Rhode Island Department of Health Institutional Review Board Application

IRB Application No. (To be filled in by RIDOH IRB)

Review Requested: ( ) Exempt ( ) Expedited ( ) Full Board
Note: Final determination regarding the type of review rests with the RIDOH IRB.

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

For Data Requests: Applications will NOT be reviewed without a completed Data Request Form.

Project Title:

Date of Request:

Principal Investigator and e-mail contact:

If 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: ( ) Yes ( ) No
If Yes, fill out the below information:
Sponsoring Agency:
Proposal Submission Date:

Does this project involve: ( ) Pregnant Women, Fetuses, Neonates ( ) Minors
( ) Prisoners
If any of the above vulnerable populations are included in the study design, provide a justification for their inclusion, information on possible risks, and a description of special procedures or forms to be used in the informed consent process.

Does This Study Preserve: Subject’s Anonymity ( ) Yes ( ) No
Subject’s Confidentiality ( ) Yes ( ) No

Do you have an approved data request form, if applicable: ( ) 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 every person named on this list. Attach any other IRB approval documents (partnering institutions) and/or letters of agreement to participate, as applicable.

Date of Review:
Approved By:
Rhode Island Department of Health Institutional Review Board Application

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

1. 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, including the expected scientific benefits to be gained by doing the project?

   Purpose:

   Scientific Benefits:

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

4. Are certain potential human subjects excluded? ( ) Yes ( ) No

   If yes, please describe criteria for exclusion:

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

6. Describe the study design. If necessary, include a discussion on the appropriateness of research methods:

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

8. Describe the proposed uses of any personally identifiable data:

9. 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: (See Guidance document, page 6, Confidentiality, Privacy and Research Risk.)

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

11. What provisions are being made for the protection of the human subjects' privacy?
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12. 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.

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

14. What is the compensation to subjects for their participation, if any?

15. What provisions are being made for the protection of confidential information related to the human subjects? (See Guidance document, page 6, Confidentiality, Privacy and Research Risk)

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

17. Any additional information or clarifications the investigator would like to present that may be relevant to Institutional Board Review of the Proposal
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: ____________________________ Date:__/__/__

Principal Investigator

Acknowledged: ____________________________ Date:__/__/__

Chair, RIDOH IRB

Last updated October 2020