

# OFFICE OF RESEARCH INTEGRITY INSTITUTIONAL REVIEW BOARD

**HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED**

APPLICATION FOR PROTOCOL AMENDMENT

**Instructions:** Your request for ANY revisions or amendments to a previously approved IRB protocol MUST be reviewed in advance and receive approval from the UNE IRB before such changes may be implemented.

To check a box in this form, simply click on it.

**Submission Requirements:** Please complete this form and submit with any required attachments to [**IRB@une.edu.**](mailto:IRB@une.edu)

Please contact the IRB Administrator at 207-602-2244 or [**IRB@une.edu**](mailto:IRB@une.edu) with any questions.

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| **PRINCIPAL INVESTIGATOR AND PROTOCOL INFORMATION** | | |
| Principal Investigator: | Email: | Department: |
| IRB Protocol Number: | IRB Protocol Title: | |
| Current IRB Review Category: | * Not Human Subject Research * Exempt * Expedited * Full Board | |
| Current Project Status: | * Currently in Progress - Number of participants enrolled to date: * Project Not Yet Started (No participants have been enrolled to date) * Project closed to participant enrollment but remains active. * Other: | |
| Are you adding or removing personnel?   * Yes\* * No   \* Please include a resume/CV and CITI training certificate for each person being added. | Personnel to be added:  Personnel to be removed:   * Please check this box if there are no other changes to this protocol, then proceed directly to the signature section. | |

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| **DESCRIPTION OF PROPOSED CHANGES** | | | | |
| **1. BRIEFLY DESCRIBE AND JUSTIFY THE PROPOSED REVISION OR AMENDMENT HERE. Please attach separately a copy of all affected study documents, including the Protocol Summary, with changes highlighted.** | | | | |
| **2. Date you would like to implement the changes described in this Amendment Application:** | **3. Do these changes increase any risks, or present new risks, to study participants?**   * Yes\* * No   \*If Yes, describe in Section 1. | **4. Do these changes involve adding a vulnerable group of participants?**   * Yes\* * No   \*If Yes, describe in Section 1. | | **5. Do these changes involve adding the collection of sensitive information?**   * Yes\* * No   \*If Yes, describe in Section 1. |
| **6. Could these changes affect the willingness of currently enrolled participants to continue in the research?**   * Yes\* * No   \*If Yes, describe in Section 1. | **7. Could these changes have any impact on previously enrolled participants?**   * Yes\* * No   \*If Yes, describe in Section 1. | **8. Do the proposed changes involve adding a new research site or collaborating institution?**   * Yes * No   **If yes, please identify:** | |  |
| **9. Do the proposed changes alter any information in previously approved versions of the following documents?**   * **No,** this Amendment does not alter any previously approved documents * **Yes,** this Amendment alters information in the following documents (Check all that apply): * Consent Forms * Recruitment Materials * Surveys or Interview Scripts * Other:   If yes, please include a copy of all affected study documents, including the Protocol Summary, with changes highlighted. | | | **10. Do the proposed changes add any new documents?**   * **No,** this Amendment does not add any new documents * **Yes,** this Amendment adds the following new documents (Check all that apply): * Consent Forms * Recruitment Materials * Surveys or Interview Scripts * Other: | |

**CHECKLIST OF ATTACHMENTS**

**Please provide a list of all attachments here, with both the email attachment label and type/title of document**

(*Example:* 1. “IRB 060720-18 ICF”: Updated Adult Consent Form.)

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| **SIGNATURES** | | |
| **This application will not be processed unless it is complete and 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. | | |
| **Print Name of Principal Investigator:** | **Signature of Principal Investigator:** | **Date:** |
|  | | |
| **Signature of Faculty Research Supervisor – Required for Student Research**  By signing this form, the faculty advisor 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:** |