Continued Approval Application

Human Research Ethics Board
Office of Sponsored Programs
800 Hawk Dr, New Paltz, NY 12561
Old Main Building B120

- 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, using the **Add Comment** function, enter a comment stating that your study is complete. The IRB Coordinator will then be notified and will administratively close your study.

Principal Investigator Name: _____

Project Title: _____

_____

Protocol Number: _____

SECTION 1: 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 2: 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. 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 3: CERTIFICATIONS

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

I certify 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, I certify 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 consent forms approved in PACS 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)