

## Clinical Trial Terms of Participation

As a participant in a PCA SKIN® clinical trial there are certain requirements and expectations of you. These must be agreed upon before the study can proceed. Outlined below are several important requirements to which you must agree and initial prior to our beginning:

- Our goal is helping you to achieve the healthy, glowing and even skin you desire. In order to accomplish this, we need you to arrive promptly for all of your scheduled appointments. Please contact us at least 24 hours prior if you must reschedule because of extenuating circumstances.  
\_\_\_\_\_ (please initial)
- In order for the study to be successful participants must adhere to their treatment schedule. In the event that you must cancel any appointment, it must be rescheduled within three days prior or three days after the cancelled appointment. If you are unable to adhere to this requirement, you will no longer be eligible for the study. \_\_\_\_\_ (please initial)
- No other skin care products other than the regimen we provide you may be used during the course of your study. Results are based on complete compliance with the home care regimen with which we provide you \_\_\_\_\_ (please initial)
- Pre and post treatment instructions will be explained to you as well as provided to you in writing. These pre and post procedure directions must be followed to ensure the best possible outcome from your treatments. \_\_\_\_\_ (please initial)

Signed \_\_\_\_\_ Date \_\_\_\_\_

Witnessed by \_\_\_\_\_ Date \_\_\_\_\_

We are very happy that you have decided to participate in our case study. With your full cooperation and compliance we believe we will be able to help you achieve your skin care goals. Please be advised that at any time during the study, should you choose to not be compliant with the requirements listed above we reserve the right to terminate the study without prior notice.

Thank you and we look forward to working with you!

# Clinical Trial Consent Form

Prior to receiving treatment, I have been candid in revealing any condition that may have bearing on this procedure, such as: pregnancy (if so, consult your physician prior to treatment), recent facial surgery, allergies, tendency to cold sores/fever blisters, or use of topical and/or oral prescription medications such as: tretinoin, Retin-A®, isotretinoin, Accutane®, Differin®, Tazorac®, Avage®, EpiDuo™ or Ziana®.

I understand there may be some degree of discomfort such as stinging, pin-prickling sensation, heat or tightness.

I understand there are no guarantees as to the results of this treatment, due to many variables, such as: age, condition of skin, sun damage, smoking, climate, etc.

I understand I may or may not actually peel and that each case is individual. I understand that the amount of peeling does not correlate with degree of improvement.

I understand this treatment is a cosmetic treatment and that no medical claims are expressed or implied.

I understand that to achieve maximum results, I may need several treatments.

I understand that although complications are very rare, sometimes they may occur and that prompt treatment is necessary. In the event of any complications, I will immediately contact the physician/clinician who performed the treatment.

I agree to refrain from tanning in tanning beds or outdoors while I am undergoing treatment and during the 14 days, prior to and following the end of treatment. This practice should be discontinued due to the increased risk of skin cancer and signs of aging.

I understand that extended direct sun exposure is prohibited while I am undergoing treatment, and the daily use of sunscreen protection with a minimum of SPF 30 is mandatory.

I have not had any other chemical peel of any kind within 14 days of this treatment. I understand I cannot have another chemical peel within 14 days of this treatment, whether it is performed at this location or any other location.

I understand that I should follow my clinician's recommendations for post-procedure skin care to minimize side effects and maximize results.

***I hereby agree to all of the above and agree to have this treatment performed on me. I further agree to follow all post-peel care instructions as I am directed.***

**Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature of Clinician:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## CLINICAL TRIAL PHOTO CONSENT FORM

In the normal course of this study, your medical professional will take photographs of you that will be kept in your file. These photographs will enable your medical professional to keep a visual record of your progress. Your privacy is important to PCA SKIN<sup>®</sup>, therefore will only use your photographs for marketing or promotional purposes if your permission is indicated below.

Please answer the following questions with respect to future use of your photographs for marketing purposes. Remember, we will not use them unless you sign this specific release for that purpose. Please circle your answer.

1. Would you permit PCA SKIN to use your image(s) for future marketing or promotional purposes?  
YES / NO
2. Would you permit us to use your image(s) in the interest of public education such as medical journals, trade journals or in an educational setting?  
YES / NO
3. Would you permit PCA SKIN to use your comments as a testimonial of the results achieved through your participation in this study?  
YES / NO
4. Would you permit PCA SKIN to use your image(s) and/or your voice for the creation of a DVD featuring products included in this study?  
YES / NO

All state and federal laws are applicable to this consent and this consent may be revoked in writing by the person granting this authorization.

I have read and understand the Photo Consent Form and grant permission for my medical professional to take photographs and/or video of me during the course of my treatment.

