The University of Rhode Island (URI) Institutional Review Board (IRB) is under the governance of the Office of Human Subject Research Protection. The Office of Human Subject Research Protection (OHRP) is the federal agency under the Department of Health and Human Services (DHHS) responsible for implementing regulations (45 CFR 45) governing Biomedical, Behavioral and Social Sciences research involving human subjects. DHHS requires federally funded research to be monitored for compliance with its regulations by an institutional Human Subject Research Protection Program. URI fosters a culture of compliance and requires all research involving humans, regardless of sponsorship, to comply with the regulations governing human subject research.

The protective oversight for human research activities are delegated to the IRB to assure compliance with the governing federal regulations for human subject research set forth by OHRP.

The IRB is charged with assuring that all human subject research, regardless of sponsorship, conducted at the URI complies with the federal regulations (45 CFR 46) of the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), the Belmont Report, State and Local Laws, and IRB policies and procedures.

All human subject research must be reviewed, prospectively approved and subject to continuing oversight (at least annually) by the IRB to assure the safety and welfare of research participants remains in compliance with governing federal regulations and guidance.

***Research requiring Registration***

Use this form to register research involving human subjects. **Human subject use may not proceed until authorization from the IRB is received**.

***Form Submittal***

**Submit via IRBNet the following:**

* This IRB Application. Please try to limit you answers to the space provided. Upload separate document if you believe additional information is valuable to the committee (refer to specific questions you are addressing).
* Any attachments (e.g., appendices, consent form(s), assent form(s), flyers, etc.)
* CITI certification (Human Subjects Group 1 (Social Behavior)) for all key personnel (no more than 3 years old)
* Relevant thesis, dissertation, or grant proposals
* Signed Proposal Approval Signature Sheet, if part of a thesis/dissertations MA/PhD
* Student Assurance form. If graduate student will be using project data to complete a thesis/dissertation

***Training***

All faculty, staff, and students listed on the Protocol must complete the on-line training course at [www.CITIprogram.org](http://www.CITIprogram.org). Register as a new user and choose URI as your institution. Complete the Human Subjects Group 1 (Social Behavioral) course. The IRB Administrator will alert you if other training modules are also required.

**Questions?**

* Contact the Office of Research Integrity at 401-874-4328 or email: [researchintegrity@etal.uri.edu](file:///C%3A%5CUsers%5Chpaskalides%5CAppData%5CRoaming%5CMicrosoft%5CWord%5Cresearchintegrity%40etal.uri.edu)
* For training materials on IRBNet or the Human Subject Research, refer to the Office of Research Integrity Website.

***Add all documents checked in this list to IRBNet Package***

**Application Contents**

Indicate the documents being submitted for this research project. Check all appropriate boxes.

[ ]  **IRB Application of Human Subjects Research – REQUIRED FOR ALL NEW PROTOCOLS**.

[ ]  **CITI certification for all personnel – REQUIRED**

[ ]  Consent form(s), Assent Form(s), Permission Form(s), and Verbal Scripts (including translated documents for all documents participants will see).

[ ]  Data Collection Form(s) for Investigator-Initiated Studies (**Section 11)**

**[ ]** Data Collection Form(s) involving protected health information (**Appendix N**)

[ ]  Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)

[ ]  Script(s) or Information Sheet(s), including Debriefing Materials

[ ]  Instruments (e.g., questionnaires or surveys to be completed by participants) (**Section 11)**

[ ]  Other Committee Approvals/Letters of Support

[ ]  HIPAA Research Authorization Form(s)

[ ]  Research Protocol of Proposal – **Required for MA/PhD Students**

**[ ]** MA/PhD Proposal Approval Form – **Required for MA/PhD Students**

**[ ]** Complete Grant Application or Funding Proposal, as applicable

[ ]  Drug Manufacturer’s Approved Labeling/Investigator’s Drug Brochure (**Appendix F**)

[ ]  Device Manufacturer’s Approved Labeling (**Appendix E**)

[ ]  All other supporting documentation and/or materials

***If box is checked, appendix must be included in IRBNet Submission, package for processing.***

***Appendices***

[ ]  Appendix B: Expedited Review (See section 1)

[ ]  Appendix C: Data Repositories (See section 11, Definition – Retain for future research)

[ ]  Appendix D: Deception (See section 11)

[ ]  Appendix E: Devices (See section 11)

[ ]  Appendix F: Drugs or Biologics (See section 11)

[ ]  Appendix G: Genetic Testing (See section11)

[ ]  Appendix H: Storage of Biological Materials (See section 14)

[ ]  Appendix I: Minors (See section 14. 12)

[ ]  Appendix J: Non- English Speaking Participants (See 14, pg. 12 and section 18, pg. 14)

[ ]  Appendix K: Pregnant Women/Fetuses/Neonates (See section 14, pg. 12)

[ ]  Appendix L: Prisoners (See section14, pg. 12)

[ ]  Appendix M1: Waiver or Alteration of Consent Process (See section 11 and section 18)

[ ]  Appendix M2: Waiver of Signed Consent (See section 18)

[ ]  Appendix N: Waiver of Alteration of HIPPA Research Authorization (See section 21)

[ ]  Appendix O: Research in International Settings (See section 7)

[ ]  Appendix P: Radiation (See section 11)

[ ]  Appendix Q: Adults with Decisional Impairment (See section 14)

[ ]  Appendix R: Change in Personnel (See section 2)

[ ]  Appendix V: Unaffiliated Investigator Agreement

[ ]  Appendix X: Conflict of Interest in HSR

**Section 1 – Administration**

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Project Title

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Create Project Short Title

Research Start Date: **Upon IRB Approval**

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| Click here to enter a date. |

***I would like to defer the start date of my research to:***

***(May be no more than 1 year)***

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| Click here to enter a date. |

Anticipated Research End Date (should be ≥ 1 year):

**Select level of review that applies to this project:** **[ ]  Full** **[ ]  Expedited 🡪 Complete Appendix B**

**Exempt Review: To qualify, research must fall into six (6) federally-defined exempt categories. If proposing Exempt research, complete the Exempt Research Form. Do not complete this form.**

**Section 2 – Personnel -** *List all personnel associated with the project*

**Principal Investigator (PI)**

**Principal Investigator must be URI Faculty or Staff**

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Position Phone Number

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If Non-URI check box [ ]  If Non-URI: Name of Institution

**If Non-URI and Investigator’s institution does not have and FWA #, submit Appendix V- Unaffiliated Investigator Agreement in IRBNet Package**

**Co-Investigator**

***Students may not be Co-Investigators***

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If Non-URI check box [ ]  If Non-URI: Name of Institution

**If Non-URI and Investigator’s institution does not have and FWA #, submit Appendix V- Unaffiliated Investigator Agreement in IRBNet Package.**

**Co-Investigator**

***Students may not be Co-Investigators***

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 Position Phone Number

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If Non-URI check box [ ]  If Non-URI: Name of Institution

**If Non-URI and Investigator’s institution does not have and FWA #, submit Appendix V- Unaffiliated Investigator Agreement in IRBNet Package.**

**MA/PhD Researcher**

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If Non-URI check box [ ]  If Non-URI: Name of Institution

**If Non-URI and Investigator’s institution does not have and FWA #, submit Appendix V- Unaffiliated Investigator Agreement in IRBNet Package**

**Will this project be used as a thesis or dissertation proposal** **[ ]  Yes *If Yes, Please submit***

**[ ]  No - *Signed MA or PhD Proposal Approval Form***

 **- *Proposal Document***

**Other Key Personnel Responsibilities**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Position** | **Non-URI** | **Consent Subject** | **Recruit**  | **Protocol Design** | **Data Analysis** | **Intervention** |
|       |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
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***Key personnel are defined as individuals who participate in the design, conduct or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent or who collect study data.***

**Section 3 – Education**

***Educational requirements (initial and continuing) must be satisfied prior to submitting the application for IRB review. See*** [***Human Subjects Protection Training***](https://web.uri.edu/research-admin/office-of-research-integrity/) ***or contact ORI for more information.***

**Have all University of Rhode Island investigators and key personnel completed the required web-based course (CITI) for Human Subject Research, Group 1 (Social Behavioral).** **[ ]  Yes** **[ ]  No *Attach PDF of CITI Training Certificate for all personnel listed.***

*If this research meets the definition of a clinical trial, “A research study in where one or more human subjects are prospectively assigned to one or more research interventions”, one of the following must be completed by all investigators:* ***GCP – Social and Behavioral Research Best Practices for Clinical Research****,* ***GCP for Clinical Investigations of Devices****, or* ***GCP for Clinical Trials with Investigational Drugs or Biologics (ICH Focus).***

***[ ]* Yes** **[ ]  No *Attach PDF of CITI Training Certificate for all personnel listed.***

**Section 4 – Financial Conflict of Interest (FCOI)**

A **financial conflict of interest** may exist whenever financial considerations or publication rights have the potential to compromise or have the appearance if compromising one’s professional judgement and independence in the design, conduct or publication of 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

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 reasonable appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonable appear to be affected by the research?

[ ]  **Yes**-**🡪** **Complete *Appendix X – Conflict of Interests in Human Subjects Research*** **[ ]  No**

**Section 5 – 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.*

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1. Is the research funded or has funding been requested? [ ]  Yes [ ]  No

 If Yes🡪 Specify funding agency and support:

[ ]  *By checking this box, you have provided a copy of the grant application or funding proposal in your IRBNet submission package. 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.*

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1. Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study? [ ]  Yes [ ]  No

 If Yes🡪 Specify provider or agency and support:

**Section 6 – Other Institutional Approvals**

Check all that apply and provide applicable documentation. ***IRB review cannot be conducted until required institutional approvals or exemptions are obtained, except as noted.***

[ ]  [Institutional Biosafety Committee (IBC)](https://web.uri.edu/research-admin/office-of-research-integrity/) – Approval required for research activity involving:

* Recombinant DNA (rDNA)
* Biological agents (e.g., viable infectious microorganisms (including prions) regardless of their pathogenicity to humans)
* Human or nonhuman primate materials (e.g., blood, unfixed tissue, cell lines, finger sticks and blood draws)
* Biological toxins subject to the National Select Agents Registry Program managed by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA).

[ ]  [Conflict of Interest Management Committee (CIMC)](https://web.uri.edu/research-admin/office-of-research-integrity/) – CIMC is responsible for the review and assessment of all financial disclosures related to research projects at URI and for determining any actions required to ensure that real or perceived financial conflicts of interest are managed or eliminated.

[ ]  None

**Section 7 – Location of Research**

1. List the **URI specific site(s)** at which the researchwill be conducted

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| **Location Name (or description)** | **Address** |
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**Research to be conducted outside of URI’s facilities will minimally require a LETTER OF AUTHORIZATION (on institutional letterhead) and may require another IRB”s approval if personnel are engaged. See OHRP Engagement Guidance or contact ORI for more information*.***

1. Location of Non-URI Research? [ ]  Domestic Sites - Upload a letter of authorization, on institution letterhead, as applicable [ ]  International Sites – Upload a letter of authorization, on institution letterhead and :

 ***Complete Appendix O – Research in International Setting***

1. List the **non-URI** specific site(s).

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|  **Location Name (or description)** | **Address** |
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**Has a letter of authorization for each non-URI site been uploaded to IRBNet?** **[ ]  Yes** **[ ]  No**

1. Are there multiple PIs at different sites? [ ]  Yes [ ]  No

 ***A multi-site project involves additional principal investigator(s) overseeing sites external to URI.***

 **If Yes, complete the following:**

 - Is an institutional IRB agreement (**IAA**) requested or in process for this protocol? [ ]  Yes [ ]  No

 If **Yes**, please elaborate.

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* Describe, the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.

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* Describe IRB oversight arrangements for each collaborative site (i.e., who will provide IRB review and approval). Upload copies of the non-URI approvals, as applicable. Contact ORI if requesting that University of Rhode Island serves as the IRB of record. Have IRB approvals included? [ ]  Yes [ ]  No

**Section 8 – Summary of Research**

Summarize the proposed research using non-technical language that can be readily understood by someone outside the discipline. Explain **briefly** (**no more than 2 or 3 paragraphs)** the:

* Research design (e.g., cross-sectional, case-control, cohort, randomized controlled trial, crossover, etc.)
* Procedures to be used with a focus on human subject interactions
* Risks and anticipated benefits for the subjects
* The importance of the knowledge that may reasonably be expected to result.

