2111 West Braker Lane, Suite 100 ● Austin, TX 78758 ● P: 512.380.1244 ● F: 512.382.8902 ● [salus@salusirb.com](mailto:salus@salusirb.com)

**SPONSOR:** **PROTOCOL #:**

**A. INVESTIGATOR AND STUDY INFORMATION:**

|  |  |  |
| --- | --- | --- |
| 1. | Name of person completing form: |  |
| 2. | Phone number of person completing form: |  |
| 3. | Email of person completing form: |  |
| 4. | Investigator Name:  **OR**  All Investigators currently approved (multi-site studies) | |

**B. REQUEST FOR REVIEW/APPROVAL (Check all that apply):**

Protocol Amendment/Revision:

**Version and date:**

Include a detailed summary of changes/redline format of revised protocol (submit in PDF format)

Include copy of final protocol amendment or revised protocol (submit in PDF format)

For Federally supported or conducted research, if the Grant is updated include a copy of the updated Grant.

*Do the changes to the protocol require modifications to the approved ICD?  No  Yes*

*If yes, please indicate in the appropriate section of the form and include the requested modifications.*

*If no, please provide a rationale for modifications not being necessary.*

Protocol Administrative/Clarification Letter:

**Version and date:**

Planned Protocol Deviations - a prospective, intentional deviation from the IRB-approved protocol (for further details on the reporting these events, see the Reporting Guidelines for Unanticipated Problems, Deviations and Other Safety Information):

Describe the planned protocol deviation:

Describe how the deviation is not consistent with the approved protocol:

Provide the rationale for the planned deviation:

Provide written documentation of the Sponsor’s approval of this deviation

If this change necessitates modifications to the ICD or addendum ICD, please indicate in the appropriate section of the form and include the requested modifications.

**SPONSOR:**   **PROTOCOL #:**

Investigator’s Brochure/Product Information (ex. package insert, device manual, etc.)

**Version and date:**

Include a detailed summary of changes/redline format of the revised document

Include copy of final Investigator’s Brochure/Product Information

*Considering the* ***modification*** *to the IB/Product Information and regardless of enrollment status, does the current Salus-approved ICD require modifications related to new findings, safety updates? Check the appropriate box and initial for confirmation.*

*Consent revision is required and modifications are included in this submission (please complete appropriate section of this form for submission for ICD revisions).*

***OR***

*There are no new findings or safety updates to the ICD.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_ Principal Investigator Initials for Single Investigator Research*

***OR***

*\_\_\_\_\_\_\_\_\_\_\_\_\_ Project Manager/Sponsor Representative Initials for Multi-Investigator Research*

Informed consent document (ICD) revisions

**Name of ICD(s)**:

* + Include a copy of the most current IRB-approved ICD in redline format [If you cannot locate the MS Word ICD on GlobeSync, contact our office for the currently approved document]
  + For Federally supported or conducted research, if the Grant is updated ensure the protocol is revised and submitted to the IRB for approval prior to implementation of the change

New additional informed consent document/addendum

**Please note:** Submit in **Microsoft Word.** Please remove all formatting such as shading, text boxes, comments, or hidden text from the ICDs before submitting to Salus IRB. ICDs submitted with such formatting may cause a delay in the review of this request and may result in additional administrative fees.

**SPONSOR:**   **PROTOCOL #:**

Recruitment and Study Material

Please submit the **Microsoft Word version of each file** requiring review.

Ensure the **document title** and **version (number and/or date)** is indicated on the source document.

Submission of New Material

Submission of Revised Material (in redline format) previously approved by Salus for this study.

**Identify the items by checking the appropriate box and the quantity (#) being submitted:**

Proposed printed advertisement, **#**  Proposed web site content, **#**

Script of proposed video recording, **#**  Script of proposed audio recording, **#**

Produced Video/Audio, **#**  Social Media advertisements, **#**

Participant screening tool, **#**  Participant Diaries, **#**

Survey instrument(s), **#**  Questionnaire(s), **#**

Participant education material, **#**

Other (describe): **#**

Request for Salus IRB to Translate Study Documents:

* + What documents would you like translated?

Consent Forms

Recruitment Material

Study Materials

* + What language would you like them translated into? Language:
  + Do you require a quote before proceeding with the translation?  Yes  No
  + Do you require back-translation?  Yes  No

Translated Documents:

* + Please ensure the following is attached to this request:

Affidavit or Certification of accuracy from the translator

A copy of the English document translated. This must be the most current IRB-approved version.

A copy of the translated document. For consent forms, ensure the document is in an electronic Microsoft Word file.

Other items requiring review (describe):

Is this an update to a previous submitted document?  Yes  No

**SPONSOR:**   **PROTOCOL #:**

***THE FOLLOWING SECTIONS ARE FOR SALUS IRB USE ONLY***

**C. REVIEW AND DETERMINATION:**

|  |
| --- |
| **Type of Review:**  Deferred for Convened Board Review – Reviewer Signature:  Reviewed Only (Identify items):  Investigator’s Brochure/Product Information  Study Material  Other  Approved  Protocol Amendment/Revision  Administrative/Clarification Letter  Planned Protocol Deviations  Revised ICD  New ICD or Addendum  Recruitment/Study Material  Request for Salus IRB to Translate Study Documents  Translated Documents  Other  Approved as modified (Identify items):  Revised ICD  New ICD or Addendum  Recruitment/Study Material  Other |

**EXPEDITED REVIEWER STATEMENT AND SIGNATURE:**

|  |
| --- |
| *The proposed modification(s) involves no more than minimal risk and represents minor changes in previously approved research during the period for which approval was granted* *and meets the criteria in accordance with 21 CFR 56.110 and/or 45 CFR 46.110. A minor modification means that the change does not change the risks of the research or affect the design of the research and all added procedures involve no more than minimal risk and that all added procedures fall into categories (1)-(7) of research that can be reviewed using the expedited procedure.*  **If the ICD is modified:**  Is re-consenting required?  No  Yes  N/A  *My review of this item represents that I have no conflicting interests with the Sponsor, Investigator, or Protocol.*  Printed name of Reviewer (Chair or Designee):  Signature of Reviewer (Chair or Designee): Date: |