INFORMED CONSENT FORM: TRIPELENNAMINE CLINICAL TRIAL

Title of the Study: Topical tripelennamine 1% cream versus diphenhydramine 1% cream for the relief of histamine-induced itching: A proof concept study in healthy adults.

Principal Investigator: Adwoa O. Nornoo, BPharm, MS, PhD

Co-Principal Investigator: Harm Maarsingh, PhD

Co-Investigator (Medical Director): Jennifer Fleigelman, DNP, ARNP, FNP-C, CNE

Institution: Gregory School of Pharmacy, Palm Beach Atlantic University

Contact Information: adwoa_nornoo@pba.edu; 561-803-2739

Introduction: You are being invited to participate in a research study. Before you decide to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Purpose of the Study: The purpose of this study is to evaluate the effectiveness of a topical tripelennamine cream versus topical diphenhydramine cream in relieving histamine-induced itching in healthy adults.

Study Procedures: If you agree to participate in this study, you will be asked to follow these procedures:

1. **Screening**
    - You will undergo a screening process that includes determining if your meet the study requirements, reviewing your medical history and taking your vital signs.
    - If eligible, the study procedures will be explained to you in detail.

2. **Baseline**
    - A small area of your skin on both forearms will be selected for the application of the creams.

3. **Application of treatment creams**
    - The study team will apply the creams to the designated area of your skin.

4. **Histamine dermal delivery by iontophoresis**
    - Histamine will be delivered to the skin via iontophoresis to induce itching at the application site.

5. **Assessment of Itching Relief**
    - You will be asked to report the level of itching relief at specified intervals using a standardized scale.

- These assessments will be conducted at various time intervals after the application of the cream via photographs and videos of the skin of the forearms only.
- During this time side effects will be monitored by study staff and monitoring personnel, and the effectiveness of the cream will be assessed.

6. **Follow-Up**
   - You will be instructed to report any adverse events up to one week after the study is completed.

Study Duration: The study will last for approximately 3hours on only one day.

Risks and Discomforts: The risks associated with this study are minimal. However, you may experience:

- Mild skin irritation at the application site.
- Temporary itching or redness due to the histamine test.

Potential Side Effects: While the risks are minimal, some potential side effects of the tripelennamine or diphenhydramine cream may include:

- Mild burning or stinging sensation at the application site.
- Dryness or peeling of the skin.
- Allergic reactions such as rash, itching, or swelling.

Potential side effects of the topical histamine include:

- Brief itching and tingling with a standard wheal and flare

Benefits: There may be no direct benefit to you from participating in this study. However, the information gained from this study may help in developing effective treatments for itching. Significant findings at the conclusion of the study will be provided to the study participants.

Compensation: You will receive a $50 gift card for your participation in this study. This compensation is intended to cover any expenses you may incur and to compensate you for your time and effort.

Confidentiality: All information collected in this study will be kept confidential. Your identity will not be revealed in any reports or publications resulting from this study. The collection of photographs and video will be collected and stored for future use. Monitoring personnel will have access to de-identified medical records.

Voluntary Participation: Your participation in this study is voluntary. You may choose not to participate or to withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled.

Withdrawal from the Study: You have the right to withdraw from the study at any time. If you decide to withdraw, you will not be asked to provide a reason, and there will be no penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, please inform the

study team so that appropriate steps can be taken to ensure your safety and well-being. Any data collected up to the point of withdrawal will be retained for analysis.

Eligibility Criteria: To participate in this study, you must meet the following criteria:

- Be willing to comply with the study procedures and visit schedule.
- Have no known allergies to tripelennamine or diphenhydramine.
- Healthy subjects must be between 18 and 50 years of age.
- Must be in general good health with no disease or physical conditions that would impair evaluation of itch perception.
- No history of chronic itch.
- Must abstain from the use of any systemic or topical antihistamine, steroid, or pain relief medications from the week prior to the study till the completion of the study.
- Not be pregnant or breastfeeding (women of childbearing age will undergo an hCG pregnancy test).
- Must abstain from the use of moisturizers on the arms 24 hours before study visit.

Contact Information: If you have any questions or concerns about this study, please contact Adwoa O. Nornoo at adwoa_nornoo@pba.edu and 561-803-2739.

Research at Palm Beach Atlantic University which involves human participants is carried out under the oversight of the Institutional Review Board. Questions or problems regarding these activities should be addressed to Dr. David M. Compton, Chair of the Office of Academic Research or Dr. Nathan Lane, Associate Provost, PO Box 24708, West Palm Beach, Florida 33416-4708 [(561) 803-2754].

Consent: I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study.

☐ I consent to participate in this study

☐ I do not consent to participate in this study

Sign only if you agree to participate in this study.

Subject's Name:

Subjects' Signature:

Date:

Investigator's Signature:

Date: