Sequential
The Skin Microbiome Testing Co.™

AIRB Approved
Christopher Staab
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INFORMED CONSENT FORM

Protocol Title: Clinical Evaluation of the Skin Microbiome and the Efficacy of an Over-The-Counter Drug for Atopic Dermatitis
Protocol Number: SS-NLP-417
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List of Definitions

Microbiome	All the microbes that naturally live on and inside our bodies
Microbes	Bacteria, fungi, viruses, and their genomes
Genomes	The entire set of DNA instructions found in an organism
Skin Microbiome Niche	The mix of different microbes that work together on and beneath the surface of the skin
Efficacy	The ability to produce a desired result
Barrier Function	Skin's ability to protect itself from harmful things while keeping skin hydrated by preventing water loss
Permeability	How easily substances like water can pass through the skin
Lipidomics	The study of fats on the body: the different kinds of fats, how they work, and how they affect our health
Atopic Dermatitis	A chronic inflammatory skin condition also known as eczema, characterized by dry, itchy, inflamed skin with periodic flare-ups

Scope, Impact and Benefits of the Study

IMPORTANT: This is a research study. The over-the-counter drug for atopic dermatitis being tested is not approved as a treatment for your atopic dermatitis condition.

The human microbiome is defined as the sum of microbes, their genomes, and interactions in a given skin microbiome niche. This study aims to evaluate the efficacy and safety of an investigational over-the-counter drug for atopic dermatitis while analyzing changes in the skin microbiome.

Before agreeing to participate in this study, you must understand the contents of this form. This Informed Consent Form describes the purposes, procedures, benefits, risks, and discomforts of the study and compensation. It also describes the alternative procedures available to you, your right not to participate, and your right to withdraw from the study at any time. We urge you to

discuss any questions about this study with our staff members. Take your time to make your decision. If you decide to participate, you must sign this form to show that you want to participate. You will receive a copy of this form. Below is some of the essential information you will need to decide whether or not to participate in the research study.

Approximately 36 people will participate in this research. If you decide to participate in this study, your participation will be for a total of two (2) study visits, lasting one (1) to two (2) hours.

In participating in this study, we will analyze your skin microbiome, measure skin hydration and barrier function, and assess clinical improvements to help us understand the potential impact of the investigational over-the-counter drug on atopic dermatitis and skin microbiome balance. If you choose to participate in this study, you will need to give your consent below.

Compensation:

You will receive a total compensation of $150 for completing this 4-week study:

- You will get 20%, which is $30, of the total after the Baseline Visit (Day 0)
- The remaining 80%, $120, will be paid after your final Week 4 Visit (Day 28)

Payment will be processed via wire transfer to your bank account.

Microbiome Results:

You will receive individual results from your baseline microbiome analysis approximately 6-8 weeks after study completion. These results are for informational purposes only and should not be used for medical decision-making.

Microbiome samples collected at your Week 4 visit will be used for research purposes only and will not be shared with you individually.

Your Consent

I agree to participate in an atopic dermatitis skin microbiome study conducted by Sequential Skin Inc., which involves:

Study Procedures:

- Upon arrival, you'll have 15 minutes to adjust to the environment before starting the study.
- Applying the investigational over-the counter drug for atopic dermatitis to either the left OR right forearm
- Leaving one forearm area untreated for comparison purposes
- Clinical measurements including:
    - Microbiome sample collection via skin swabs from both treated and untreated forearm areas.
    - Trans-Epidermal Water Loss measurements using VAPOMETER on both forearm areas (a handheld device with the following dimensions: around 7 inches in length. The dimensions of this device are similar to a smartphone.
        - During the test, the clinical staff will place the probe of the device on the skin for 2-5 seconds to measure the evaporation and permeability.

- Skin hydration measurements using MoistureMeterSC on both forearm areas (a handheld device with the following dimensions: around 7 inches in length, according to the manufacturer's website. The dimensions of this device are similar to those of a smartphone
  - During the test, the clinical staff will place the probe of the device on the skin for 5-10 seconds to measure how hydrated your skin is.

