

Goodwyn Institutional Review Board, Ltd.

Protocol Continuing Review Report

Protocol No:

Protocol:

Sponsor:

Expiration Date*:

*The expiration date of approval corresponds to one year from the date the first principal investigator was approved/renewed for this study.

This report is due by

Complete and return this report by the due date. ***If your report is not received by the due date, Board review of the protocol and the investigators may be delayed and Board approval may expire.***

1. Are participants continuing to be screened for this study?

Yes No

2. Please provide the total number of participants enrolled in this study for all US sites (if known)

A. Total number of people who are enrolled in this study (if known) _____

3. Does your response to question 2 represent a significant over enrollment (greater than 10%) beyond the number of participants stated in the Goodwyn IRB approved protocol?

Yes No

If "yes" and Goodwyn IRB was NOT previously notified, please attach an explanation that addresses the cause, the reason why Goodwyn IRB was not notified of this earlier, and the measures taken to provide adequate resources and minimize risk to participants.

4. Are there IND safety reports or MedWatch reports of serious and unexpected adverse events for this study that have NOT already been reported to the study investigators?

Yes No If "yes", please attach reports.

5. Have any known risks or side effects as outlined in the Investigator's Brochure, package insert, device manual, or product literature occurred at a higher rate than anticipated?

Yes No If "yes", please attach a description.

6. A) Does this study have a data safety monitoring board (DSMB)?

Yes No

B) If this study has a DSMB, have they requested changes to or discontinuation of the study for safety reasons?

Yes No If "yes", please attach a description.

C) Please attach all DSMB reports that have NOT already been submitted to Goodwyn IRB. (Please provide the summary portions of such reports, not raw adverse event data.)

7. Have any other findings become available that have NOT already been reported to Goodwyn IRB, but could affect the risk/benefit analysis or a participant's willingness to be in the study? (e.g. FDA advisories, related clinical study data, scientific literature, and/or post-marketing safety reports)

Yes No If "yes", please attach a description.

8. Have the participants experienced any unexpected benefits?

Yes No If "yes", please attach a description.

9. Has there been a change in the overall risk/benefit ratio since Goodwyn IRB last reviewed this research?

Yes No If "yes", please attach a description.

10. Given the events and findings relating to the study over the past approval period, is there a need to modify the protocol?

Yes No If "yes", please attach a description.

11. Given the events and findings relating to the study over the past approval period, is there a need to modify the consent form(s) for the study?

Yes No If "yes", please attach a description.

12. Please indicate the most current version(s) and date(s) of the Investigator's Brochure(s), package insert(s), or device manual for all primary and comparative drugs/devices for this Protocol:

(If you have not yet submitted any of these items, please submit a copy, a summary of changes, and a completed Updates and Alerts Report with this form.)

- a) Product: Version/Edition: Date:
- b) Product: Version/Edition: Date:
- c) Product: Version/Edition: Date:

I certify that the information provided above is true and accurate to the best of my knowledge and hereby request a continuing review by Goodwyn IRB for the purpose of securing Board approval to continue this research.

Signature

Date

Printed Name and Title

Please forward this completed document directly to:

Goodwyn IRB
9380 Main Street
Cincinnati, OH, 45242
Fax: 513-793-2800 or 513-793-4800