***Use complete sentences***.

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**Section 9 – Scientific Background & Literature Review**

Summarize existing published knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. Explain **briefly** (**no more than 2 or 3 paragraphs). *Use complete sentences.***

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**Section 10 – Research Objectives**

List the specific scientific or scholarly aims of the research study. Explain **briefly** (**no more than 2 or 3 paragraphs). *Use complete sentences.***

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**Section 11 – Research Methods & Activities**

1. Identify and describe all interactions and interventions (if applicable) that are to be performed solely for the research study. Distinguish research (e.g., observational, experimental) activities from non-research activities. ***Provide descriptions (e.g., spreadsheet, forms, or flow charts) of data being collected if appropriate. Do not include case report forms for multi-site industry-sponsored or cooperative group studies.***

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1. Check all research activities that apply:

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| **General Research** |
| [ ]  Data repositories 🡪 Complete ***Appendix C – Data Repositories*** (future unspecified use, including research databases) | **[ ]** Program Protocol (Umbrella Protocol) |
| **[ ]** Randomization | [ ]  Clinical Trial  |

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| **Social / Behavioral Research** |
| [ ]  Audio, video, digital, or image recordings | **[ ]** Data, publicly available (**Provide source below**) |
| **[ ]** Deception 🡪 Complete ***Appendix D - Deception & M1 – Waiver or Alteration of Consent Process***  | Provide source:       |
| **[ ]** Diet, exercise, sleep modifications or assessment | [ ]  Data, not publicly available (Provide source below) |
| **[ ]** Focus Groups | Provide source:       |
| **[ ]** Health related intervention prospectively assigned | [ ]  Surveys, questionnaires, or interviews (one-on-one) |
| **[ ]** Internet or e-mail collection  | [ ]  Surveys, questionnaires, or interviews (group) |
| **[ ]** Materials that may be considered sensitive, offensive threatening or degrading | [ ]  Observation of participants (including field notes) |
|  | [ ]  Other 🡪 Specify:       |

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| **Bio/Medical Research** |
| [ ]  Biohazards (e.g., rDNA, infectious agents, select agents, toxins) – **IBC Approval Required** | **[ ]** Non-invasive medical procedures (e.g., EKG, Doppler) |
| **[ ]** Biological sampling (other than blood) – **IBC Approval Required** | [ ]  Pregnancy Testing  |
| **[ ]** Blood drawing – **IBC Approval Required** | [ ]  Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) 🡪 Complete ***Appendix P - Radiation*** |
| **[ ]** Clinical Trial | [ ]  Record Review – **If HIPAA, include *Appendix N – Waiver or Alteration of HIPAA Research Authorization*** |
| **[ ]** Devices 🡪 Complete ***Appendix E******– Devices*** | [ ]  Specimen Research |
| **[ ]** Drugs or biologics 🡪 Complete ***Appendix F – Drugs or Biologics*** | [ ]  Stem Cell Research – **IBC Approval Required** |
| [ ]  Food Supplements | [ ]  Storage of Biologic Materials 🡪 Complete ***Appendix H – Storage of Biologic Materials & Appendix C – Data Repositories*** |
| [ ]  Genetic Testing 🡪 Complete ***Appendix G – Genetic Testing***   | [ ]  Surgical Procedures (including biopsies or other invasive medical procedures) |
| [ ]  Magnetic Resonance Imaging (MRI) | [ ]  Other 🡪 Specify       |

**Section 12 – Duration**

Estimate the time (i.e., minutes, hours) required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any. (If complicated design, please attach a flowchart).

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**Section 13 – Number of Participants**

*The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are 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.*

1. Provide the number of participants (or number of participant records, specimens, etc.) for whom you are seeking URI IRB approval.