- Lipidomic sample collection using sterile (22mm diameter, the size of a button cell battery) adhesive tape applied for 10 seconds to forearm skin surface, then removed - a procedure that only collects dead skin cells from the outermost layer (subset of 15 participants selected at random). There can be a possibility of mild skin reaction or allergy to tape adhesive material
  - Mild Reactions (common):
    - Temporary redness that fades within 1-2 hours
    - Light pink marking where the tape was applied
    - Minor skin indentation that disappears quickly
    - Slight itching sensation during or after tape removal
  - Allergic Reactions to Tape (uncommon):
    - Persistent redness lasting more than 4 hours
    - Small raised bumps or hives at the application site
    - Continued itching or burning sensation
    - Skin that feels warm or tender to touch
  - Participant Selection: The first 15 participants who enroll in the study will be selected for lipidomic sampling. If you are among the first 15 enrolled, you will be informed during your baseline visit
- Clinical visual grading assessments by trained technicians
- Photographic documentation of both left and right forearm areas
  - Setup and Positioning:
    - You will sit comfortably in a chair next to a clean examination table
    - Both of your forearms will rest flat on a white, non-reflective tabletop
    - Your arms will be positioned parallel to each other with palms facing down
    - The photographer will ensure your forearms are fully supported and relaxed
  - Photographic Standards:
    - Background: Plain white tabletop surface with neutral surroundings
    - Lighting: Consistent LED lighting positioned to avoid shadows
    - Camera angle: Photos taken from directly above your forearms
    - Distance: Camera positioned at a standard height for consistent magnification
    - Coverage: Only the area between your wrist and elbow will be photographed
  - Privacy Protection:

- No facial features, identifying marks, or other body parts will be included
- Photos will be labeled with your study ID number only
- All images will be stored securely and used only for research purposes

  - Consumer perception questionnaires, including Patient Oriented Eczema Measure (POEM) and Sequential questionnaires.

Study Timeline:

- Baseline Visit (Day 0): Initial assessments and first supervised over-the-counter-drug for atopic dermatitis application
- 15-minute assessment: Immediate effects questionnaire
- Week 4 Visit (Day 28±3): Final assessments and sample collection
- Daily home use: Over-the-counter drug for atopic dermatitis application twice daily for 4 weeks

Step-by-Step Application Instructions:

BEFORE APPLICATION:

1. **Wash your hands** thoroughly with handwash and water
2. **Check which forearm** you should treat (this was assigned during your baseline visit):

   ☐ Left forearm (treatment area)

   ☐ Right forearm (treatment area)

APPLICATION PROCESS:

1. **Amount to use:**
   Squeeze approximately a dime-sized amount (~0.25 mL) of cream onto your fingertip.
   Where to apply:
   Apply only to the designated forearm area; between your wrist and elbow.
2. **How to apply:**
   Gently spread the cream over the treatment area.
   Use circular, massaging motions.
   Continue massaging until fully absorbed.
   Be gentle and do **not** rub vigorously, especially on sensitive skin.
3. **Absorption time:** Allow the cream to absorb for at least **10 minutes** before covering the area with clothing.
4. **Frequency of use:** Apply **twice daily**. Always apply to the **same designated forearm**.

AFTER APPLICATION:

1. **Wash your hands thoroughly** again to remove any residual over-the-counter drug
2. **Record application** in your daily log (provided at baseline visit)

DAILY APPLICATION SCHEDULE

MORNING APPLICATION (AM):

- **Recommended time**: After morning shower/hygiene routine. Continue using your routine body wash for other parts of the body.
- **Before**: Getting dressed for the day
- **Allow**: 10-15 minutes for absorption before putting on clothes

EVENING APPLICATION (PM):

- **Recommended time**: After evening shower/before bedtime
- **Before**: Putting on sleepwear
- **Allow**: 10-15 minutes for absorption

HYGIENE INSTRUCTIONS FOR FOREARMS

Daily Cleansing:

- **Both arms (treated and untreated):** Use only **water**; no soap, no cleanser, or no other hygiene product, no other over-the-counter drug.
- Pat dry gently with a clean towel; **do not rub**.

Showering/Bathing:

- Use your regular body wash on other parts of the body; **avoid applying to forearms**.
- Keep water exposure to the forearms brief.
- Use **lukewarm** (not hot) water.
- Avoid strong water pressure on forearms.
  Pat dry immediately after bathing.

