Study Title:

A Retrospective, Multi-center Real-world Study of StimLabs Human Placental Membrane Tissue Used for Treatment in Hard-to-Heal Wounds

Protocol #: REL2501.000-M (07/25)

Protocol Date: 28 July 2025

Sponsor: StimLabs, LLC

Study Principal Investigator & Primary Coordinating Center
TBD

SIGNATURE PAGE

The signatures below constitute the approval of this protocol and the attachments. They provide the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations.

The Principal Investigator (PI) from the participating clinical site and other key parties should sign the signature page as appropriate.

Sponsor Representative

Sign: _____ Date: _____

Print: _____ Title: _____

Lead Investigator

Sign: _____ Date: _____

Print: _____ Title: _____

Principal Investigator

Sign: _____ Date: _____

Print: _____ Title: _____

1.0 STATEMENT OF COMPLIANCE

This document is a protocol for an observational human research study. This study will be conducted according to applicable US standards of Good Clinical Practice, applicable government regulations, Master Clinical Study Participating Site Agreement, and Institutional research policies and procedures.

All individuals responsible for the design and conduct on this study have completed Human Subjects Protection Training and are qualified to be conducting this research prior to the enrollment of any subjects.

As PI, I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol. Modifications to the study are acceptable only with an approved protocol amendment. I agree to obtain approval from the IRB and/or regulatory bodies of competent jurisdiction before initiation the study, to ensure the HIPAA waiver of authorization is in place for the review of existing health records, to collect and record data as required by this protocol and case report forms to prepare adverse event and study reports as required by this protocol and to maintain study documentation for the period of time required.

Sign: _____ Date: _____

Print: _____ Title: _____

2.0 VERSION HISTORY

Version	Approval Date	Modifications
01	Date	Original Issue

3.0 STUDY CONTACT INFORMATION

3.1 Sponsor Contact Information

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4.0 ABBREVIATIONS

AATB	American Association of Tissue Banks
AE	Adverse Event
AR	Adverse Reaction
CAMP	Cellular, Acellular, Matric-like Product (formerly skin substitute)
CFR	Code of Federal Regulations
CRF	Case Report Form
DFU	Diabetic Foot Ulcer
dCHPM	Dehydrated Complete Human Placental Membrane
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HCT/Ps	Human Cells, Tissues and Cellular and Tissue-Based Products
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
PI	Principal Investigator
PHI	Protected Health Information
SOC	Standard of Care

5.0 STUDY DESIGN & RATIONALE

This is a retrospective, multi-center observational study to assess real-world outcomes of StimLabs human placental membrane tissue used in the treatment of hard-to-heal wounds, including chronic ulcers, diabetic foot ulcers (DFUs), and venous leg ulcers (VLUs). The collection of retrospective real-world data provides a broad range of experiences related to patient healthcare and treatment. This study will include real-world data from up to 50 subjects at up to 10 participating sites. The Relese product has been utilized in diabetic patients attending wound clinics for treatment of DFUs, VLUs, and minor amputation wound sites. Medical records will be reviewed, and data will be collected from consecutive subjects who received the Relese product as a treatment for lower extremity ulcers and who meet the inclusion criteria. The baseline, first presentation, treatment, and follow up data, including any available images, will be reviewed to determine efficacy endpoints.

6.0 OBJECTIVE

The objective of this observational study is to assess the safety and efficacy of Relese as a skin substitute/Cellular, Acellular, Matrix-like Product (CAMP) when added to the standard of care (SOC) treatment of lower extremity hard-to-heal wounds. Efficacy will be determined by observing wound closure rates, percent area reduction in wound size over treatment time, number of product applications required during treatment, mean time to wound closure, proportion of wounds with >50% area reduction by week 4, and adverse events.

7.0 SAFETY ANALYSIS

Any intra-treatment and post-treatment complications that occurred within 12 weeks, or until the time of wound closure following the use of the Relese product, will be reviewed and reported. Data will be recorded if subjects reported amputations, wound-related infections, or mortality.