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1. Explain how this number was derived and provide details, such as sample size calculation, convenience sample, pilot study, saturation estimation or other. **This must be consistent across all documents.**

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**Section 14 – Participation Population**

1. Specify the age range(s) of the individuals who may participate in the research: **This must be consistent across all documents.**

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1. Specify the participant population(s). Check all that apply:

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| [ ]  Adults | [ ]  Pregnant women/fetus 🡪 Complete ***Appendix K – Pregnant Women, Fetuses, Neonates***  |
| **[ ]** Children (< 18 years) 🡪Complete ***Appendix I - Minors*** | [ ]  Neonates (uncertain viability/nonviable 🡪 Complete ***Appendix K – Pregnant Women, Fetuses, Neonates***  |
| [ ]  Adults with decisional impairment🡪 Complete ***Appendix Q – Adults with Decisional Impairment***  | [ ]  Prisoners 🡪 Complete ***Appendix L – Prisoners***  |
| [ ]  Non-English speaking 🡪 Complete ***Appendix J – Non-English Speaking Participants***  | [ ]  Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program protocols) |
| [ ]  URI students (e.g., psychology, linguistics, non-targeted surveys, program protocols) 🡪 | Specify:       |

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1. Describe the characteristics of the proposal participants, and explain how the nature of the research requires/justifies their inclusion.
2. Will any participants be excluded based on **age**, **gender**, **race**/**ethnicity**, **pregnancy status**, **language**, **education** or **financial** **status**? [ ]  **Yes** [ ]  **No**

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 If **Yes** 🡪 Explain the criteria and reason(s) for each exclusion. ***Consider the study’s scientific or scholarly aims and risks.***

1. Are any of the participants likely to be vulnerable to coercion or undue influence? [ ]  Yes [ ]  No. ***This includes students, employees, terminally ill persons, or others who may have limited autonomy?***

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 If **Yes 🡪** Describe additional safeguards to protect participants’ rights and welfare. ***Consider strategies to ensure voluntary participation.***

**Section 15 – Participation Identification, Recruitment, and Selection**

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1. Provide evidence that you will be able to recruit the necessary number of participants to complete the study.
2. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

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1. Describe the process that will be used to determine participant eligibility. ***Upload recruitment scripts to IRBNet.***

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1. Describe the recruitment process; including the setting in which recruitment will take place.

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***Are copies of proposed recruitment materials and guidelines (e.g., ads, flyers, website postings, recruitment letters, and oral/written scripts) uploaded onto IRBNet?*** [ ]  Yes [ ]  No

1. Explain how the process respects potential participants’ privacy.

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**Section 16 – Incentives to Participate**

Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study? Compensation plans should be pro-rated (not contingent upon study completion) and should consider participant withdrawals, as applicable. [ ]  Yes [ ]  No

If Yes 🡪 Describe the incentive, including the amount and timing of all payments.

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 **Section 17 – Alternatives to Study Participation**

Other than choosing not to participate, list any specific alternatives, including available procedures or treatments that may be advantageous to the subject. If giving student credit for participation, there needs to be a time equivalent alternative.

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Or [ ]  N/A

**Section 18 – Informed Consent Process**

Indicate the consent process(es) and document(s) to be used in the study. Check all that apply. ***Upload copies of consent forms, documents and/or complete relevant appendices, as needed, to IRBNet.***

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| [ ]  Assent – Form | [ ]  Parental Permission - Form |
| **[ ]** Assent – Oral Script | [ ]  Parental Permission – Oral Script 🡪 Complete ***Appendix***  |
| [ ]  Written Consent – Form  | [ ]  Translated Consent/Assent – Form(s) 🡪 Complete ***Appendix J – Non-English Speaking Participants***  |
| [ ]  Oral Script 🡪 Complete ***Appendix M2 – Waiver of Signed Consent*** | [ ]  Waiver or Alteration of Consent Process 🡪 Complete ***Appendix M1 – Waiver or Alteration of Consent Process***  |
| [ ]  Consent – Online  | [ ]  Waiver of Signed Consent 🡪 Complete ***Appendix M2 – Waiver of Signed Consent*** |

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1. Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. **Will a teach-back method be utilized**? *A teach-back method is a confirmation procedure to check to see of a participant understands what they are consenting.* [ ]  Yes [ ]  No or [ ]  N/A
2. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

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Or [ ]  N/A

1. Will any other tools (e.g., **quizzes, visual aids, information sheets**) be used during the consent process to assist participant comprehension? [ ]  Yes [ ]  No

 If ***Yes****🡪* ***Upload copies of these forms to IRBNet***.

1. Will any other **consent forms** be used (e.g., for clinical procedures such as MRI, surgery, etc. and/or consent forms from other institutions? [ ]  Yes [ ]  No

If ***Yes****🡪* ***Upload copies of these forms to IRBNet***.

