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| **APPLICATION INSTRUCTIONS**:Submit your completed application along with any required supplemental documentation (see [Appendix A](#AppendixA)) to irb@une.edu for review.Contact the Office of Research Integrity at irb@une.edu for any questions you may have with regard to this application.  |

|  |  |
| --- | --- |
| Version Date: | Enter date when form is first completed or date when form is last updated  |
| IRB Study Number: | Enter text |
| Title of Study: | Enter text |

| 1. **PRINCIPAL INVESTIGATOR & RESEARCH TEAM**
 |
| --- |
| **Principal Investigator Name**:Enter text | **You are**:[ ]  Faculty[ ]  Staff[ ]  Student[ ]  Resident | **Estimated End Date1**:*(refer to footnote below)* | Enter text |
| **E-Mail**: | Enter text | **UNE Center or College**: | Enter text |
| **Phone #**: | Enter text | **UNE Program of Study**: | Enter text |
|  |
| **Faculty Advisor Name**:Enter text | **E-Mail**:Enter text | **Phone #**:Enter text |
|  |
| 1. **Please provide a list of all *current* key personnel on this research project, and specify their institutional affiliation.**

*Key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the research project.* *Examples include participant screening, recruitment, and consenting activities, data collection via intervention or interaction with participants, or obtaining/using/analyzing personally identifiable information or biospecimens pertaining to a research participant.****Note****: The Principal Investigator and Faculty Advisor(s) must be listed as key personnel in this section.* Enter text1. **Have there been any changes to key personnel since the *last* *approval period*?** [ ]  No [ ]  Yes *(explain below)*

If yes, was an ‘**Application for Amendment**’ submitted to the IRB for review? [ ]  Yes [ ]  No *(explain below)*Enter text |
| **1** | Record the date when you expect to stop (1) obtaining data through interaction or intervention with participants; ***and/or*** (2) collecting, using, or analyzing personally identifiable information about participants.  |

| 1. **STUDY STATUS**
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| --- |
| 1. **At what stage is the research?** *(Check only ONE box)*

[ ]  Enrolling/recruiting participants, or review of records/specimens continues[ ]  Data registry or specimen bank/repository study (collecting information about participants)[ ]  Closed to enrollment, but protocol-specific interactions/interventions are still occurring[ ]  Closed to enrollment, and all protocol-specific interactions/interventions are completed[ ]  Data analysis and/or write-up of the results (involves access to personally identifiable information or specimens directly, or through codes/links to the data)[ ]  Study not started yet***Note****: If you are no longer collecting data via interaction/intervention from participants and have stopped collecting/using/analyzing personally identifiable information about participants, please submit a ‘****Study Closure Report Form****’ in place of this application.*1. **If the study is closed to enrollment and you are conducting protocol-specific activities with participants, indicate below what interactions/interventions are still occurring.**

Enter text |

| 1. **STUDY ENROLLMENT & ACCRUAL**
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|  |  |
| --- | --- |
| Enrollment | Occurs when an eligible, potential participant undergoes the initial informed consent process (e.g., signs the consent form) and voluntarily agrees to participate in a research study, or the subject is enrolled via a waiver of consent (e.g., records review study).  |
| Screen Failure  | Individuals who undergo screening activities (e.g., medical tests) AFTER providing informed consent and are excluded from further participation in the research study (e.g., testing reveals participant does not meet study inclusion/exclusion criteria). |
| Accrual  | The number of participants who have completed or are actively in the process of completing a research study at UNE. This does NOT include screen failures. It DOES include withdrawals and participants lost to follow up. *Accrual = [Enrollment] minus [Screen Failures].*  |
| Withdrawal | This includes participants who voluntarily discontinue their participation in an ongoing research study, or when an investigator terminates an individual’s participation in a research study (e.g., noncompliance with research procedures, participant has an unexpected reaction, entire study has been stopped, etc.). |
| Lost to Follow-Up | This refers to participants who at one point in time were actively participating in research, but have become lost (e.g., error in computer tracking system, no longer reachable, relocation, disability, death, etc.) at the point of follow-up in the study.  |

1. **What is the anticipated total number of participants to be enrolled or records to be reviewed for this study (based on the original IRB application or subsequent amendment)?**

 Enter text1. **Have there been any problems meeting the enrollment target?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Has the study exceeded the planned enrollment period or enrollment numbers?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Record the total number of participants for each category using the table below.** *(refer to the definitions provided at the beginning of Section C of this application for an explanation of each category)*

|  |  |
| --- | --- |
| Category | Total # of Participants *during the Life of the Study* |
| Enrolled  | Enter text |
| Screen Failures | Enter text |
| Accrued | Enter text |
| Withdrawals | Enter text |
| Lost to Follow-Up | Enter text |

1. **How many participants are currently active in the study?** *(e.g., engaged in protocol-specific interactions or interventions)*

Enter text1. **How many participants have completed all study activities *during the life of the study*?**

Enter text1. **Provide an explanation for any participants lost to follow-up *during the life of the study*?**

Enter text1. **Provide an explanation for any participants that withdrew from the research, or were withdrawn by the investigator *during the life of the study*?**