8.0 PRODUCT DESCRIPTION - RELESE

All commercial products are sourced from donor materials that undergo a stringent internal screening and testing process. Recovery/acquisition and manufacturing are performed in accordance with FDA 21 CFR 1271 and AATB standards. Processing occurs in an FDA-registered and AATB-accredited facility. StimLabs' placental-based CAMP products are classified by the FDA as a Human Cell, Tissue, and Cellular Tissue-Based Products (HCT/Ps) that are solely regulated under Section 361 of the Public Health Service Act (PHS). The products are intended for homologous use as wound covering or selective barrier over acute and chronic wounds including dermal ulcers and defects.

Release is a fenestrated dehydrated complete human placental membrane (dCHPM) allograft. Fenestration of the allograft creates a selective barrier that protects the wound from the surrounding environment while allowing wound exudate to drain. Through the patented Clarify technology, all three layers of the native placental membrane (amnion, intermediate layer, and chorion) and key structural proteins and components are retained.

9.0 STUDY DESIGN & PROCEDURES

9.1 Retrospective Case Review

Designated study personnel at each site will review the medical records of each Relese treatment to collect the available baseline, treatment and follow-up data. The case review will occur retrospectively to include all subjects that received Relese between May 2023 to April 2025. The data may include but is not limited to:

- Patient demographics
- Diabetes status
- Co-morbidities
- Current medications (e.g., diabetic medications, prednisone, chemotherapy, biologic)
- Previous treatments to the ulcer area prior to this first presentation
- Wound characteristics:
    - Number of wounds per subject
    - Wound(s) presentation
    - Baseline size, depth, location
    - Treatment details and summary, including wound type and product type
- Wound-related and post-operative complications (if any occurred)
- Wound closure rate by wound type and wound size
- Time to wound closure (days between first product application and wound closure)
- Wound surface area at each visit
- Number of grafts used during treatment
- Follow up days between each visit

9.2 Images

If available, photographs or images of the treated ulcer area may be collected. De-identified images will be part of a clinical review by the Investigator and may be used for taking wound measurements and possibly included in publication in the future.

10.0 SUBJECT SELECTION

10.1 Inclusion Criteria

10.1.1 ≥ 18 years of age;

10.1.2 All consecutive diabetic subjects that received a Relese product application during treatment in the following retrospective cohort between May 2023 and April 2025.

10.1.3 The target ulcer must have been present for a minimum of 4 weeks of standard of care treatment prior to receiving the Relese product.

10.2 Exclusion Criteria

10.2.1 Subjects not receiving an initial Relese application during treatment.

11.0 DATABASE

Each site will collect and enter clinical study data on case report forms (CRFs) that will be transferred to a password protected Excel database. Every effort will be made to secure data in a de-identified manner and no patient identifiers will be collected. The site is responsible for reviewing each subject's related medical records to complete the database. Clinical study data will be stored in a secure and HIPAA compliant cloud platform.

12.0 STATISTICAL ANALYSIS

Categorical variables will be summarized using relative frequencies and percentages. Continuous variables will be summarized using mean ± standard deviation, median, and minimum and maximum. Missing wound outcome data will be imputed where possible, but other missing data will be excluded from analysis and reported as unknown. All statistical analyses will be performed using Stata version 17.0 or newer and detailed in the study Statistical Analysis Plan.

12.1 Study Populations for Analysis

Safety population: All patients who receive at least one StimLabs Relese product application will be included in the safety population.

Full Analysis Set: All patients who have at least 4 post-baseline measurements will be included in the Full Analysis set.

13.0 HIPAA WAIVER & AUTHORIZATION

This study will be conducted in accordance with all applicable institutional policies and HIPAA regulations regarding subject privacy. This research poses no more than minimal risk to be involved in this retrospective chart review and a waiver of HIPA authorization will be requested for approval from the IRB. All data and records will be kept confidential according to institutional policies and only used for study purposes.

14.0 STUDY REGISTRATION & PUBLICATION

14.1 Registration

If trial registration is applicable, the study details, a description of the study, and information about its registration can be found on Clinicaltrials.gov.