State University of New York at Delhi
Institutional Review Board
Research Study Renewal/Termination Report

Complete form electronically and upload in PACS. All paperwork is filed electronically.

Current IRB #:

Protocol Title:

Principal Investigator:

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I. Status of the Protocol

Note: Studies designated as **minimal risk** either through an expedited review process or by a full board committee can be expedited at the time of renewal unless substantial modifications which change the risk/benefit ratio are requested.

This research protocol:

☐ Remains ongoing (open to additional enrollment).

☐ Remains ongoing (permanently closed to additional enrollment but subjects continue to undergo research-related interactions).

☐ Remains ongoing (permanently closed to additional enrollment and all subjects have completed protocol-related treatments/interactions but the research remains active for long-term follow-up of subjects). **Renewal may be expedited.**

☐ Remains ongoing (the **ONLY** research activity is data analysis). **Renewal may be expedited.**

☐ Is terminated (Date of termination: _____).

For **terminated research protocols**, a final progress report shall be submitted to the IRB office. This progress report shall address at a minimum:

- The final number of subjects enrolled in the study.
- A summary of outcomes and conclusions, to include a statement of the extent to which the specific aims of the protocol were addressed and the impact of the study on the relevant scientific issues under investigation (e.g., a description of new knowledge, findings, or information).

II. Abstract

Provide a brief (1-2 paragraphs) updated abstract of the research study to address the current status of the study including its specific aims, rationale and significance, experimental design and methods. Also, please respond to each of the following requests for information.

III. Research Subject Enrollment:

A. A total of _____ subjects have been entered into this research protocol at this site during this **renewal** interval.

1. Breakdown of subjects by gender: Female: _____; Male: _____
2. Breakdown of subjects by race/ethnicity:
   White: _____; Hispanic: _____; Black: _____; Asian: _____; Other _____

For studies that involve children, please provide the following:

3. Breakdown of subjects by age:
0-2: _____; 3-4: _____; 5-10: _____; 11-13: _____; 14-18: _____

B. A total of _____ subjects have been entered into this research protocol at this site since its **initial** approval.

Note: If enrollment into this research study, to date, is less than 20% of the projected enrollment based on the proposed annual accrual rate [i.e., proposed total number of subjects at this site/proposed total study duration] provide a rationale for this slow enrollment and a justification as to why this research should be continued:

C. Have there been any subject withdrawals from the study? Please note that this includes any subject who signs a consent form and then decides not to participate or subjects that are withdrawn from the study by the investigator.
☐ No ☐ Yes; Reasons for withdrawal include the following:

IV. Adverse Events

- If any of the following adverse events have been reported previously to the IRB, summarize problem/event below, and describe outcome.
- For those events that have not been reported previously, complete an Adverse Event Form and attach a copy to this submission.

A. Describe any **UNEXPECTED** adverse events, including risks to participants or others, associated with the conduct of this research protocol.

☐ None; ☐ New (Form attached)

B. Describe any deviations from the IRB-approved protocol.

☐ None; ☐ New, Description:

C. List any subject complaints and your response to them.

☐ None; ☐ New, Description:

D. Describe any breaches of subject confidentiality.

☐ None; ☐ New, Description:

V. Risk/Benefit Considerations:

A. Describe any change in the benefit and risk considerations of study participation as defined in the currently approved research protocol

☐ None; ☐ Yes, IRB modifications attached.

B. Are you aware of any recent scientific publications or other reports that may potentially impact the continued conduct of this research study or the benefit and risk assessment of study participation?

☐ No; ☐ Yes, a copy of the article is attached.

C. Is there any new information on risks and/or benefits associated with study participation that may influence the willingness of current or future research subjects to participate in this research project?

☐ No; ☐ Yes, a copy of the relevant information is attached, and a description of how this information will be disseminated to current and future research subjects (if appropriate):

VI. Required Submissions (All paperwork is required regardless of the status of the protocol):

☐ 1. Renewal/Termination Report Form (including abstract)
☐ 2. Protocol (with any modifications highlighted)
☐ 3. Consent Document(s) (with any modifications highlighted)
☐ 4. Adverse Event Form (if applicable)

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I certify that the above information is correct:

_____ _____

Principal Investigator Signature Date

Last revision 8/2024