NEW YORK INSTITUTE OF TECHNOLOGY
Institutional Review Board for the Protection of Human Participants
Northern Blvd, Old Westbury, NY 11568
516-686-7748 http://www.nyit.edu/ospar/irb/

PROTOCOL RENEWAL FORM

- This form must be submitted for renewal of the IRB approval beyond the initial approval.
- Please note that studies must be submitted for continuing approval until all analysis is complete.
- Submit this form, and all previous modifications, and the original application at least 45 days prior to the approval expiration date to the IRB office (see the Sponsored Programs website http://
- www.nyit.edu/ospar/irb/).

Please type or print.

1. Initial review type: ☐ Expedited, Category_____ ☐ Full

2. IRB Protocol Number: _____

3. Principal Investigator: _____

4. Current approval period: ____/____/____ - ____/____/____

5. Study Status:

☐ Active. Expected end date: ____/____/____

☐ Enrollment closed as of ____/____/____.

- ☐ Participants will continue study treatment until ____/____/____.
- ☐ Participants are not receiving study treatment. Follow up involves procedures that would not be done if the participant were not in the study. Participants will be followed until ____/____/____.
- ☐ Participants are not receiving study treatment. Follow up procedures are the same for participants managed on or off protocol.

6. Number of participants enrolled in the past 12 months — Female ☐ Male ☐ Total 0.0

7. Total number of participants enrolled since study began:
   NYIT sites: Female ☐ Male ☐ Total 0.0
   Other sites: Female ☐ Male ☐ Total 0.0
8. How many participants have withdrawn from the study? Female ☐ Male ☐ Total 0.0
   Reasons for withdrawal:

If no participants are enrolled within three renewals, the protocol will be not be renewed by the IRB.

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9. Total number of participants yet to be recruited:
   NYIT sites: Female ☐ Male ☐ Total 0.0
   Other sites: Female ☐ Male ☐ Total 0.0

10. Have events, toxicities, or complications occurred (physical, psychological, social, or with the consent process or enrollment)? ☐ Yes ☐ No
    If yes, explain on a separate sheet.

Expected and unexpected adverse events must be reported in writing to the IRB immediately.

11. Were any grievances or complaints received about this study? ☐ Yes
    if yes, explain on a separate sheet. ☐ No

Please respond to the following questions on a separate sheet. Provide enough detail to enable the IRB to conduct a substantive and meaningful review.

12. List all publications resulting from this study.

13. Provide a short description of the goals of the study, and provide a summary of activities to date.

14. Summarize revisions previously approved by the IRB.

15. If you propose any change to the protocol, its funding source, recruiting materials, or consent documents, please summarize the changes you propose, the reasons for them, and submit a copy of an updated version of your original protocol application that shows all proposed changes in bold or underlined. If you have changes to co-investigators or student researchers, please list them and describe their proposed contribution. Remember that no changes may go into effect until you have received IRB approval. **Copies of certificates of completion of the required training program must be attached for all new key personnel.**

16. Provide a listing of investigators and students remaining on protocol along with email addresses so a COI can be issued.

17. Describe any findings to date and provide any additional information from your own work or that of others in the field that might affect the conduct of the study.

18. Attach the following:
    A copy of the consent form currently in use for this study. If the consent form and/or the authorization form are written in a language other than English, include copies of the form in both languages.

    A copy of all current, un-expired approval form(s) from all other institutions involved with your study.

By signing this document, I certify that in my opinion the protocol and safeguards described in this application meet the standards of the New York Institute of Technology (NYIT) and all Federal regulatory requirements concerning experiments that use human participants. I accept responsibility for assuring adherence to Federal and NYIT policies relative to the protection of the rights and welfare of participants in this study. I certify that my participation and the participation of any co-investigators do not violate the NYIT policy on conflicts of interest.

By signing below, I certify that I have undergone training in basic human participant protections and will ensure that all key personnel complete this training before working on this protocol.

PI Signature: _____ Date: ____/____/____

Department Chair Signature: _____ Date: ____/____/____

Please email the completed form to the Office of Sponsored Programs and Research at grants@nyit.edu
Along with copies of the previous signed consent forms.