Salus IRB

FINAL/CLOSE-OUT REPORT

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SPONSOR: Eko Devices, Inc. **PROTOCOL #:** 1.3

PRINCIPAL INVESTIGATOR: Steven Forman, MD

This form should be utilized for notification of site closure. If you require assistance in completing this form, please contact us at the phone number listed above.

A. CONTACT INFORMATION:

1.	Name of person completing this form:	**Spencer Kieu**
2.	Contact phone number:	**714-623-6652**
3.	Contact email:	**spencer.kieu@ekohealth.com**

B. STUDY STATUS:

1.

The Research at this site is:

☐ Cancelled: No participants were enrolled at this site *(skip to section D)*

☒ Completed: (check each box)

☒ All participants have finished their final visits and follow-up,

AND

☒ Data collection is complete at this site,

AND

☒ The sponsor has indicated the study is closed at your site. *(Salus IRB does not require a sponsor close-out visit prior to submission of this report. Please verify with your sponsor that your site can be closed.),*

AND

☐ If the study was conducted under a Federalwide Assurance (FWA), all data analysis at this site is completed,

OR

☒ N/A This research was not conducted under a FWA.

☐ Closed: Sponsor terminated the study at this site due to *(describe):*

☐ Other (describe):

C. UNANTICIPATED PROBLEMS AND PARTICIPANT INFORMATION:

1.	Has the Investigator had any adverse regulatory inspections for this research (ex. FDA issued Form 483), that have not been reported to Salus IRB (not meeting the criteria of an Unanticipated Problem)? **If yes, provide a copy of the report and related responses.**	☒ No ☐ Yes
2.	Have you received <u>any</u> concerns, questions or complaints from your study participants that did not qualify as an unanticipated problem (UP) reportable to Salus IRB, which have <u>not</u> been resolved? **If yes, provide an explanation.**	☒ No ☐ Yes

D. PRINCIPAL INVESTIGATOR CERTIFICATION STATEMENT AND SIGNATURE:

Notification to close the research at my site:

I certify that the above information is true and accurate and no further study activities will take place at this site.

Signature of Principal Investigator/Authorized Designee — Date: 1/28/21

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FOR SALUS IRB USE ONLY:

ACKNOWLEDGEMENT:

Criteria for Acknowledgement (submission must meet the criteria below, or forward for review at a convened meeting):

- ☐ No unreported UPs or unresolved safety concerns
- ☐ No unresolved serious or continuing non-compliance concerns
- ☐ No unresolved participant complaints

This report has been received and we acknowledge the completion/closure of the research at this site. This form will be filed in the IRB study file.

Printed Name of Administrative Staff: _____

Signature of Administrative Staff: _____ Review Date:_____

FULL BOARD REVIEW AND DETERMINATION:

Action Taken by Full Board:

☐ Reviewed and Acknowledged

Printed Name of Reviewer (Chair or Designee): _____

Signature of Reviewer (Chair or Designee): _____ Meeting Date:_____