RHODE ISLAND DEPARTMENT OF HEALTH

INSTITUTIONAL REVIEW BOARD

Human Subjects Research Progress Report

Date:

- Project Identification -

Project Title:
IRB Number:
Date of Initial Approval:
Date of Latest Approval:
Agency or Funding Source:

- Principal Investigator Contact Information -

Principal Investigator:
Organization (P.I.):
Street Address (P.I.):
City, State, Zip (P.I.):
Telephone (P.I.):
Fax (P.I.):
Email Address (P.I.):

1. Have you modified your research protocol or your consent form in any way since your last review?

[ ] Yes [ ] No

If you have made modifications, you are required to submit a revised protocol and/or revised consent form to the IRB.

2. Are the subjects under study members of a special population such as minors, fetuses, aborted fetuses, pregnant women, prisoners, or the mentally disabled?

[ ] Yes [ ] No

If yes, specify which populations:

3. Are human subjects in this project considered to be at more than "minimal risk" as defined in the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects? ("Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.)

[ ] Yes [ ] No

4. Number of subjects entered into the project during the last project year:

N =

5. Number of solicited subjects who declined to participate in this project during the last project year:

N =

Human Subjects Research Progress Report

6. Number of subjects who withdrew from the project during the last project year:

N =

If any, attach a description of the reason(s) for withdrawal.

7. Number of consent forms signed during the last project year:

N =

8. Were any adverse events, side effects, untoward clinical reactions or newly recognized risks, etc., noted during the last project year?

[ ] Yes [ ] No

If yes, attach a description of all adverse consequences and the number of times noted. Identify any that were unanticipated and not specified as risks in the informed consent statement. Describe the strategies adopted to reduce or avoid the observed adverse consequences.

9. Are subjects paid a fee or offered other inducement to participate?

[ ] Yes [ ] No

10. Write a brief (200 words or less) report describing the progress of your research thus far. Include a summary of any recent literature, findings or information that has become available since the last review concerning risks associated with the research.

Report:

11. Please attach a copy of your current consent form.

12. Electronic Signature of P.I.: