THE UNIVERSITY OF RHODE ISLAND

URI Office of Research Integrity

Initial Review of Human Subjects Research

IRB

Continuing Review of Human Subjects Research

Protocol Number:

Project Title:

1. Principal Investigator

Name | Department

Email | Phone Number

If any contact information has changed since last IRB review - provide below:

University Academic Title | Phone Number

College/Department | Email

Has there been a change in the Principal Investigator?

- ◯ Yes --> **Complete Appendix R**
- ◯ No

2. Education

Educational requirements (initial and continuing) must be satisfied prior to submitting the application for IRB review. See Human Subject Research Training or contact ORI for more information.

Are the human subjects protection education requirements (CITI) current for all URI investigator(s) and key personnel?

- ◯ Yes
- ◯ No

3. Financial Conflict of Interest (FCOI)

A conflict of interest may exist whenever financial considerations or publication rights have the potential to compromise or have the appearance of compromising one's professional judgment and independence in the design, conduct or publication of research. For more information, see the Office of Research Integrity's Conflict of Interest in Research.

The IRB considers the investigator's financial interests when evaluating the protection of human subjects. If a financial interest is reported, the IRB will assess the investigator's objectivity in:

- Communicating Risks
- Selecting Subjects
- Promoting informed consent
- Gathering, analyzing, and reporting data

a. Have all URI investigators and key personnel completed the required COI disclosure?

- ◯ Yes
- ◯ No

b. Does any University of Rhode Island investigator (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?

- ◯ Yes --> Complete COI
- ◯ No

4. Funding and/or Location Changes

a. Has there been any changes to funding?

- ◯ Yes --> Complete Section 5.
- ◯ No --> Skip Section 5.

b. Has there been any changes to location?

- ◯ Yes --> Complete Section 6.
- ◯ No -->Skip Section 6.

5. Changes in Funding or Other Support

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact ORI for more information.

a. Is the research funded or has funding been requested?

- ◯ Yes
- ◯ No

If **Yes -->** Specify internal or external support and provider or funding agency:

Upload a copy of the grant application or funding proposal. The university is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.

b. Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?

- ◯ Yes
- ◯ No

If **Yes** --> Specify internal or external support and provider or funding agency:

6. Changes in Location of Research

List the specific site(s) at which the URI research was or is being conducted (include both domestic and international locations). ***Provide copies of all current IRB approvals for non-URI sites, as applicable.***

Location Name (or description)	Address (street, city and state, or country)

7. Expedited Review

Are you requesting expedited review?

- ◯ Yes --> Complete **Appendix B**
- ◯ No

8. Research Status

a. Indicate the status of the research:

☐ No research participants have been enrolled (or participant records, specimens, etc. obtained).

Explain:

☐ Research participants have been enrolled (or participant records, specimens, etc. obtained)

b. If participants have been enrolled, check all that apply:

☐ Recruitment is ongoing

☐ Recruitment has been completed -->

☐ Participants have not completed research interventions.

☐ All participants have completed all research interventions.

☐ Research remains active only for long-term follow-up (or re-contact) and data analysis

☐ Research remains active only for data analysis.

9. Summary of Research

a. Summarize the research using ***non-technical*** language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may be expected to result. ***Use complete sentences.***

10. Research Progress

a. Summarize the progress of the URI research, including any interim findings.

b. For multi-site studies, summarize the overall progress of the research. ***Upload a copy of the most recent multi-site study report, if any***.

☐ N/A

c. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation.

☐ N/A

d. Summarize recent literature or other new information relevant to the research, if any, since last IRB review (initial or continuing).

☐ N/A

e. Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could affect participants' willingness to continue in the research and how participants have been or will be informed.

☐ N/A

f. Are you requesting any changes to the research, other than a change in study personnel or participant numbers (e.g., change in PI or changes to protocol, data collection forms, recruitment or consent processes, etc.)?

Yes --> **Complete the "Amendment/ Changes to Research" Form**

No

g. Projected or actual completion date: _____ (Month and Year)

Indicate "ongoing" for repository research or program protocols

11. Number of Participants

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

a. Is this a multi-site study?

Yes --> **Indicate the total number of participants across all sites:** _____

No

b. For research approved by the University of Rhode Island IRB, provide:

1) IRB approved number of participants (or records, specimens, etc.): _____

2) Total number of participants enrolled in the research to date: _____

3) Number of participants enrolled since last IRB review (initial or continuing): _____

c. If actual total enrollment to date (10b.2) is significantly different (over or under) from IRB approved number (10b.1), provide an explanation:

_____

d. Are you requesting an increase in the total number of participants?

Yes --> **Complete Appendix T**

No

12. Participant Population

a. Specify the age(s) of the individual(s) who may participate in the research:

Age(s): _____

b. Specify the participant population(s) - check all for which you have approval:

☐ Adults	☐ Pregnant women/fetuses
☐ Minors (<18 years)	☐ Neonates (uncertain viability/nonviable
☐ Adults with decisional impairment	☐ Prisoners
☐ Non-English speaking	☐ Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program protocols)
☐ Student research pools (e.g., psychology, linguistics, non-targeted surveys, program protocols) -->	Specify: _____

13. Recruitment & Informed Consent Process:

a. Were recruitment materials used to enroll participants?

◯ Yes
◯ No

If **Yes** --> Are recruitment materials still being used?

◯ Yes
◯ No

If Yes --> *Upload copies of the current recruitment materials (ads, radio/TV scripts, internet solicitations, etc.).*

b. How **was/is** informed consent or assent obtained? Check all that apply.

Upload into the IRBNet submission package:
-- The most recently used consent document that has been signed and whited out so that all personal information is no longer visible.
-- A new, clean copy of the consent document with the bottom right corner BLANK.

☐ Assent - Form	☐ Parental Permission - Form
☐ Assent - Verbal Script	☐ Parental Permission - Verbal Script
☐ Informed Consent - Form	☐ Translated Consent/Assent- Form(s)
☐ Informed Consent - Verbal Script	☐ Waiver or Alteration of Consent Process
☐ Informed Consent - Addendum	☐ Waiver of Consent Documentation

c. Is deception of participants part of the research?

◯ Yes
◯ No

If Yes --> Upload a copy of current debriefing script or other information sheet(s) used to inform participants.

14. HIPAA Research Authorization

a. Is individually identifiable protected health information (PHI) accessed, used, or disclosed in the research?

◯ Yes
◯ No

If **Yes -->** Check all that apply:

☐ Written Authorization ***Provide current Authorization Form***
☐ Partial Waiver (recruitment purposes only)
☐ Full Waiver (entire research study)
☐ Alteration (written documentation)
☐ Informed consent (or waiver) was obtained for all participants prior to April 14, 2003

15. Risk Assessment

a. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occur in research at URI or at a site(s) approved by the URI IRB?

◯ Yes --> **Complete Appendix S**
◯ No

b. Was the research subject to Data and Safety Monitoring Board (DSMB) or other similar committee/group review?

- ◯ Yes --> Provide a copy of the most current report
- ◯ No

c. Provide an assessment of the risks and potential benefits based on study results since last IRB review.

16. Participant Complaints & Voluntary Withdrawals

a. Have any participants made complaints about the research since the last IRB review?

- ◯ Yes
- ◯ No

If **Yes -->** List and describe each **complaint** and any **actions taken** to resolve the complaint(s).

b. Have any participants voluntarily withdrawn from the research since last IRB review? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.***

- ◯ Yes
- ◯ No

If **Yes --> List and describe each** withdrawal **and any** actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s).

17. Principal Investigator's Assurance

I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators, including, but not limited to, the responsibilities described in the URI IRB policy.

I verify that the information provided in this Continuing Review of Human Subjects Research application is accurate and complete.

Principal Investigator (print): _____ Date _____