Enter text1. **Did any participants withdraw from the research, or were withdrawn by the investigator since the *last approval period*?** [ ]  No [ ]  Yes *(see below)*

If yes, how many participants were involved? Are there any additional details that may be helpful for the IRB to know? Enter text1. **Was race/ethnicity and/or gender data collected for this study?** [ ]  Yes [ ]  No *(If your study is federally funded by the National Institute of Health (NIH), the collection of this data may be required)*

**If yes, indicate accrual by race/ethnicity and gender *during the life of the study***:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | American Indian or Alaska Native | Asian | Black or African American | Hispanic or Latino | Native Hawaiian or Pacific Islander | White | Others | Total |
| Male | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text |
| Female | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text |
| Other | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text |
| Total | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text | Enter text |

1. **Were any accrued participants members of a vulnerable population as noted below?** [ ]  Yes [ ]  No

If yes, provide cumulative accrual totals by vulnerable population *during the life of the study*:

|  |  |  |
| --- | --- | --- |
| Vulnerable Population | Is inclusion of the population described in the research protocol?  | Total Accrual |
| Adults with impaired decision-making capacity | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| Children | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| Economically or educationally disadvantaged persons | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| Persons with limited English proficiency | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| Pregnant women, fetuses, or neonates | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| Prisoners | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| UNE Employees | [ ]  Yes [ ]  No [ ]  N/A | Enter text |
| UNE Students | [ ]  Yes [ ]  No [ ]  N/A | Enter text |

*If necessary, use the space below to provide any clarifications or additional information to the IRB.* Enter text |

| 1. **NEW INFORMATION**
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| --- |
| 1. **Have there been any unanticipated study-related problems that involve risk to participants or others that have not been reported to the IRB?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have there been any significant protocol deviations that have not been reported to the IRB?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have any benefits of the research been observed in participants since the *last approval period*?**

[ ] N/A *(benefit to society only)* [ ]  No [ ]  Yes *(explain below)*Enter text1. **Have there been any significant or interesting findings/results since the *last* *approval period?*** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Since the *last approval period*, have you received any participant complaints, and/or have any participants sought compensation for a research‑related injury?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Has the funding source for this study changed since the *last* *approval period*?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have any study documents been modified since the *last* *approval period*?** [ ]  No [ ]  Yes *(explain below)*

If yes, was an ‘**Application for Amendment**’ submitted to the IRB for review? [ ]  Yes [ ]  No *(explain below)*Enter text |

| 1. **ADDITIONAL INFORMATION**
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| 1. **Are you aware of any scientific publications, news, or any multi-center trial reports relevant to the risk and benefits of this research?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Is there any additional information about this study that is important for the IRB to know?** [ ]  No [ ]  Yes *(explain below)*

Enter text |

**Appendix A: Renewal Submission Checklist**

| REQUIRED SUPPLEMENTAL DOCUMENTATION *(as applicable to your study)* | Yes | No | N/A |
| --- | --- | --- | --- |
| 1 | Copy of CITI training completion certificates for all UNE-affiliated key personnel currently part of the study (as outlined within **Section A** of this application)* *All UNE-affiliated key personnel are required to take the applicable UNE-specific CITI training course(s) outlined below.*

***Note****: The Office of Research Integrity does NOT accept CITI training certificates completed at other institutions when key personnel are affiliated with UNE.* * *CITI training completion certificates are NOT required for non-UNE affiliated personnel or collaborators. If the external personnel or collaborators are affiliated with an organization with its own IRB, they will need to ensure they meet the human subjects training requirements of their own institution.*

***Note****: If the external personnel or collaborators are not affiliated with an organization with its own IRB, they may take the applicable UNE-Specific CITI training course(s) outlined below.*

|  |  |
| --- | --- |
| **UNE-Specific CITI Training Courses** | **Take when the research study…** |
| Biomedical Research Investigators  | Involves the collection of biomedical data, or biometric or physical data from participants (e.g., blood or saliva sampling, weight, timing movements, or measuring performance on a physical task) |
| Social & Behavioral Research Investigators | Involves the collection of data via focus groups, interviews, surveys, educational or psychometric tests, or observation of non-public behavior |
| Data or Specimens Research | Involves existing data (e.g., retrospective chart review) or biospecimens |
| Conflict of Interest | Is funded or sponsored by a federal Public Health Service (PHS) agency |

 |[ ] [ ]   |
| 2 | Signed copy of the ‘**Submission Attestation Form**’ (click [here](https://www.une.edu/research/integrity/irb))* *If the PI is a student, the document must also be signed by the respective Faculty Advisor*
 |[ ] [ ]   |
| 3 | **If enrollment is still open**, attach a copy of one signed consent form that was obtained during the last approval period* *If your study involves the use of multiple consent forms (e.g., patient vs. clinician consent forms), attach a copy of one signed consent form for EACH consent form type used in the study*
* ***Note****: The name of the participant/personal representative MUST be redacted or blacked out prior to submitting the consent form(s) to the IRB for review*
 |[ ] [ ] [ ]