WPI IRB USE	
NEW IRB # _____	
IRB#	_____
Date:	_____

WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Study Renewal Application

Complete and submit this application at least 14 days prior to the study expiration date. This form should be sent to the WPI IRB c/o Ruth McKeogh 2nd floor Project Center. If you have any questions, please call (508)831-6699.

WPI IRB PROTOCOL #: _____ DATE OF REPORT: _____
Investigator: _____ Approval Expiration Date: _____
Project Title: _____
Department: _____
Name: _____
Phone: _____
E-mail: _____

The Principal Investigator or designee may complete and sign this report.

The study is:
- ☐ In Progress Date:
- ☐ Not Begun
- ☐ Inactive

1. Study Summary

a. Results obtained to date, if any.	☐ None	☐ Attached
b. Have there been any significant new findings?	☐ Yes	☐ No
c. Has there been an interim analysis?	☐ Yes	☐ No
d. Interim reports, findings, or abstracts are attached.	☐ Yes	☐ No
e. Do investigators seek to recruit additional subjects and request permission to continue use of an approved informed consent form?	☐ Yes	☐ No
f. Is the collection of human subjects data complete for this study?	☐ Yes	☐ No
g. Have there been any changes to the approved protocol that have not been reviewed by the WPI IRB? If yes, a study modification form should be filed	☐ Yes	☐ No

2. Subject Accrual and Follow-up:

A. Subject Goal *(Total number of subjects anticipated at onset of study.)*

B. Actual Subjects

- Total number of subjects who signed consent form at your site:
- Number of screen failures *(signed consent form and did not enroll)*:
- Number of subjects who were discontinued due to an adverse event:
- Number of subjects who withdrew, were lost to follow-up or were discontinued *(not due to an adverse event)*:

- Please summarize why subjects dropped out or were discontinued at your site:
- Number of subjects who completed the study:

C. If there is a discrepancy in actual versus anticipated subject numbers, please explain why this might have occurred:

D. Subject Categories *(this section is **mandatory** for studies with Federal funding and **optional** for other studies)*

1. Specific target:

2. If your population is general, please submit the following:

Please provide the percentage of subjects accrued in each of the following categories:

American Indian/Alaskan Native		Asian/Pacific Islander		Hispanic	
White, Not Hispanic		Black, Not Hispanic		Other or unknown	

Percent of subjects that are female	
Percent of subjects that are male	
Percent of subjects that are minors	

Is your subject data similar to the demographics of your geographic location? ☐ Yes ☐ No
To obtain local demographic data you may search this website: ***http://www.census.gov/***
If you use another source to obtain demographics, please list here:

Whether you use census data or another source for local demographics, please attach a copy. ☐ Attached

If your accrual data is not comparable to the demographics of your location, provide an explanation as to why your subject demographics do not match the demographics of your area. For example, the condition being studied may be more prevalent in a certain population.

3. Serious Adverse Events *(A serious adverse event can be any serious undesired and unintended, although not necessarily unexpected, effect of the research occurring in subjects as a result of the interventions or interactions used in the research, or from the collection of privately identifiable research data)*

Number of Serious Adverse Events which occurred at your site:

Have all serious adverse events, whether related to the study article or not, been reported to the WPI IRB?
☐ Yes ☐ No ☐ N/A

Include reports of all *serious* Adverse Events not previously reported.
In addition, please submit all sponsor generated reports, regarding adverse events, if applicable.

4. Informed Consent

a) Have all subjects signed and received a copy of the approved informed consent document? ☐ Yes ☐ No
If no, please explain:

b) Please include a copy of the informed consent for the last subject consented at your site. ☐ Attached
(Please black out the subject's name only – do NOT black out the date the subject signed)

Submitted by: _____ Date: _____
Signature

_____
Printed Name