If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **The Role of Skin Care Regimen in Skin Health**

Application No.: **IRB00165140**

Sponsor: **Unilever Research U.S.**

Principal Investigator: Anna L. Chien, MD
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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital,

Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to evaluate the role of a regular skin care regimen consisting of a mild soap and moisturizer in improving dry skin, skin appearance, and overall skin health.

Dry skin is a common phenomenon and can dramatically decrease a person's quality of life as well as contribute to a wide variety of skin diseases. Skin care products hydrate the skin and breaks the dry skin cycle. While there is extensive evidence of benefits of using mild cleansers and moisturizers, much of the previous studies are limited to the effects of single cleanser or moisturizer. In this study, we hope to learn the importance of a regular skin care regimen in improving dry skin and overall skin health.

People over the age of 18 with dry, itchy skin may join.

How many people will be in this study?

About 100 people are expected to participate in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following:

You will be asked to complete up to 3 study visits within a four week period, including all the study procedures described below.

Visit 1:

During this visit, we will ask about your medical history and conduct clinical evaluations of your skin to determine whether you would qualify for the study. During this visit, the study staff will perform a clinical assessment, take photographs using a digital camera, and administer questionnaires.

You will be asked to undergo a washout period of one week in which you are asked to refrain from the use of all moisturizers on your skin. You will be supplied with a skin cleanser, Dove® Soap, to use during this period and application log for daily use. All applications should be reported in the application log.

Visit 2 (Baseline):

After the wash-out period, you will return for Visit 2. You will be randomly (by chance, like a flip of a coin) assigned to one of two groups. You will have a 3 in 4 (75%) chance of being assigned to the skin care regimen group and a 1 in 4 (25%) chance of being assigned to the control group.

Skin care regimen group: Participants in the skin care regimen group will receive Vaseline® Moisturizer, Dove® Soap, and application log. These participants will be asked to apply the Vaseline® Moisturizer twice a day and use Dove® Soap daily for 2 weeks. . We will show you how and where to apply the products and give you the application log for daily use. All applications should be reported in the application log.

Control group: Participants not in the skin care regimen group will continue with the provided Dove® Soap and refrain from the use of all moisturizers on skin. All applications should be reported in the application log.

During this visit, the study staff will again perform clinical assessments, take photographs and administer questionnaires. You will not be identifiable from the photographs.

Visit 3 (day 14±2):
During this visit, the study staff will again perform clinical assessment, take photographs and administer questionnaires. You should return all the application logs at this visit.

How long will you be in the study?
You will be in this study for 3 weeks.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future. **Please check box and sign to indicate your choice below:**

YES _____
Signature of Participant

NO _____
Signature of Participant

4. What are the risks or discomforts of the study? Vaseline® Moisturizer and/or Dove® Soap

It is possible that you develop a rash or irritation of the skin as a result of using Vaseline® Moisturizer and/or Dove® Soap.

Confidentiality:
There is the risk that information about you may become known to people outside this study. To protect against this, the study information will be kept in password-protected computers in locked rooms accessible only to study staff. Photograph files will be coded to remove personal identifiers and stored on a secure server in the Cutaneous Translational Research Program, CTReP.

5. Are there benefits to being in the study?

There may or may not be a direct benefit to you from being in the study. Participants with dry skin in the skin care regimen group may experience improvement in their overall skin health but this cannot be

guaranteed. There will be no direct benefit to the participants in the control group. We hope to learn more about the role of a routine skin care regimen in improving dry skin and reducing symptoms. This could improve quality of life for patients who suffer from dry skin.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

8. Will you be paid if you join this study?

You will receive $60 for completing this study.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be redisclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

12. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you? The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Anna Chien at 410-502-7546. If you wish, you may contact the principal investigator by letter. The address and phone number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What happens to Data that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

13. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

_____

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

Approved April 10, 2018