Registry Informed Consent Form

Sponsor / Study Title:	**Siddhey LLC / "An Observational Clinical Registry to Collect Safety and Efficacy Data on Wound Care in Medical Centers"**
Protocol Number:	**SIDDXAC02**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Participant ID: _____

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing and dating this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

Introduction

We invite you to take part in a research registry SIDDXAC02 at the study site, which seeks to identify a more effective means of treating wounds. Taking part in this registry is entirely voluntary. We urge you to discuss any questions about this study with our study staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

Approximately 5,000 people will take part in this research nationwide.

If you decide to take part in this study your participation will last a maximum of 12 weeks. Information about you may be collected for up to 1 year.

Purpose of the Research

This clinical registry is an observational study to collect prospective (in the future) and retrospective (already existing) data on participant health, wounds and wound care procedures from medical centers, including skilled nursing facilities, hospitals, outpatient clinics, Home Health and any other medical environment where wounds are treated. Structured data

including wound photos are to be collected at the point of care in the participant electronic Case Report Form. The registry will enroll data of 1,000-5,000 wounds in up to 100 wound care locations. The dataset includes all wound and ulcer types. Data will be collected from original participant files, hospital records, laboratory test results and original recording/tracings from automated instruments, etc.

Procedures

The wound care team in addition to standard of care where deemed appropriate will utilize advanced treatment modalities with any biological or synthetic grafts products. These products will be added to your standard of care treatment practice, by being placed topically on your wound and secured with standard of care bandage, wrap, or gauze.

Time Duration of the Procedures and Study

If you agree to take part in this study, your involvement will last approximately 12 weeks, with continued data collection for one (1) year if the same/similar wound or injury needs treatment. You will be asked to return to the clinic 1 or 2 times per week at your treating providers treatment plan.

Risks

There are no physical risks associated with your participation in this study.

Alternatives to Participation

This research study is for research purposes only. The only alternative is to not participate in this study.

New Findings

Any new important information that is discovered during the study which may influence your willingness to continue participation in the study will be provided to you.

Benefits

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

Compensation for Participation

You will not receive any monetary compensation for your participation in this study.

Confidentiality

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

SIDDXAC02 will not collect personal identifiers of any participants. This document will be filled and collected by the treating facility and saved electronically for a period of five (5) years.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Costs

There will be no charge to you for your participation in this study.

Whom To Contact About This Study

During the study, if you have questions, concerns or complaints about the study such as:

- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00070536.

Voluntary Participation / Withdrawal

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor or the sponsor can stop your participation at any time without your consent.

Enrollment of Employees

If you are an employee of this research center, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and neither your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance appraisal or employment at this clinical research center. You may refuse to participate or you may withdraw from the study at any time without penalty or anyone blaming you.

Enrollment of Students

If you are a student, your participation will not place you in good favor with the study doctor or other faculty (for example, receiving better grades, recommendations, employment). Also, not participating in this study will not adversely affect your relationship with the study doctor or other faculty.

**Please provide the participant a copy of this signed document.*

Consent

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Participant's Printed Name

_____ _____

Participant's Signature Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative Date

_____

Authority of Legally Authorized Representative to act on behalf of Participant

Witness Signature for Participants Who Cannot Read (if applicable)

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study staff, discussed with the participant by a member of the study staff, and the participant has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date