

**OFFICE OF RESEARCH INTEGRITY INSTITUTIONAL REVIEW BOARD**

**HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED**

CONCLUSION REPORT

## Research Project Title: IRB #

**Principal Investigator(s): Approval Expiration Date:**

Each letter approving an initial or renewed research application indicates the date on which approval expires. At least 30 days prior to the expiration date, the investigator must submit an Application for Renewal or a Conclusion Report.

For submission requirements, see Sections III.B.1 and IV.E of the UNE Policies, Procedures and Guidance on Research with Human Subjects.

For help completing this form, consult the IRB Administrator at [**IRB@une.edu**](mailto:IRB@une.edu).

# REQUIRED ATTACHMENTS

##  Most recent Letter of Approval

** Protocol Summary**

Using no more than one page, provide a **brief, non-technical synopsis** of the research. Identify the participant population, the recruitment procedures, and informed consent process. Describe the study location, the procedures, any interventions, and the major risks of the study.

##  Progress Report

Briefly describe the progress of the research since the last approval.

** A stamped copy of the approved Informed Consent document.**

# DETAILED REPORTING

1. At what stage is the research? *CHECK ONE ON EACH ROW.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| (a) Recruitment/Enrollment | Not started | Active\* | Closed | Date completed |
| (b) Intervention (if any) | Not started | Active\* | Closed | Date completed |
| (c) Data collection | Not started | Active\* | Closed | Date completed |
| (d) Data analysis | Not started | Active\* | Closed | Date completed |
| (e) Write-up of results | Not started | Active | Closed | Date completed - |

## \* Any of these answers may disqualify the study from closure. See Section IV.E of the UNE Policies, Procedures and Guidance on Research with Human.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **As of Last Approval** | | **Since Last Approval** | **Total Since Initial**  **Approval** |
| 2. How many participants did the IRB approve? |  | |  |  |
| 3. How many participants have:  Given consent (or enrolled under a waiver of consent)? | \**If the last approval was the initial approval, enter 0* | |  |  |
| a. Discontinued due to adverse event\* |  | |  |  |
| b. Withdrawn\* |  | |  |  |
| c. Lost to follow up |  | |  |  |
| d. Completed participation |  | |  |  |
| e. Currently active |  | |  |  |
| 4. How many participants are members of these populations? | **Permitted to Enroll?** | |  | **Total Since Initial Approval** |
| a. Adults lacking capacity to consent | yes | no |  |  |
| b. Non-English speakers | yes | no |  |  |
| c. Pregnant women, fetuses or neonates | yes | no |  |  |
| d. Prisoners | yes | no |  |  |
| e. Minors. | yes | no |  |  |
| f. Children who are in foster care or wards of the state. | yes | no |  |  |

1. \*Please provide an explanation for all subjects who have discontinued participation or withdrawn since the last approval:

Since the last approval, did any of the following occur?

1. Complaints about the research? yes no
   1. If yes, Has a Report of Important Event been filed? yes no
   2. If yes, date: Result & date:
   3. If no, please explain.
2. Change to study personnel since the last approval?
   1. If yes, Was an Application for Amendment filed? yes no
   2. If yes, date: Result & date:
   3. If no, please explain.

yes no

1. Change to an investigator’s financial situation that requires a financial interest disclosure?
   1. Was an Application for Amendment filed? yes no
   2. If yes, date: Result & date:
   3. If no, please explain.

yes no

1. Change to an study protocol?
   1. Was an Application for Amendment filed? yes no
   2. If yes, date: Result & date:

yes no

* 1. If no, does the change represent a “significant protocol deviation”, as defined in Section IV.F.1 of the UNE Policies, Procedures and Guidance on Research with Human Subjects? yes no
  2. If yes, **** **Attach a Report of Important Event**
  3. If no, please explain.

1. An important event (significant protocol deviations, unanticipated problems, or serious adverse events  see Section IV.F of the UNE Policies, Procedures and Guidance on Research with Human Subjects)? Change to an study protocol?or serious adverse events  see Section IV.F of the UNE

Policies, Procedures and Guidance on Research with Human Subjects)? yes no

* 1. If yes, Has a Report of Important Event been filed? yes no
  2. If yes, date: Result & date:
  3. If no, please **** **Attach a Report of Important Event**

1. Any significant study findings? yes no

##  Attach all relevant report(s).

Primary Principal Investigator Signature Date

**Because this form is new, the Board welcomes any feedback on how this form works, any problems, and suggestions for improvement. Please email your feedback to the IRB Administrator at** [**IRB@une.edu.**](mailto:IRB@une.edu) **It will have no effect on your application.**

# CHECKLIST OF ATTACHMENTS

**To assist Board members, please apply a label to all attachments. Please list below the label and title of each attachment:**

|  |  |
| --- | --- |
| **Label** | **Title** |
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