

**OFFICE OF RESEARCH INTEGRITY INSTITUTIONAL REVIEW BOARD**

**HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED**

REQUEST FOR IRB REVIEW

**Instructions: The UNE Assurance for the protection of human subjects prohibits the start of any research, including the recruitment of subjects that has not been reviewed and approved by the IRB. The Principal Investigator, all research staff, including Faculty Advisors, must complete the CITI training module in advance of their submission. Please contact the Human Protections Administrator at 207-602-2244 or** **IRB@une.edu** **with questions. Highlighted sections denote instances where more detailed information may be required in the Research Protocol and/or where additional study documents may need to be attached and included with the final submission to the IRB. To check a box double click on it.**

**The UNE Research Integrity program and the IRB welcome any feedback on how this form works, any problems, and suggestions for improvement. Please email your feedback to the Human Protections Administrator at** **IRB@une.edu.** **It will have no effect on your application.**

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|  | **PRINCIPAL INVESTIGATOR** |  |
| Principal Investigator: |  |  | Are you:Faculty StaffGraduate Student Undergraduate Student Other | External Review (PI not affiliated with UNE): YesNo |
|  |  |  | Estimated Project Duration: |
| Email: |  |  | Start Date: |
|  |  |  | End Date: |
| Address: | Department: | Phone Number: |
| Study Title/Location: |
| Faculty Advisor: | Email: | Phone Number: |
|  |
|  | **RESEARCH INFORMATION** |  |
| **1. Type of Funding(please attach funding application):** Federal Health and Human Services (ACF, AoA, AHRQ, CMS, FDA, HRSA, HIS, NIH, PSC, SAMHSA)Federal, Other (DoD, DoE, ED, EPA, DoJ) State of Maine (all agencies)University of New England Internal Award Other/PrivateNot Funded | **2. Special Populations:** Minors (under 18) Pregnant Women PrisonersPhysically or mentally challenged Diminished capacity to give informed consent. | **3. Subject Age:**0-7 (parental permission and oral child assent)8-17 (parental permission and child assent)18-6565+ |
| **4. Will this study offer compensation for participation?****Yes If Yes, how much?****No** | **5. Why is this research being conducted?**Master’s thesis Doctoral Dissertation Other (please specify): | **6. Please list any research staff handling or collecting data:** |
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| **PROJECT ATTRIBUTES** |  |
| **7. Does this study involve any of the following procedures (check all that apply)?** |
| YES | NO |  |
|  |  | Deception or Punishment |
|  |  | Use of Drugs |
|  |  | Covert Observation |
|  |  | Induction of mental and/or physical stress |
|  |  | Procedures which may risk physical/mental harm to the subjects |
|  |  | Materials/issues commonly regarded as socially unacceptable |
|  |  | Information relating to sexual attitudes, preferences, or practices |
|  |  | Information relating to the use of alcohol, drugs or other addictive products |
|  |  | Information pertaining to illegal conduct |
|  |  | Information normally recorded in a patient’s medical record which, if released, could lead to social stigmatization or discrimination |
|  |  | Information that, if released, could reasonably damage an individual’s financial standing, employability, or reputation within the community |
|  |  | Procedures that might be regarded as an invasion of privacy |
| **8. Check all that apply(attach samples of all intervention protocols and data collection instruments):** |
| Use of recruitment materials (i.e. flyers, emails, letters, etc.) | Focus groups |
| Surveys/Questionnaires | Audio or video recording |
| Administration of tests | Medical procedures |
| Interviews | Use of existing data |
| **9. Will this study use an online survey in its methodology? Yes****No** | **9a. If yes, please describe:** |
| **10. Will you be requesting an alteration or waiver of informed consent or assent?** |
|  | Yes | All of the following **must** apply for an alteration or waiver to be granted ([45 CFR 46.116 (d)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116))1. the research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration;
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
 |
|  | No |
| \*If YES, provide a justification statement, in the **Research Protocol (Section 13).** |
| **11. Will you be requesting a waiver of documentation of informed consent?** Federal regulations require written and signed evidence of informed consent unless a waiver of documentation of informed consent is granted by the IRB.No (If **yes**, please **provide a justification statement in the Research Protocol (Section 14).**The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
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| **12. Do you or any investigator participating in this study have a financial interest in the research?**Yes (If **yes**, please explain in Section 11 of the **Research Protocol** below) No |
| **13. Will this study involve the transfer from a covered entity as defined under HIPAA of protected health information (PHI) to you?****Yes (If yes, continue to number 13a) No (If no, continue to number 15)** | **13a. Prior to the transfer of this information, will all** [**18 identifiers**](http://edocket.access.gpo.gov/cfr_2002/octqtr/pdf/45cfr164.514.pdf) **be stripped?****Yes No** |

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| **14. Will you be submitting a Data Use Agreement or Business Associates Agreement?****Yes (If yes, continue to number 14a)****No (If no, continue to number 15)** | **14a. Has the Data Use Agreement or Business Associates Agreement been reviewed by system counsel?****Yes No** | **15. Is this study being conducted at other institutions?** \*If YES, please list other institutions and attach a copy of IRB Approval from each (as applicable). If not yet approved list the status of the application.Yes No |
| A. |
|  | B. |
|  |  | C. |
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| **RESEARCH PROTOCOL** |
| **16. Research Protocol****Important: The following guidelines are designed to help investigators write a comprehensive, yet succinct Research Protocol to facilitate review by the IRB. Not all guidelines and guiding questions will be applicable to your project. The Research Protocol should provide sufficient detail in each of the applicable sections below. Please use the format below with the headers provided (if you feel that a section is not applicable to your project indicate- not applicable). Enter your own text for each section. Highlighted sections denote instances where additional study documents may need to be attached and included with the final submission to the IRB. Please label all attached additional documents submitted as part of the IRB submission (i.e., last name, consent form).****Research Project Tile: [*Enter project title here]***1. **Purpose:**

-State the purpose of the research study.1. **Background, specific aims and significance:**
* State clearly and succinctly the objectives of the research and the question(s) to be answered.
* Summarize the prior literature, rationale and intended significance of the study.
1. **Procedures:**

-Describe all the activities in which subjects will participate (e.g., completing a survey, taking a test, answering questions in an interview, completing a specific task, completing tasks on a computer, running on a treadmill, etc.). **Copies of all questionnaires, surveys, test instruments, etc. must be submitted with the request for review.**-Describe the method of data recording (i.e., videotape, audio tape, photographs etc.). If reasonable, participants (and their legally authorized representatives, if applicable) should be given the opportunity to review audio tapes, videotapes, or photographs, particularly if they will be shared for purposes other than data collection.1. **Subject compensation and costs:**
 |

-Discuss any compensation or reimbursement (amount and type) and why this is reasonable and non-coercive.

-If you are conducting research in a classroom environment, state what alternative activities will be available for students not participating in this research. Describe procedures for reducing peer pressure or stigma for non-participants, if applicable.

-Discuss any anticipated costs to participants. Are these out-of-pocket expenses and/or expenses covered by insurance?

# Provisions to monitor data to ensure the safety of participants (if applicable):

-**If applicable**, discuss what provisions you will take in monitoring the data during the study to ensure the safety of participants. For example, who will be responsible for monitoring the data? How often? Who will be notified of any concerns regarding participant safety? How will these concerns be reported to the IRB?

# Research setting:

-Clearly explain where the interaction or intervention with subjects will occur (i.e., UNE, telephone, home setting, class setting, collaborating institution, etc.).

-List any collaborating sites where research will be performed, and describe the role of these sites. **Signed letters of support/collaboration from all sites should be included with the IRB submission. The letter should include: a) authorization by the institution for the investigator to conduct the study at the institution; b) assurance that the project has been reviewed by institution personnel with respect to appropriateness for its human subjects population.**

# Subject recruitment:

-Discuss any screening methods used to select subjects.

-Estimate the approximate number of subjects that will be included in the study and how the proposed number was calculated.

-Describe where and how subjects will be contacted.

-Explain how individual privacy will be maintained.

# -Please include a copy of the proposed recruitment language with the protocol submission. If a flyer or other advertisement will be used, include it. Include script(s) for oral recruitment and copies of any letters that will be distributed. Take care to consider [readability](https://www.kpwashingtonresearch.org/about-us/capabilities/research-communications/prism) and ensure consistency in language throughout all study documents.

1. **Participants and inclusion/exclusion criteria:**
* Describe the characteristics of the subject population, including the anticipated number, age range, and health status. Discuss why this subject population was selected for the research.
* Identify the inclusion/exclusion criteria by which potential subjects will be ruled in or out.
* Explain the rationale of the involvement of vulnerable populations, such as fetuses, neonates,

 pregnant women, children, prisoners, institutionalized individuals, or others considered to be

vulnerable to coercion or undue influence (see also the vulnerable population section at the bottom of page 5).

# Provisions to maintain confidentiality of data:

-How will data be maintained? How will this be communicated to the participants?