\_\_\_\_\_  
Signature of patient or legal representative

\_\_\_\_\_  
Signature of witness

Date: \_\_\_\_\_

Date: \_\_\_\_\_

# Clinical Trial Patient Profile

Name: \_\_\_\_\_ DOB: \_\_\_\_\_ Age: \_\_\_\_\_ Sex: \_\_\_\_\_

Address: \_\_\_\_\_ City \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

- Are you pregnant or lactating? Yes \_\_\_ No \_\_\_ **(Please consult with your obstetrician. Only the Oxygenating Trio or Detox Gel Deep Pore Treatment is appropriate.)**
  - Do you wear contact lenses? Yes \_\_\_ No \_\_\_ **(Remove contacts if eyes are sensitive or if having microdermabrasion.)**
  - Do you have permanent makeup? Yes \_\_\_ No \_\_\_ (If so, to what areas of the face?) \_\_\_\_\_
  - Do you currently use or receive dipilatories or waxing? Yes \_\_\_ No \_\_\_ (Discontinue use five days pre- and post-treatment.)
  - Do you currently have a sunburn/windburn/red face? Yes \_\_\_ No \_\_\_ Why? \_\_\_\_\_
  - Are you in the habit of going to tanning booths? Yes \_\_\_ No \_\_\_ (If within past 14 days, decline treatment. This practice should be discontinued due to increased risk of skin cancer and signs of aging.)
  - Are you applying any topical medications at this time? Yes \_\_\_ No \_\_\_ Which one(s)? \_\_\_\_\_  
(High percentages of certain ingredients may increase sensitivity)
  - Are you currently using any topical Retinoid prescriptions (tretinoin/Retin-A®/isotretinoin/Accutane®/Renova®/Differin®/Tazorac®/Avage®/EpiDuo™/Ziana®)? Yes \_\_\_ No \_\_\_ What strength? \_\_\_\_\_ For how long? \_\_\_\_\_ (Discontinue use five days before and after treatment. Consult your physician before discontinuing use of any prescription.)
  - Are you currently undergoing isotretinoin therapy (Accutane®)? Yes \_\_\_ No \_\_\_ For how long? \_\_\_\_\_ (It is OK to apply ONE layer of Ultra Peel® I, Sensi Peel®, Ultra Peel® II, Esthetique Peel or Oxy Trio to skin that has been undergoing isotretinoin therapy (Accutane®)). **Those who are currently undergoing isotretinoin therapy (Accutane®) should be directed to their dispensing physician.**
  - Have you had a chemical peel or any type of procedure with a medical device? Yes \_\_\_ No \_\_\_  
Within the last 14 days? Yes \_\_\_ No \_\_\_ What type? \_\_\_\_\_
  - Do you have regular collagen, Botox® or other dermal filler injections? Yes \_\_\_ No \_\_\_ (Peels should precede or follow injections by two days to prevent movement of the filler or stinging at the injection site.)
  - Have you recently had facial surgery? Yes \_\_\_ No \_\_\_ Describe: \_\_\_\_\_ How long ago? \_\_\_\_\_
  - Have you recently had laser resurfacing? Yes \_\_\_ No \_\_\_ When? \_\_\_\_\_ What type? \_\_\_\_\_
  - What type of work do you do? \_\_\_\_\_ Regular airline travel? Yes \_\_\_ No \_\_\_ How often? \_\_\_\_\_
  - Do you participate in vigorous aerobic activity or sports? Yes \_\_\_ No \_\_\_ What type? \_\_\_\_\_
  - Do you smoke or use tobacco? Yes \_\_\_ No \_\_\_
  - Do you develop cold sores/fever blisters? Yes \_\_\_ No \_\_\_ Last breakout? \_\_\_\_\_
  - Are you allergic/sensitive to? (Check all that apply) milk \_\_\_ apples \_\_\_ citrus \_\_\_ grapes \_\_\_ aloe vera \_\_\_ aspirin \_\_\_ perfumes \_\_\_ latex \_\_\_ hydroquinone \_\_\_ mushrooms \_\_\_ If any other allergies, what? \_\_\_\_\_
  - Are you sensitive to alcohol-based products? Yes \_\_\_ No \_\_\_
  - Have you ever used any other products that caused a bad reaction? Yes \_\_\_ No \_\_\_ Describe \_\_\_\_\_
  - Are you taking any medication at this time? (antibiotics may increase sensitivity) \_\_\_\_\_
  - What is your hereditary background? \_\_\_\_\_
- Natural eye color: Blue \_\_\_ Green \_\_\_ Hazel \_\_\_ Gray \_\_\_ Lt. Brown \_\_\_ Med. Brown \_\_\_ Dk. Brown \_\_\_
- Natural hair color: Blond \_\_\_ Red \_\_\_ Lt. Brown \_\_\_ Med. Brown \_\_\_ Dk. Brown \_\_\_ Black \_\_\_ Gray/Silver \_\_\_ White \_\_\_
- Skin tone: Pale/White \_\_\_ Light \_\_\_ Medium \_\_\_ Reddish \_\_\_ Freckled \_\_\_ Sallow \_\_\_ Lt. Olive \_\_\_ Med. Olive \_\_\_  
Dark Olive \_\_\_ Lt. Brown \_\_\_ Med. Brown \_\_\_ Dark Brown \_\_\_ Soft Black \_\_\_ Black \_\_\_
- Do you consider your skin: Sensitive \_\_\_ Resilient \_\_\_ Unsure \_\_\_
  - Describe your skin (check all that apply): Normal \_\_\_ Dry \_\_\_ T-Zone/Combination \_\_\_ Thick \_\_\_ Thin \_\_\_ Saggy \_\_\_ Firm \_\_\_ Oily \_\_\_ Acne \_\_\_ Comedones/Blackheads \_\_\_ Milia \_\_\_ Cysts \_\_\_ Breakouts \_\_\_ Acne-scarred \_\_\_ Large pores \_\_\_ Small pores \_\_\_ Flurid \_\_\_ Rosacea \_\_\_ Eczema \_\_\_ Freckled \_\_\_ Sun-damaged \_\_\_ Melasma \_\_\_ Hyperpigmentation \_\_\_ Perfume-stained \_\_\_ Hypopigmentation \_\_\_ Uneven/blotchy \_\_\_ Mature \_\_\_ Wrinkled \_\_\_ Patchy dryness \_\_\_ Sallow \_\_\_ Psoriasis \_\_\_ Dehydrated/lacking moisture \_\_\_ Asphyxiated \_\_\_ Telangiectasia/broken surface capillaries
- What are the changes you'd most like to see in your skin? \_\_\_\_\_

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

ClinicianSignature:: \_\_\_\_\_ Date: \_\_\_\_\_