Also If **Yes**🡪 Indicate if another IRB has approved them and which one(s). Indicate that approval is pending if that is the case.

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**Section 19 – Privacy of Participants**

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1. Describe the provisions to protect the privacy interests of the participants. ***Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants’ expectations of privacy.***

1. Does the research require access to personally identifiable private information? [ ]  Yes [ ]  No

If **Yes** 🡪 Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.)

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**Section 20 – Confidentiality of Data**

1. Explain how information is handled, including storage security measures (as necessary), and who will have access to the information. Include both electronic and hard copy records. **Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Please include URI Building & Room Location. Note: paper copies of informed consent forms must be stored ON CAMPUS**.

Explain here:

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Or [ ]  N/A

1. Explain if any personal or sensitive information that could be potentially damaging to participants (e.g., relating to illegal behaviors, alcohol or drug use, sexual attitudes, mental health, etc.) will be collected. Indicate when data will be destroyed and how.

Explain here:

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Or [ ]  N/A

1. Will you be obtaining an **NIH Certificate of Confidentiality**?

 [ ]  Yes [ ]  No if **Yes** 🡪 Upload a copy to IRBNet when Certificate of Confidentiality is issued

1. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality.

Explain here:

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Or [ ]  N/A

1. Indicate what will happen to identifiable data at the end of the study. Research data should be retained for a minimum of **three years** after final project closeout, **five years** if **FDA** Study. Usually only one of these apply unless necessary based on research design.

 [ ]  Identifiable data will not be collected

 [ ]  Identifiers will be permanently removed from the data and destroyed (resulting in de-identified data)

 [ ]  Identifiable or coded/linked data will be retained and stored securely (as appropriate)

 [ ]  Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)

**Section 21 – HIPAA Research Authorization**

Will individually identifiable Protected Health Information (PHI) subject to the [HIPAA Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/index.html) requirements be accessed, used or disclosed in the research study? [ ]  Yes [ ]  No

If Yes 🡪 Check all that apply:

 [ ]  Written Authorization 🡪 Provide a copy of the Authorization Form

 [ ]  Partial Waiver (recruitment purposes only) 🡪 ***Complete Appendix N – Waiver or Alteration of HIPAA Research Authorization***

 [ ]  Full Waiver (entire research study) 🡪 ***Complete Appendix N*** ***– Waiver or Alteration of HIPAA Research Authorization***

 [ ]  Alteration (written documentation) 🡪 ***Complete Appendix N – Waiver or Alteration of HIPAA Research Authorization***

**Section 22 – Reasonably Anticipated Benefits**

1. List the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants. ***Compensation is not to be considered a benefit.***

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1. List the potential benefits that society and/or others may expect as a result of this research study.

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**Section 23 – Risks, Harm & Discomforts**

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1. Describe all reasonable expected risks, harms and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. ***Consider the range of risks, including physical, psychological, social, legal and economic. All research involves at least minimal risk.***
2. Describe how risks, harms and/or discomforts will be minimized. ***If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.***

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**Section 24 – Monitoring**

Does the research involve greater than minimal risk (i.e., are the harms or discomforts described in Section 22 beyond what is ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? [ ]  Yes [ ]  No

If Yes 🡪 Describe the plan to oversee and monitor data collected to ensure participant safely and data integrity. Include the following:

* The information that will be evaluated (e.g., incidence and severity or actual harm compared to that expected)
* Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee)
* Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled)
* Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

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**Section 25 – Assessment of Risks vs. Benefits**

Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

**\* Must be answered by all researchers**

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**Section 26- Participant Costs/Reimbursements**

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1. List any potential costs participants (or their insurers) will incur as a result of study participation (e.g., parking, study drugs, diagnostic test, etc.)

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1. List any costs to participants that will be covered by the research study.

**Assurance – Certifications and Endorsements by Principal Investigator**

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](https://web.uri.edu/research-admin/office-of-research-integrity/).

[ ]  I verify that the information provided in this IRB Application for Human Subjects Research is accurate and complete.

[ ]  I verify that this IRB Application has been sheared (on IRBNet) with the PI, all Co-Investigators, and the Department Chair.