ARCADIA UNIVERSITY
— COMMITTEE ON THE PROTECTION OF RESEARCH SUBJECTS

Institutional Review Board (IRB)
Continuing Review/ Progress Report

Please attach the completed form to your IRBNet package along with a cover letter, application with any new amendments that were not previously approved highlighted, consent/assent forms, all supplemental materials (i.e. recruitment materials, data collection tools, etc.), and current CITI certificates for all study team members. If you have any questions please contact Karen Dudley at russok@arcadia.edu or 267-620-4111.

1. **Current Date:** **Date of original IRB approval:**

2. **Project Status -** Please provide a brief report of what has been accomplished to-date.

   a. Please provide a brief description of how the project will proceed.

3. **Were there any changes to the approved protocol during the course of the project that have not been previously reviewed by the IRB through an amendment request?**

   ☐ Yes, changes were made. (Complete and submit a Protocol Deviation Form and the revised protocol)

   ☐ No changes

4. **Enrolled Subjects*:**

   a. Total number of subjects/sample/charts approved for enrollment/to be studied in this project per original protocol approved by the IRB:

   b. Total number of subjects/samples/charts enrolled/studied to date:

   c. Have any subjects withdrawn from the study?

   ☐ Yes

   ☐ No

If YES, please explain below the reasons for withdrawal—give the unique subject identifier, date enrolled, reason for withdrawal (if known), and any additional information. Reasons for withdrawal might include but are not limited to: lost to follow-up (participant is lost from the study and the PI is not aware of the reason why), moved from the study area, serious adverse events, non-compliance on the part of the subject, request from the participant, etc.

d. Is there a fully executed consent form in the study file for each subject reported in 4B?

☐ Yes

☐ Waiver of written consent was used

☐ No, please explain

e. Were more subjects enrolled than were IRB approved?

☐ Yes, please explain

☐ No

***Enrolled subjects** are those who signed consent forms and are participating in (or completed) all activities they consented to. (Participating e.g., filling out questionnaires, answering questions, taking drugs, having surgery, being called on the telephone, having data collected.) Enrollment is a finite number usually dictated by the sponsor or by statistical methods.

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5. Adverse events

Were all adverse events (if any) reported to the IRB?

☐ Yes

☐ No, if not previously reported, complete the Adverse Event form and attach to this document.

☐ Not applicable