Rhode Island Department of Health Institutional Review Board Application

IRB Application No. (RIDOH IRB USE ONLY)

RIDOH's Role In This Study:
- ☐ Principal/Co-Investigator
- ☐ Project Team Member
- ☐ Data Holder (see next line)
- ☐ Other, Specify:

For Data Requests: Applications submitted without a completed Data Use Agreement will not be reviewed.

Project Title:

Date of Request:

Principal Investigator and e-mail contact:

If the Principal Investigator is a student working with a faculty advisor, provide their information below:

Advisor:
Institution:
E-Mail Address:

Anticipated Number of Subjects:

Projected Start Date: Projected End Date:

Has Funding Been Requested or Awarded: ☐ Yes ☐ No

If Yes, identify the sponsoring agency and award number:

Does this project involve:
- ☐ Pregnant Woman, Fetuses, Neonates
- ☐ Minors
- ☐ Prisoners

Does this study preserve:

Subjects Anonymity	☐ Yes	☐ No
Subject's Confidentiality	☐ Yes	☐ No

Do you have an approved Data Use Agreement? ☐ Yes ☐ No

As an attachment to this application, identify every project team member who will have access to identifiable/ potentially identifiable, protected health information, or who will have direct contact with study participants. Evidence of current CITI training, or equivalent, is required for each person on this list. Attach any other supplemental documents (informed consent/enrollment forms, waivers, letters of support etc...) to this application as needed.

Application Reviewed By:

Rhode Island Department of Health Institutional Review Board Application

Complete all sections unless otherwise indicated. Attach continuation pages as needed.

1. Describe the Principal Investigator's professional qualifications to do the research, including a description of any necessary support services and facilities:

2. What is the purpose of the project? Include any expected scientific benefits to be gained.

3. Is this study being conducted to answer a public health question or will the results of this study be used to influence/direct public health policies or regulations? If yes, please explain:

4. What are the potential benefits of the research, if any, to the individual human subjects, the community, or society.

5. Are certain potential human subjects excluded? If yes, please describe criteria for exclusion:

6. If applicable, provide justification for the inclusion of any vulnerable population (i.e. pregnant women, fetuses, children, prisoners).

7. Describe the study design. If necessary, discuss the appropriateness of research methodologies..

8. Describe the procedures to be performed on human subjects.

9. Indicate below whether or not any personally identifiable data will be generated or received by the research team. If applicable, provide a justification for the use of identifiable information. List each member of the research team that will have access to identifiable data and explain why that access is necessary.

10. Describe all potential risks of harm to subjects, subjects' families, the community, or society, including those related to any proposed use of personally identifiable data.

11. What are the provisions for managing adverse reactions, outcomes, or events resulting from participation in the research?

12. What provisions are being made for the protection of confidential information related to the human subjects? (See Guidance document, page 10, Confidentiality, Privacy and Research Risk)

13. Describe the informed consent process including procedures for documenting informed consent, addressing language barriers, and subject autonomy concerns. Attach a final copy of your informed consent document to this application. If the PI is seeking "verbal informed consent" then attach a final copy of the script project members will be utilizing.

14. What are the costs to subjects for their participation in the study, if any?

15. What compensation will subjects receive for their participation, if any?

16. What are the procedures for protection, erasure, or destruction of confidential data when the project ends?

17. Generalizable knowledge is information contributing to the expansion of a scientific field or discipline. Will the conclusions drawn from this study 1) be applicable to a larger population beyond the project's targeted demographic and/or 2) be used to develop, test, or support scientific theories or public policy. If yes, please explain the applicability of either 1 or 2:

19. Is the proposed work 1) being used to evaluate the effectiveness of a current public health program and/or 2) serving as an exploratory study to determine if RIDOH, as the State's Public Health Authority, needs to amend current policies, or implement new ones, to address a potential public health concern? If yes, please explain the applicability of either 1 or 2:

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ASSURANCE OF PRINCIPAL INVESTIGATOR

Principal Investigator:

Institutional Affiliation:

Project Title:

I CERTIFY as follows concerning the above-named research proposal in which I am the principal investigator:

1) The rights and welfare of the subjects will be adequately protected.

2) Risks or discomfort (if any) to subjects have been clearly and fully presented, and it has been shown how they are outweighed by potential benefits to the individual subject or by the importance of the knowledge to be gained.

3) The informed consent of subjects is an ongoing process. Consent will be obtained and documented by appropriate methods, which meet the requirements of federal regulations and the IRB.

4) Any proposed changes in research activity will be reported to the IRB. Those changes may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazard to the subjects.

5) Any unanticipated problems involving risks to human subjects or others will promptly be reported to the IRB.

6) I have reviewed and agree to comply with all federal, state, and local laws, rules, regulations, policies, and procedures related to the protection of human subjects.

Signature:

Principal Investigator

Acknowledged:

Chair, RIDOH IRB