|  |
| --- |
| **FORM INSTRUCTIONS**:Submit your completed form 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 form.  |

|  |  |
| --- | --- |
| 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 & FACULTY ADVISOR**
 |
| --- |
| **Principal Investigator Name**:Enter text | **You are**:[ ]  Faculty[ ]  Staff[ ]  Student[ ]  Resident | **UNE Center or College**: | Enter text |
| **E-Mail**: | Enter text | **UNE Program of Study**: | Enter text |
| **Phone #**: | Enter text |
|  |
| **Faculty Advisor Name**:Enter text | **E-Mail**:Enter text | **Phone #**:Enter text |

| 1. **STUDY STATUS**
 |
| --- |
| 1. **Is the study expired?**

[ ]  No *(skip Section D)*[ ]  Yes *(Section D is required)* | 1. **Enter the date the study was closed permanently**:

Enter text | 1. **Identify the reason for study closure**:

Enter text |

| 1. **STUDY DATA INFORMATION**
 |
| --- |
| 1. **Answer the following**:
2. The collection of personally identifiable information is complete: [ ]  Yes [ ]  No [ ]  N/A
3. The analysis of personally identifiable information is complete: [ ]  Yes [ ]  No [ ]  N/A
4. The link to identifiers (e.g., master list or key) has been destroyed: [ ]  Yes [ ]  No [ ]  N/A
 | 1. **Date data were de-identified**:

Enter text |
| 1. **Provide information about data linkage and the process for de-identifying the data** *(as applicable)*:
2. Describe how data were linked (e.g., master list or key) to individual participants.

Enter text1. Describe the process that was used to de-identify data and/or destroy the link to identifiers.

Enter text1. If data will remain identifiable, justify retention of identifiable data and describe procedures that will be put into place to protect the confidentiality of any identifiable data (including storage and security for electronic and hard copies).

Enter text |

| 1. **EXPIRED STUDY INFORMATION** *(as applicable)*
 |
| --- |
| 1. **Has the study’s funding source been notified that IRB approval has expired for this project?**

[ ]  N/A – Study is not funded[ ]  Yes *(attach relevant documentation)*[ ]  No *(explain below)*Enter text | 1. **Since the study’s IRB expiration date…**

*(check all that apply)*[ ]  No research related activities or recruitment activities have occurred[ ]  No participants have been enrolled or records/specimens reviewed[ ]  No interactions/interventions have been conducted[ ]  No data have been obtained***Note****: Submit an ‘****New Reportable Event Form****’ if any item above is left unchecked* |

| 1. **STUDY ENROLLMENT & ACCRUAL**
 |
| --- |
|

|  |  |
| --- | --- |
| 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 was 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. **Were there any problems meeting the enrollment target?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Did the study exceed 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 E 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 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. **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. **FINAL PROGRESS REPORT**
 |
| --- |
| 1. **Were there any unanticipated study-related problems that involved risk to participants or others that were not reported to the IRB?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Did any significant protocol deviations occur *during the life of the study* that were not reported to the IRB?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have any benefits of the research been observed in participants?**

[ ] N/A *(benefit to society only)* [ ]  No [ ]  Yes *(explain below)*Enter text1. **Have there been any significant or interesting findings/results from this study?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have you received any participant complaints *during the life of the study*?** [ ]  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. **Did any participant seek compensation for a research-related injury that has not been reported to the IRB?** [ ]  No [ ]  Yes *(explain below)*

Enter text1. **Have any study documents been modified or key personnel added 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 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: Study Closure Submission Checklist**

| REQUIRED SUPPLEMENTAL DOCUMENTATION *(as applicable to your study)* | Yes | No | N/A |
| --- | --- | --- | --- |
| 1 | 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*
 |[ ] [ ]   |
| 2 | Provide a copy of any publications or reports (abstracts, journal articles, posters, etc.) that have been created as a result of this study |[ ] [ ] [ ]