Continuing Review Form

Please submit this form and all required study documentation to the IRB Office at least one (1) month prior to the expiration date of current IRB approval. All information must be typed. Do not omit any required fields (in bold) or the form will be returned for completion.

**Date of submission:** Click or tap to enter a date.

**IRB OFFICE USE ONLY**

**□ Full board □ Expedited**

**Review date: \_\_\_\_\_\_\_\_\_\_**

**Expiration date of current IRB approval:** Click or tap to enter a date.

**Study Title:**

Protocol #:       **Clinical Phase:** Choose an item.

[ ]  **Check the box to indicate you have no undisclosed conflicts of interest. Please note any conflicts of interest, financial or otherwise, here:**

**Principal investigator (PI) name, credentials:**

Co-principal investigator (Co-PI) name(s), credentials:

Research coordinator name, credentials:

**Primary business address:**

**Telephone:**       **Email address:**

**Current protocol status (check one):**

[ ]  Open for new enrollment (remember to also submit a clean consent form for new approval stamp).

[ ]  Closed to enrollment; subjects are continuing study treatment according to the protocol.

[ ]  Closed to enrollment; subjects are continuing in follow-up according to the protocol.

[ ]  Closed to enrollment; no subject contact. Study remains active for data analysis only.

[ ]  Other (please describe):

Current protocol version date: Click or tap to enter a date.

**Were any changes to the protocol already made (and not approved previously by the IRB), or are you proposing any new changes now?** [ ]  No [ ]  Yes **(please explain)**:

Current consent form version date: Click or tap to enter a date.

**Were any changes to the consent form already made (and not approved previously by the IRB), or are you proposing any new changes now?** [ ]  No [ ]  Yes **(please explain)**:

**Describe the current progress of the study (regarding timeline, meeting objectives, etc.):**

**Have there been any changes in risk (i.e. physical, emotional, financial) to the subjects of this study?**

[ ]  No [ ]  Yes **(please explain)**:

**Describe the safeguards still in place for vulnerable subjects** (type N/A if vulnerable subjects will not be enrolled per your original IRB protocol application):

**Participant Status Update for Local Site (all fields required)**

How many subjects have been enrolled (consented) since your last IRB approval submission?

What is the total number of subjects enrolled since initial IRB approval?       (this # should = A + B + C)

1. How many of those are in current treatment or follow-up?
2. How many of those have withdrawn\* from the study?
3. How many of those have completed the study?

\*Please note and explain any subject withdrawals occurring since your last IRB approval submission:

Were any new subject complaints reported? [ ]  No [ ]  Yes (please explain):

**Did an audit or a for-cause site monitor visit\*\* take place since your last IRB approval submission?**

[ ]  No [ ]  Yes **(please explain and/or submit any relevant documentation)**:

\*\*Do not count routine site monitoring that finds no significant issues for follow-up. However, please do submit a copy of relevant documentation from all site monitoring visits regardless of this fact.

[ ]  **Check the box to confirm that all known local adverse events or protocol deviations have been reported to the IRB (submitted previously or at this time).**

**Documentation being submitted along with this form (check all that apply):**

[ ]  Clean copies of all consent forms (including any child assent forms), if still enrolling subjects

[ ]  Any revised study documents (protocol, participant materials, etc.), if not IRB-approved

[ ]  Any relevant audit or site monitoring documentation, if not previously submitted

[ ]  Submission forms for all previously unreported issues (adverse events, protocol deviations, etc.)

**PI name:**

 **PI signature:**

**Date:** Click or tap to enter a date.

Co-PI name(s):

 Co-PI signature:

Date: Click or tap to enter a date.

Please send this original form (email preferred) along with all relevant supporting documentation to:

Toshia Jones, IRB Coordinator

McLeod Health – Research Department

(843) 777-2013

toshia.jones@mcleodhealth.org

**FOR IRB REVIEWER USE ONLY:**

**Comments:**

Reviewer name:

 Reviewer signature:

Date: Click or tap to enter a date.

**FOR IRB OFFICE USE ONLY:** □ Approved □ Deferred □ Conditional Approval (explain below)

 □ Disapproved or Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Approval Date: \_\_\_\_\_\_\_\_\_\_ Approval Expiration Date: \_\_\_\_\_\_\_\_\_\_ Letter Sent Date: \_\_\_\_\_\_\_\_\_\_\_

□ HIPAA Waiver of Authorization □ HIPAA Authorization □ IRB Waiver of Informed Consent