CLOTHING RECOMMENDATIONS

- **Wear loose-fitting sleeves** that don't rub against your forearms
- **Choose breathable fabrics** like cotton
- **Avoid tight cuffs** or sleeves that create friction
- **Remove watches or bracelets** that might interfere with the study area

CRITICAL DO'S AND DON'TS

DO:

- Apply to **affected areas on your designated forearm only**
- Use **twice daily**
- **Apply a dime-sized amount** to adequately cover the affected areas
- **Massage gently** until absorbed
- **Wash hands** before and after application
- **Maintain** a stable hygiene routine according to the **HYGIENE INSTRUCTIONS FOR FOREARMS** section
- **Record each application** in your daily log
- **Bring your daily log** to the Week 4 visit
- **Store the over-the-counter drug** in a cool, dry place below 30°C/86°F
- **Contact the study center** if you have any concerns

DON'T:

- **NEVER apply to the forearm** other lotions, creams, or treatments to either forearm
- **Don't share** the over-the-counter drug with anyone else
- **Don't skip days** - use twice daily
- **Don't apply** if you notice severe irritation (contact study center immediately)
- **Don't wash** the treated area for at least 12 hours after application
- **Don't** use bodywash directly on the treated forearm area - use only water

Unknown Risks / New Findings
There may be risks to participating in this study that are unknown or unforeseeable at this time such as redness, swelling, infection, and worsening of your eczema. If you accidentally expose your eyes to the over-the-counter drug, please rinse immediately with running water for one minute and contact the clinical staff at clinical@sequential.bio or call (718) 902-6228 (24-hour number). You will be informed of any significant new findings during the study and/or any amendments to the study protocol that could influence your willingness to continue your study participation. You may be asked to sign and date a revised informed consent to continue participating.

General Benefits
As a result of participating in this study, you may experience a temporary improvement in the severity of your atopic dermatitis, itchiness, redness, or you may experience no benefit at all.

Privacy/Confidentiality
Participation in research requires us to collect and retain your personal information. We use our best efforts to keep your personal information confidential and only to necessary parties. Your de-identified data will be kept in a secure cloud-based file storage service with restricted access. Your data will be kept for 5 years after study completion, then destroyed according to federal regulations.

Only people who need to review your information can access study files. Organizations or people that may review and copy your information include:
- Members of the research team
- Allendale Investigational Review Board (AIRB)

- Department of Health and Human Services (DHHS) agencies
- The U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- Regulatory Authorities from other countries.
- The study sponsor, Good Molecules and its affiliates

Your personal information may also be disclosed if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All confidential data will be kept in a secure cloud-based file storage service folder.

Data Sharing
De-identified data from this study may be shared with the research community to advance science. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one can identify you from the information we share.

Future Use of Identifiable Data or Specimens Collected in this Research
The de-identified information might be used for future research without your additional consent.

Alternative Procedures
You may choose not to participate in this study.

I understand and agree to the following:
- My participation is voluntary, and I may withdraw from the study at any time without penalty.
- All information about me will be kept strictly confidential and stored securely on encrypted servers.
- My skin microbiome samples and data will be analyzed in a de-identified manner to protect my identity.
- Study results are intended for research use only and should not be interpreted as medical advice. Participants should consult a licensed healthcare provider for personal health decisions.
- Sequential Skin Inc. is not liable for any medical or personal outcomes related to use or interpretation of study results or the investigational product tested.
- Any information gathered may be used in group-level research publications or reports, with no identifying personal details.
- I have been diagnosed with atopic dermatitis and currently have active flare-ups suitable for this study.
- I understand that I must avoid certain medications and treatments during the study period as instructed.

If you have questions
The primary researcher conducting this study is Albert Dashi, Ph.D. Please ask any questions you have now. If you have questions later, you may contact Albert Dashi directly at 718-902-6228 or sibora@sequential.bio and omera@sequential.bio. If you have any questions or concerns regarding your rights as a participant in this study, you may contact the Allendale Investigational Review Board (AIRB) at 860-434-5872 or subjectrights@allendaleirb.com.

Statement of Consent
I have read the above information and have received answers to any questions I asked. I understand the risks of this study, and I consent to participate in it.

Participant Name (printed):_____Date of Birth:_____

Address:_____

Signature:_____Date:_____

Witness Name:_____

Witness Signature:_____Date:_____

Photography and Consent to Publish

As part of the study, forearm images will be collected at baseline and Week 4 to support microbiome findings and clinical outcomes. These will be used for scientific documentation only and may be provided to the study sponsor (Good Molecules).

☐ **I give permission** for de-identified images of my forearms to be used in scientific publications, presentations, or provided to the study sponsor.
☐ **I do not give permission** for any images to be used beyond internal research documentation.

Signed: _____ Date:_____