-Describe how the data will be transferred, where the data will be stored and who will have access to it. Identify any additional security provisions in place if the data will be electronically transferred.

-If applicable, describe what will happen to video and/or audio tapes after transcription. Will they be destroyed or used later for research and/or educational purposes? How will photographs be used, maintained and/or destroyed?

-Will individually identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) be recorded or obtained?

-How likely are the data to be identifiable by external third parties or in a publication?

-Is the use of identifiers necessary?

-When and how will identifiable data be destroyed?

-If conducting record or chart reviews, clarify if the researcher will have access to the entire record or be provided select information from the chart/record. In these cases, who will provide the records or information? Discuss whether or not this information is individually identifiable.

-If applicable, discuss here and in the consent form whether research data and information will be placed in medical records.

# Provisions to protect privacy interests of participants:

-When appropriate describe the provisions to protect the privacy of subjects. Where will data collection, interventions or interactions with participants occur?

-Describe how the privacy of subjects' responses will be protected (i.e., responses will be anonymous, assigning pseudonyms, assigning codes, etc.).

-How will the results be shared, with whom, and in what form?

-Will photographs, audiotapes or videotapes be shared? If yes, for what purpose?

# Investigator experience/conflict of interest:

-Briefly describe the principal investigators experience conducting similar research.

-Briefly describe the principal investigators experience with the proposed subject population.

-**Include an updated CV or resume for all research staff.** NOTE: If a student will interact with subjects the faculty advisor may be asked (as determined by the Human Protections Administrator) to provide a letter attesting that the student’s qualifications are commensurate with the level of skill required, and indicate the extent of supervision the advisor will provide.

-Explain any specific financial relationships that may create financial interests in the research.

-How may these financial interests adversely impact the rights and welfare of subjects?

-Does the research involve financial relationships that could create potential or actual conflicts of interest? If yes, explain how these conflicts of interest may be managed by eliminating them or mitigating their impact.

# Resources available(if applicable):

-Please discuss the resources needed to conduct the project and discuss the availability of resources, particularly as they relate to participant safety.

# [Consent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)/[assent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402) process:

Except in very rare circumstances, all human subjects (or their legally authorized representatives) must give consent to participate in research. It is essential that researchers remember that [consent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)/[assent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402) is a process. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability or negligence. The [general requirements for informed consent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116) must be reviewed by all investigators. **Investigators may request to use a consent procedure that does not include, or which alters some or all of the elements of informed consent but are required to address (in this section) why they feel this may be appropriate based on** [**45 CFR46.116 (d).**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116) **Only the IRB can determine if an alternate consent/assent procedure is appropriate.**

# Investigators are strongly encouraged to use the consent templates on the [IRB](https://www.une.edu/research/compliance/irb) [website](https://www.une.edu/research/compliance/irb).

-Describe procedures for obtaining initial and ongoing informed consent/assent. Who are the individual(s) obtaining consent/assent from participants?

-Describe the process for providing sufficient time, privacy, and adequate setting for the subject to consider participation.

-Describe special provisions for individuals who might have trouble comprehending the consent information. For example, if participants do not speak English, explain how translators will be involved in the project. Will information be provided orally as well as through documentation?

-If applicable, describe how assent will be secured from children or people who have a diminished capacity to give consent. NOTE: In studies involving children, seek the permission of parents BEFORE seeking the assent of their minor children. In studies involving subjects with a diminished capacity to consent, seek the permission from a legally authorized representative BEFORE seeking assent/consent from the subject.

-How is comprehension assessed throughout the consent process? Is the manner in which information is presented appropriate for the population? In cases where subject comprehension is severely limited what special provisions have been made? Is there a third party involved in the consent process?

# Process to document consent/assent:

-If applicable, describe how consent/assent will be documented and at what point in the informed consent/assent process this will occur. **Investigators are strongly encouraged to use the consent templates on the** [**IRB website**](https://www.une.edu/pdfs/consent-template-adults) **. Guidance on assent is also available.**

If you are requesting a waiver from the requirement to obtain a signed consent document please discuss why you feel that your project is eligible under the [waiver criteria-46.117 (c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117). NOTE: If consent documentation is waived you may be required to provide subjects with a written statement

 regarding the research (there are templates available on the [IRB website](https://www.une.edu/research/compliance/irb)). If you project involves

[children](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402) and you seek a waiver of [parental/guardian](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402) permission, please discuss why you feel that your project is eligible under the [waiver criteria-46.408 (c)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408).

# Interpretation of data:

-Explain how the data will be analyzed or studied (i.e., quantitatively or qualitatively).

