جامعة نيويورك ابوظبي

NYU | ABU DHABI

PROCESSING OF IRB PROTOCOL AT EXPIRY DATE

This application must be typed and filled in completely. Hand written and/or incomplete submissions will be returned.

Name of Principal Investigator: _____ **Date:** _____

Full Title of Protocol: _____

IRB Protocol #: _____ **Date of Protocol Expiration:** _____

Funding Source(s):
- ☐ Internal funds ☐ NYUAD Program
- ☐ Non-NYUAD (external), award #: _____
- ☐ US Federal, award #: _____

Name of funding Agency/Program: _____

Part 1: Determining Status of Research

In order to determine the status of the research and whether this IRB protocol should be renewed, please select the **ONE** statement that best describes the current status:

☐ (A) No human subjects participation is involved, only use of secondary data where data is private and personally identifiable: Analysis is on going

☐ (B) Data collection is on-going: Enrollment of participants is yet to begin or is on going.

☐ (C) Data collection has ended and analysis is taking place, but there is a possibility of re-opening sessions for participant enrollment and resuming data collection.

☐ (D) Participant intervention/participation is completed with no plans to restart. **Data analysis is underway using data that still contains personal identifiers or where links to identifiers still exist (key codes, etc.)**

☐ (E) Participant intervention/participation is completed with no plans to restart. **Data analysis is underway using data that has been completely scrubbed of personal identifiers with no way for any investigators to re-identify the data (no key codes, etc.)**

☐ (F) ALL data collection and data analysis has been completed.

Other/Comments:

_____

If you selected any of the options A - D, your IRB protocol for this research will need to be renewed as there is some element of human subjects work being done. **Please complete Part 2 of this form.**

If you selected any of the options E or F, all human subjects research has been completed and the IRB protocol can be closed.

Part 2: Request to continue IRB protocol

I. Summary of Progress

A) Give a summary of your progress to date. *Attach a separate sheet, if necessary. If funded, please attach a **complete** copy of your agency progress report.*

B) Have you had any publication additions or recent literature citations of your study? ○ Yes ○ No

Have you presented your study at any conference or other events? ○ Yes ○ No

If yes, describe and list all publications and presentations.

C) Please list any amendments or modifications to the protocol approved during the last approval period.

D) Other relevant information associated with your study should be given below.

II. Further details on Current Status of Human Participant Use.

A) ☐ Participants have been enrolled.

Total enrollment to date:

☐ No participants enrolled to date. No additional risks identified.

Enrollment will begin on:

☐ Participant intervention/participation is completed. Study remains open only for ☐ long-term follow-up and/or ☐ for data analysis.

Completion expected by :

B) What is the total number of participants by site currently approved by the IRB?

Site: Number:

Site: Number:

C) Do you want to increase or decrease this number? ○ Yes ○ No

If yes, give the exact desired number of participants you wish to enroll per site:

Site: Number:

Site: Number:

Explain reason for increase/decrease:

III. Alterations to Protocol

Are there any changes to the protocol requested during this review period including addition of new investigators? ○ Yes ○ No

If yes, indicate what those changes are and complete the Request for Protocol Modification form

IV. List of all Investigators

Please list names and roles of all Investigators active on this protocol

Name:	Role:

V. Data and Safety Monitoring

Have any new or increased risks been identified since the most recent IRB review? ○ Yes ○ No

If yes, explain the risks and what precautions have been taken to minimize those risks.

Note: New or increased risks may require revision of the informed consent document.

VI. Withdrawal, Complaints, and Adverse Events

A) Have participants been withdrawn in the past approval period by the Principal Investigator? ○ Yes ○ No

Have participants self-withdrawn from the study in the past approval period? ○ Yes ○ No

If you answered yes to either of the above, explain how many of each and the reasons for withdrawal.

B) Have there been participant complaints about the research during this past approval period? ○ Yes ○ No

If you answered yes, explain how many complaints have been received as well as what they were and what measures were subsequently taken to guard against similar occurrences.

C) Have there been any adverse events during the past approval period? ○ Yes ○ No

If you answered yes, for each event, detail what occurred, the date of occurrence, and whether the event was reported.

VII. Consent Form

Are you requesting changes to the consent form(s)? ○ Yes ○ No

If yes, explain the changes requested.

Attach copies of the currently approved (stamped) informed consent document(s) and the new and/or clean (unstamped) copies that you plan to use for the requested approval period.

VIII. Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

The information provided for on all pages is correct and no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents and I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators, any change in procedure, or changes requested by agency in the case of externally funded research). I will comply with IRB and NYUAD policies for conducting ethical research and I will be responsible for ensuring that my co-investigator(s)/student researcher(s) comply with this protocol. Any unexpected, adverse, or otherwise significant events in the course of this study will be promptly reported to the IRB.

PI/Faculty Advisor's Name:

Date:

PI/Faculty Advisor's Signature (If PI is student)

NYUAD E-mail address: