

(office use only)		
___ Exempt ___	Expedited ___	Full

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

APPLICATION for CONTINUED APPROVAL/FINAL REPORT

Principal Investigator Name: _____

SECTION 1: PROTOCOL SUMMARY
 Provide a brief summary of the initial protocol and all subsequent modifications

SECTION 2: GENERAL INFORMATION
Project Title: _____

A. Investigators:

Principal Investigator:		Co-Investigator:
<input type="checkbox"/> Faculty	<input type="checkbox"/> Grad Student*	<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate <input type="checkbox"/> Undergrad <input type="checkbox"/> Staff
<input type="checkbox"/> Undergrad Student*	<input type="checkbox"/> Staff	Co-Investigator:
Campus Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate <input type="checkbox"/> Undergrad <input type="checkbox"/> Staff
Campus Phone:	Campus Fax:	Co-Investigator:
E-mail Address:		<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate <input type="checkbox"/> Undergrad <input type="checkbox"/> Staff
*Faculty Advisor (if PI is student)		
Name:	Department:	

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

<input type="checkbox"/> Externally Funded	Sponsor (s):	
<input type="checkbox"/> Internally Funded		
<input type="checkbox"/> Seeking Funding	Sponsor(s):	Sponsor Deadline
<input type="checkbox"/> Not Seeking Funding		

SECTION 3: STATUS OF STUDY (check applicable statement)

A. Active Projects with Accrual of Human Subjects:

- Accrual and research intervention will continue: Complete Sections 3 and 4 and** submit a copy of the current consent/permission /assent form(s) to be used during the upcoming approval period.
- Accrual is complete, but research intervention continues with those enrolled: Complete Sections 3 and 4 and** submit any consent/permission/assent modifications that may be used during the next approval period.
- Accrual and research intervention are complete, but follow-up data collection continues: Complete Sections 3 and 4.**
- Accrual, research intervention, data collection are complete, but data analysis continues: Complete Sections 3 and 4.**

B. Active Projects with No Human Subjects Accrued:

No accrual to date, but recruitment is continuing
 If checked, **complete Section 3C**, submit a copy of the current consent/permission/ assent form(s) to be used in the upcoming approval period, and provide reason for no accrual:

C. Completed/Terminated/Withdrawn Studies: **Completed Study** **Terminated Study (ended before completion)** If either of the above are checked, **complete Section 3** as a final report (i.e., include information from the entire duration of the study, not just the past approval period). **Withdrawn Study (project has not and will not be conducted)** If checked, **complete Section 3****SECTION 4: PROGRESS REPORT****A. On-Site Subject Enrollment Since Date of Last IRB 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

B. Adverse Events, Complications, Complaints, Subject Withdrawal Since Date of Last IRB Approval:

(For all items in this section, use additional sheets as necessary.)

Were there any adverse events or unanticipated problems involving risks to subjects or others? YES NO
 If yes, summarize the reported events, and briefly describe their nature and relationship to the study:

Based on your knowledge of adverse events that have occurred in subjects 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 adverse events 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 IRB review? YES NO

If yes, please explain the nature of all complaints:

C. 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. **If the study was terminated before completion, explain why.** (Use additional sheets as necessary)

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, so state, and explain why. (Use additional sheets as necessary)

E. Additional Required Materials Checklist:

Publications:

Attach a reprint of any publications/abstracts derived from your study since last approval.

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).

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.

Audit Reports

Attach a copy of any reports from audits/monitoring visits conducted by external organizations (e.g., HHS, sponsors) since last IRB review.

Relevant Recent Literature

Attach a summary of any relevant recent literature if applying for continuation.

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 5 – 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 IRB,
- promptly report any revisions or amendments to the research activity for review and approval by the IRB 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 or adverse events 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 IRB-approved, stamped consent forms will be used in the consent process.

Signature of Principal Investigator (PI)

Date

Signature of Faculty Advisor (if Student is PI)

Date

B. Approval of the IRB:

IRB Chair

Date