REVISED PROTOCOL APPROVAL WITH MODIFICATIONS

DATE:	27 Sep 2023
TO:	Chinmay Chauhan
PROTOCOL:	Siddhey LLC - SIDDXAC02, An Observational Clinical Registry to Collect Safety and Efficacy Data on Wound Care in Medical Centers (Pro00070536)
APPROVAL DATE:	23 Aug 2023
EXPIRATION DATE:	23 Aug 2024

Per the request of the Sponsor, the previously released Protocol Approval with Modifications Notice (Dated 31 Aug 2023) has been revised to remove the Product Information. Please retain this revised notice along with the original.

IRB APPROVED DOCUMENTATION:

Protocol Version(s):	• Protocol (Dated 14 February 2023)
Consent Template(s):	• Main Informed Consent Form (Advarra IRB Approved Version 29 Aug 2023)
Recruitment Material:	• Questionnaire, Pain Assessment (Version 1.0, Dated 14 February 2023)

The IRB approved the above referenced protocol with the modifications listed below on 23 Aug 2023:

- **Modifications to the Main Informed Consent Form.**

On 29 Aug 2023, the IRB reviewed and approved additional revisions to the Main Informed Consent Form.

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.

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

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.

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.

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