INSTITUTIONAL REVIEW BOARD
(856) 761-3844
Fax: (856) 761-3834

IRB Continuation/Final/Status Report Form

1. Study Information

Principal Investigator (include degree(s)/certifications): Click here to enter text.
Date of last Human Participants Protection training: Click here to enter text.

Co- Investigator(s) (include degree(s)/certifications): Click here to enter text.
Date of last Human Participants Protection training: Click here to enter text.

Study Personnel (include degree(s)/certifications): Click here to enter text.

Since the last IRB review, have there been any changes to study personnel, Co-I, or PI?
☐ *Yes, please complete and submit the IRB Modification Form for review.*
☐ *No*

IRB Protocol Number: Click here to enter text.

Study Title: Click here to enter text.

Expiration Date: Click here to enter text.
IF IRB APPROVAL HAS EXPIRED OR WILL EXPIRE PRIOR TO REAPPROVAL, NO RESEARCH RELATED ACTIVITIES MAY TAKE PLACE AFTER THE PROTOCOL EXPIRATION DATE. Please provide:
- *Description of any study activities that occurred during study lapse* Click here to enter text.
- *Explanation for delayed CR submission* Click here to enter text.
- *Corrective and preventative action plan to avoid future lapses* Click here to enter text.

Please check what type of submission:

	Continuation Report
	Final Report ** By selecting this option, you are acknowledging there will be no further contact with participants, all data queries have been resolved and there will be no further access to collected data.*
	*Status Report***

2. Research Activity Summary

(Please check one)
☐ *Enrollment is temporarily suspended for the following reason:* Click here to enter text.
☐ *Enrollment is closed. Participants are not receiving study treatment.*
☐ *The protocol remains active only for long-term follow-up of participants.*
☐ *The protocol is active and currently enrolling participants.*

Provide a brief general summary of the progress of the study. Use this section to provide overview of activities that occurred during the last approval year, including notable experiences, delays in study activities, and plans for the upcoming year. Click here to enter text.

Please list the sites where this study is taking place. Click here to enter text.

3. Enrollment

If Virtua IRB is the IRB of record for multiple sites (multi-center study), please provide enrollment metrics for each site relying on Virtua Health IRB. For enrollment numbers below, those listed in A = B + C + D

Total number of participants/records approved: Click here to enter text.

A. *Number of participants/records enrolled/reviewed to date: Click here to enter text.*
B. *Number of participants who are active (receiving intervention): Click here to enter text.*
C. *Number of participants who are in follow-up (no longer receiving intervention): Click here to enter text.*
D. *Number of participants who have completed all research activities: Click here to enter text.*

Number of participants who voluntarily withdrew after enrolling: Click here to enter text.

Number of participants terminated/withdrawn from the study by the investigator due to adverse events: Click here to enter text.

Number of participants terminated/withdrawn from the study by the investigator due to other reasons: Click here to enter text.

Number of screen failure: Click here to enter text.

Number of participants lost to follow-up: Click here to enter text.

Number of participants no longer participating for reasons other than those above: Click here to enter text.

Has enrollment been lower than anticipated?

☐ *Yes, please explain the reason for low or no enrollment and, if relevant, what steps have been/will be taken to increase enrollment. Consider including what has been successful, what has not been successful, and any changes to the recruitment plan in the future to improve future enrollment. Click here to enter text.*

☐ *No*

4. Unanticipated Problems/Adverse events

Since the last IRB review and as assessed by the Principal Investigator, have any unexpected, serious adverse events occurred that were considered related to participation in the research that have not been previously reported to the IRB?

☐ *Yes, please complete the IRB Reportable Event Form for review and provide reason event was not reported in real time: Click here to enter text.*

☐ *No*

Since the last IRB review, have any other unanticipated problems involving risks to participants or others occurred?

☐ *Yes, please complete the IRB Reportable Event Form for review.*

☐ *No*

5. Protocol Deviations/Violations/Complaints

Have any protocol deviations/violations occurred that have not been previously reported to the IRB?

☐ *Yes, please attach the deviation listing.*

➔ *As assessed by the Principal Investigator, did the protocol deviation/violation affect participants rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data?*

☐ *Yes, please complete the IRB Reportable Event Form for review.*

☐ *No*

☐ *No*

Have any participants or others complained about the research?

☐ *Yes, please provide a summary of the complaints and how they were resolved: Click here to enter text.*

☐ *No*

6. ClinicalTrials.gov

Please provide your ClinicalTrials.gov ID number, If applicable: Click here to enter text.

If your study is registered at ClinicalTrials.gov, provide the date of your last ClinicalTrials.gov update: Click here to enter text.

7. Abstracts and Publications

Have any abstracts or publications arisen from this study, since the date of last review?

☐ *Yes, please attached them.*

☐ *No*

8. Safety Review Committee

Is this study overseen by a Data Safety and Monitoring (DSMB) Data Monitoring Committee (DMC), other similar body, or group whose responsibilities include review of adverse events and interim findings?

☐ *Yes, please attach most recent report or include the reason a report is not included: Click here to enter text.*

☐ *No*

9. Overall Study Risk/Benefit

Since the last IRB review, have there been major advances, changes in standards of care, drug approvals, device recall, new black box warning, new adverse events/safety letters, or key publications in major peer-reviewed journals which would alter the risk/benefit assessment of this study, as assessed by the investigator?

☐ *Yes, please attach the updated information.*

☐ *No*

10. Identifiable Information

Do you have Protected Health Information (PHI)/Private Identifiable Information (PII) for this study?

☐ *Yes,* **please describe where research/project data will be stored, including both electronic and physical storage locations, as applicable. For electronic storage, identify the system or platform used. For physical storage, provide the address, building, floor, and room number.** *Click here to enter text.*

☐ *No*

11. Study monitoring/quality control

Please check the appropriate quality control plan for your study.

☐ *N/A; The study was determined to be minimal risk study by IRB*

☐ *N/A; The study has not enrolled any participants*

☐ *N/A; The study is closed to enrollment and had no active participants during the last year.*

☐ *The Regulatory Sponsor's designated study monitor conducts quality control activities by reviewing the study records.*

☐ *There is no Sponsor monitor for the study. The PI and study team conduct all quality control activities.*

12. Additional Information

Have there been any updates to the products or agents administered on this trial in the past year? This may include updated FDA labeling, revised package inserts, updated investigator brochures, any product recalls or bans, updated manufacturer, etc.

☐ *Yes, please attach the updated information and include an explanation why they were not submitted in real time: Click here to enter text.*

➔ *Has The protocol, Sponsor, PI or any CoI been inspected by the FDA or other health authority?*

☐ *Yes, was a FDA Form 483 or other report issued? Click here to enter text.*

☐ *No*

☐ *No*

☐ *N/A; this study does not administer any products or agents*

If applicable, please attach any other documents that have not been specified in previous questions, but are needed for IRB review: Click here to enter text.

Continuation Application Checklist

- ☐ *Provide the completed application with verified (scan of wet-ink signature/date or if electronic, must be verified) investigator signature*
- ☐ *(if continuation) Attach a copy of all currently approved informed consent forms,*
- ☐ *(if continuation) Provide signed new COI forms completed and signed (by each study team member, and*
- ☐ *(if continuation) Ensure all study team member CITI training is up to date.*

Documentation must include a signed and dated signature page. Accepted formats include a scanned copy of a wet-ink signature and date, or a verified electronic signature.

Electronic signatures are accepted only if verification is evident on the document. Verification may include an electronic signature certificate, audit trail, timestamp, authentication record, or other system-generated information demonstrating who signed the document and when it was signed.

If the electronic signature cannot be verified, please either:

- *Submit a scanned copy of the form with a wet-ink signature and date, or*
- *Have the investigator email the completed form(s) directly to IRB@virtua.org, including the*

13. INVESTIGATOR SIGNOFF

Signature of PI: _____ *Date:* _____