-Explain how the interpretation will address the research question(s).

-Explain how data will be reported (i.e., aggregated, anonymously, pseudonyms for participants, etc.)

# Risks to participants:

Risk is the probability and magnitude of harm anticipated as a result of participation in the research. Any project involving risk of physical injury, civil penalty, financial or criminal liability, and risk to a subject's employability, or instances where the research involves sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol has the potential of involving more than [minimal risk](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102).

-Describe any risks of harm to subjects that are reasonably foreseeable, even if unlikely, and the safeguards in place to minimize these risks. Risks of harm may include: psychological harm, physical harm, legal harm, social harm and economic harm.

-Describe any group harms. If appropriate, has the researcher consulted the community?

-Address issues of confidentiality and risks associated with a breach of confidence. The researcher must clearly outline specific situations in which they are mandated to disclose confidential information, therefore potentially putting participants at risk for legal action (e.g. reporting suspected child/elder abuse and/or neglect).

-Researchers cannot promise to maintain confidentiality of highly sensitive information unless they obtain a [Certificate of Confidentiality](http://www.hhs.gov/ohrp/policy/certconf.html) for the project against forced disclosures.

# Potential benefits to participants:

A benefit refers to something of positive value related to health or welfare.

-Describe any benefits that flow directly to participants or that could affect the subject class/population.

-If there are no benefits, state this.

-Address how risks relate to benefits.

# Importance of knowledge to be gained:

* Discuss the importance of the knowledge to be gained as a result of the proposed research.
* Discuss why the risks and burdens to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

# Additional protections for vulnerable populations:

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| -If vulnerable populations (persons or groups who may be vulnerable to undue influence1 and/or coercion2) are included in the research what are the additional safeguards in place to protect the rights and welfare of those participants? Examples of steps to minimize coercion and undue influence may include: assessment of capacity, permission of a legally authorized representative, [assent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402), and witness to the consent process.-Vulnerable subjects/groups may include: institutionalized persons ([prisoners](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.303)), [fetuses](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.202), [neonates of](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.202) [uncertain viability](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.202), [non-viable neonates](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.202), [children](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402), persons with a diminished capacity to consent, educationally disadvantaged, economically disadvantaged, students, employees, persons with life threatening disease, racial minorities. |
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| **ADDITIONAL DOCUMENTATION (ATTACH TO FINAL SUBMISSON AS APPLICABLE)****17.*** **If applicable, include copies of the instruments used for data collection such as questionnaires, interview questions etc.**
* **If applicable, include recruitment flyers, letters, scripts etc. Recruitment materials guidance can be found on the** [**UNE IRB website**](https://www.une.edu/research/compliance/irb)**.**
* **If you are collaborating with an external group, agency, or organization attach a letter of collaboration/support (see Research Protocol (Section 16-6) for details).**
* **If applicable, include consent/assent documents. A sample template for the consent document can be found on the** [**UNE IRB website**](https://www.une.edu/research/compliance/irb)**. Assent guidance is also available.**
* **Attach a current copy of your C.V. or resume. We do not keep copies on file.**
* **If the project is funded, attach the funding application-please highlight the areas of the finding application that are relevant to the project.**
* **Confidentiality statement.**
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| **SIGNATURES** |
| **Original Signatures are required. The application will not be processed until all signatures are obtained.** |
| **Signature of Principal Investigator**The undersigned accept(s) responsibility for the study, including adherence to DHHS, FDA, and UNE policies regarding protections of the rights and welfare of human subjects participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies. |

1. Influence: To produce an effect on by imperceptible or intangible means; to sway. Undue: Exceeding what is appropriate or normal; excessive.
2. Coercion: to compel to an act or a choice; to achieve by force or threat.

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| **Print Name of Principal Investigator:** | **Signature of Principal Investigator:** | **Date:** |
|  |
| **Signature of Faculty Advisor – Required for Student Research**By signing this form, the faculty research supervisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above. |
| **Print Name of Faculty Advisor:** | **Signature of Faculty Advisor:** | **Date:** |

**UNE IRB Submission Requirements**

**Only complete submissions to the IRB will be reviewed.*Please ensure that each submission includes all attachments requested in the form.* Each submission submitted electronically to** **IRB@une.edu** **including scanned signatures.**

**UNE IRB**

**IRB@une.edu**

**Campus Mail:**

106 Pickus Biddeford Campus

**U.S. Mail**

UNE IRB

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**Questions? Please call: (207) 602-2244 E-mail:** **IRB@une.edu**