# DOCUMENT 1: STUDY PROTOCOL

*(Includes Statistical Analysis Plan)*

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## COVER PAGE

**Official Study Title:**
Apple Peptide Complex Post-Aesthetic Care Protocol *(use your exact registered title as-is)*

**NCT Number:** Pending

**Document Type:** Study Protocol and Statistical Analysis Plan

**Sponsor:** Grow Out Oils Clinical Aromatherapy Company

**Date:** March 2026

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## 1. BACKGROUND AND RATIONALE

Post-procedural skin recovery following aesthetic interventions such as laser treatments, chemical peels, and micro needling presents a critical period requiring optimized supportive care. Standard post-procedural care varies widely and may not fully address inflammation, hydration, and skin barrier repair.

The Apple Peptide Complex, developed by Grow Out Oils, is a topical formulation designed to support skin recovery through hydration, barrier protection, and antioxidant activity. This study aims to evaluate its effectiveness compared to standard post-procedural care.

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## 2. STUDY OBJECTIVES

### Primary Objective

To evaluate the effectiveness of Apple Peptide Complex in improving post-procedural skin recovery compared to standard care.

### Secondary Objectives

- To assess reduction in visible redness and irritation
- To evaluate improvement in skin hydration
- To assess participant-reported comfort and satisfaction

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# 3. STUDY DESIGN

- Study Type: Interventional
- Allocation: Randomized
- Intervention Model: Parallel Assignment
- Masking: Open Label
- Primary Purpose: Supportive Care

### Study Arms

- **Arm 1:** Apple Peptide Complex Post-Aesthetic Care Protocol
- **Arm 2:** Standard Post-Procedural Care

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# 4. INTERVENTIONS

### Experimental Group

Application of Apple Peptide Complex as directed post-procedure.

### Control Group

Standard post-procedural care per clinical practice guidelines.

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# 5. ELIGIBILITY CRITERIA

### Inclusion Criteria

- Adults 18 years and older
- Undergoing aesthetic procedures (laser, peel, micro needling)
- Willing to comply with study protocol

### Exclusion Criteria

- Known allergy to formulation ingredients
- Active skin infection or condition in treatment area
- Participation in another clinical study

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# 6. OUTCOME MEASURES

### Primary Outcome

- Improvement in skin recovery (clinical assessment scale)

### Secondary Outcomes

- Reduction in redness
- Skin hydration levels
- Participant-reported outcomes (comfort, satisfaction)

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# 7. SAFETY MONITORING

- Monitoring for adverse skin reactions
- Documentation of irritation, sensitivity, or allergic response
- Participants may withdraw at any time

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# 8. STATISTICAL ANALYSIS PLAN

### Sample Size

Sample size will be determined based on feasibility and recruitment capacity for this initial clinical evaluation.

### Analysis Methods

- Descriptive statistics for baseline characteristics
- Comparative analysis between groups
- Evaluation of primary and secondary outcomes using appropriate statistical tests (e.g., t-tests or non-parametric equivalents depending on data distribution)

### Handling of Data

- Missing data will be documented and addressed using standard statistical methods
- Analysis will follow an intention-to-treat approach where applicable

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# 📄 DOCUMENT 2: INFORMED CONSENT FORM

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## COVER PAGE

**Official Study Title:**
Apple Peptide Complex Post-Aesthetic Care Protocol

**NCT Number:** Pending

**Document Type:** Informed Consent Form

**Sponsor:** Grow Out Oils Clinical Aromatherapy Company

**Date:** March 2026

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## INFORMED CONSENT FORM

### Introduction

You are being invited to participate in a clinical study evaluating a topical product used for post-procedural skin care.

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## Purpose of the Study

The purpose of this study is to evaluate the effectiveness of the Apple Peptide Complex in supporting skin recovery following aesthetic procedures.

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## Procedures

If you agree to participate:

- You will receive either the study product or standard care
- You will apply products as instructed
- Your skin will be evaluated over a defined period

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## Risks and Discomforts

Risks are minimal but may include:

- Skin irritation
- Redness
- Sensitivity

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## Benefits

You may experience improved skin recovery; however, benefits are not guaranteed.

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## Confidentiality

Your personal information will be kept confidential and will not be publicly disclosed.

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## Voluntary Participation

Participation is voluntary. You may withdraw at any time without penalty.

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## Contact Information

For questions about the study, please contact:
Grow Out Oils Clinical Research Team

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# Consent Statement

I have read and understand the information above. I voluntarily agree to participate in this study.

**Participant Name:** _____
**Signature:** _____
**Date:** _____