the participant’s identifying information (e.g., name, signature) blacked or whited out. Be sure to leave the date visible.

B. Modifications To The Study:

Provide a **brief summary of any changes** that have been made to the project during the last approval period (changes in consent/assent form or process, investigators, protocol amendments). Include copies of approval letters for all modifications. Highlight those changes that resulted in an increased risk to subjects. (Use additional sheets as necessary)

C. Unanticipated problems, complications, complaints, subject withdrawal since date of last HREB approval:

Were there any unanticipated problems (this can include a lost or stolen memory stick or laptop with data, unanticipated negative reactions to your procedures, a potential breach of confidentiality) that could potentially increase the risk of harm to subjects or others (including the principal investigator, your research assistants, and other relevant constituents)?

- YES NO

If yes, summarize the reported events, and briefly describe their nature and relationship to the study:

Note: All unanticipated problems should have been reported to the HREB chair as soon as you were aware of them.

Based on your knowledge of unanticipated problems that have occurred in this study (including those occurring at other sites, if applicable), do you feel there has been a significant increase in risks to subjects?

- Not applicable (no unanticipated problems have occurred)
 YES Please explain your assessment:
 NO Please explain your assessment:

Were any subjects removed from your study without their consent? YES NO

If yes, how many subjects? What was the reason in each case?

Did any subjects withdraw themselves from your study? YES NO
If yes, how many subjects? What was the reason in each case?

Did any problems occur in the process of obtaining and documenting informed consent? YES NO
If yes, please explain the nature of the problem:

Were any complaints about the research received since the last HREB review? YES NO
If yes, please explain the nature of all complaints:

D. Study Findings:

Provide a brief summary of the a) goals and b) results (preliminary or final) obtained in the study. If there are no results to report at this time, state that there are no results and explain why. (Use additional sheets as necessary)

E. Additional Required Materials Checklist:

- Redacted Consent/assent forms:**
If there has been accrual in the study, **attach a copy of the form** used to enroll subjects **since the last approval date** (redact subject's name and signature to preserve confidentiality).
- Consent/assent forms to be stamped for continued data collection:**
If you plan to continue accruing subjects over the next approval period, **submit a 'clean' original consent/assent form(s) for review.**
- Subject Recruitment Materials:**
If there will be continued recruitment of subjects, **submit** copies of all materials (advertisements, letters, flyers) to be used to recruit new subjects.
- Relevant Recent Literature:**
Attach a summary of any relevant recent literature if applying for continuation.
- Publications:**
Attach a reprint of any publications/abstracts derived from your study since last approval.
- Audit Reports:**
Attach a copy of any reports from audits/monitoring visits conducted by external organizations (e.g., HHS, sponsors) since last HREB review.
- Relevant Multi-Center Reports:**
Attach relevant multi-center reports if applying for continuation.
- Other Relevant Information:** (especially about risks associated with the research)
Attach other relevant information, especially about risks associated with the research if applying for continuation.

SECTION 4: CERTIFICATIONS

A. Certification of Principal Investigator (and Faculty Advisor if PI is a student):

My signature below certifies that the research described in this application and supporting materials will be conducted in full compliance with SUNY New Paltz policies and Federal regulations governing human subject research.

In addition, my signature certifies that I will:

- conduct all aspects of the project as approved by the HREB,
- promptly report any revisions or amendments to the research activity for review and approval by the HREB prior to commencement of the revised protocol, noting the only exception to this policy being in situations where changes in protocol are required to eliminate apparent, immediate hazards to the subject,
- promptly report any unanticipated problems affecting risks to subjects,
- assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials, **and**,
- where consent form(s) have been approved for the research activity, only HREB-approved, stamped consent forms will be used in the consent process.

Continued approval for projects is valid for only one year. Investigators must request another continuation of the approval yearly if the activity is ongoing (this includes continuing data analysis).

Signature of Principal Investigator (PI)

Date

Signature of Faculty Advisor (if Student is PI)

Date

Please submit two (2) hard copies and one electronic copy via e-mail attachment to the HREB secretary. Mail 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 original signed form and all relevant materials, i.e., consent form(s), redacted informed consent form, etc. The electronic copy must include all of the relevant materials in ONE single file in either MS Word or PDF format.