PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 20 Apr 2026

TO: Nia Bozeman

PROTOCOL: National Heart, Lung, and Blood Institute (NHLBI) - WINDSURFER, WIN ratio analysis to Determine a strategy of non-invasive Support for Respiratory Failure in the Emergency Department (WINDSURFER) A multicenter, randomized clinical trial to identify the best non-invasive respiratory support (NIRS) strategy for emergency department (ED) patients with acute hypoxemic respiratory failure (AHRF). (Pro00092316)

APPROVAL DATE: 9 Mar 2026

EXPIRATION DATE: 9 Mar 2027

IRB APPROVED DOCUMENTATION:

Protocol Version(s):

- Protocol (Version 2, Dated February 11, 2026)
- Exception from Informed Consent (EFIC) Investigators' Implementation Plan (Version 1.0, Dated February 27, 2026)

Consent Template(s):

- Continued Participation of Participants Enrolled Under EFIC Informed Consent Form (Advarra IRB Approved Version 9 Apr 2026)
- Prospective Informed Consent Form (Advarra IRB Approved Version 9 Apr 2026)

Product Information:

- AIRVO2 User Manual (Not Dated)
- HVT 2.0 High Velocity Therapy System Instructions for Use (Rev E)
- HAMILTON-C1 Operator's Manual (Dated 2019-08-30)
- Respironics V60/V60 Plus Ventilator User Manual (Rev AB, Dated 2022-10)

Other Material:

- 4:18 Produced Video, Community Informed Video
- WINDSURFER Interview Slides and Guide (Not Dated)
- WINDSURFER Community Info Slides (Not Dated)
- Questionnaire, WINDSURFER COMMUNITY SURVEY (Not Dated)
- Flyer, poster, or bulletin board, WINDSURFER EFIC Flyer (Not Dated)
- WINDSURFER EFIC LAR Notification Letter (Dated 2/26/2026)
- WINDSURFER EFIC No Consent Notification Letter (Dated February 26, 2026)

- Internet, WINDSURFER Social Media Ads (Not Dated)
- WINDSURFER Trifold Brochure (Not Dated)
- Internet, WINDSURFER Website Content (Not Dated)

The IRB approved the above referenced protocol with the modifications listed below on 9 Mar 2026:

- **Modifications to the Informed Consent Form templates**
- **Modifications to the Questionnaire, WINDSURFER COMMUNITY SURVEY**

On 9 Apr 2026, the IRB reviewed and approved additional revisions to the Informed Consent Form templates.

Please Note: This approval notice is for the IRB approval of the protocol only. The Principal Investigator for each site must complete a separate site submission to receive an IRB Approval notice allowing them to conduct the study.

Exception from Informed Consent (EFIC) is Approved.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

Please note that all community/subject-facing materials should be submitted to the IRB for review prior to being used in Community Consultation, Public Disclosure, or post-trial Public Disclosure. These include the survey, Facebook ads, webpage, PowerPoint slide deck or other presentation materials used for the online forums as well as any other materials used for Public Disclosure (such as press releases or flyers).

Documentation of Full HIPAA Waiver Approval

The IRB has approved the Full Waiver of HIPAA Authorization after determining that the waiver of authorization satisfies the criteria set forth in the HIPAA Privacy Rule at (45 CFR 164.512(i)(2)).

The waiver of authorization was reviewed and approved under full board review procedures. The IRB has determined that the protected health information necessary to be used/accessed is as outlined in the protocol and/or IRB application.

Use of eConsent is Approved. Based on the confirmations provided to the IRB, it is expected that:

1. **The eConsent(s) will include the complete and exact contents of the most current, IRB approved study consent(s).**
2. **The eConsent process includes obtaining signature(s) in compliance with applicable law and a method to confirm the identity of the signer(s).**
3. **The stored eConsent(s) identify the signers and date (time, if applicable) of signing; signed eConsent(s) are stored with appropriate access, and all versions are retrievable.**
4. **The signers must review all consent contents prior to signing the eConsent (i.e., there is no function available to skip directly to the signature field(s)).**
5. **All subject-facing materials used during the eConsent process (e.g., web-linked materials, graphics, videos, glossary, etc.) will be submitted for IRB approval.**

6. **If CIRBI eConsent Attestation responses change, an eConsent Modification will be submitted to the IRB for review. Note: An eConsent Modification is not required when revisions are only to the IRB approved study consent document(s).**

Individual sites using a different eConsent system/process (e.g., different app, vendor) or different eConsent subject-facing materials from the sponsor (e.g., Video Storyboard, Glossary of Terms, links, etc), require a site-level eConsent review (reviewed as part of the initial site/SSU submission or in a site eConsent Modification).

The IRB determined that the use of a Legally Authorized Representative (LAR) is approved for this study. During the course of the study, if the subject regains the capacity to consent, informed consent must be obtained from the subject and the subject must be offered the ability to leave the study if desired.

Based on the information available, the IRB determined that the device is a Significant Risk device.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

If the study is in an FDA 30-day wait period, subjects **may not** be consented or screened, as consent would be required before study-specific screening activities may begin. However, some initial activities related to determining a potential subject's interest in the upcoming study may occur. Such activities should be limited to recruitment efforts to inform potential subjects, or a community that a study may soon begin on a given condition. However, screening subjects to determine eligibility would not be acceptable until the IND is in effect.

It is the IRB's expectation that any placeholders in approved subject-facing material(s) will be accurately populated with the IRB approved content in all applicable instances.

Audio/visual recruitment or subject material approved in script format only must be submitted in final format for the IRB to review what potential subjects will see or hear. The IRB does not review the content found in embedded links or QR codes, therefore this content must be submitted for review and approval separately, prior to use.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Approved investigators and sites are required to submit to Advarra for review, and await a response, prior to implementing any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects' rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Compliance Statement/REB Attestation (Applicable for research conducted in Canada):

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair