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Protocol title: The Cutaneous Microbiota of Psoriasis: Lesional Variation and a Phase IV, Interventional Study of its Response to Phototherapy.

Short title: Psoriasis Microbiome and Phototherapy

Protocol number: 821876

NCT number: NCT02552316

15.6 Appendix F – Informed Consent Form

UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT

INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM

Protocol Title: **Short Title:**	**The Cutaneous Microbiota of Psoriasis: Lesional Variation and a Phase IV, Interventional Study of its Response to Phototherapy** **Psoriasis Microbiome and Phototherapy**
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Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

Psoriasis is a common skin disease. The exact causes or triggers of psoriasis are not well-understood. It has been suggested that different microorganisms on the skin (e.g., bacteria, viruses) may contribute to psoriasis. Therefore, the purpose of this research study is to examine the microbes (e.g., bacteria) within psoriasis skin lesions compared with normal skin. We will also examine the effect of NB-UVB (narrow-band ultraviolet B) phototherapy (i.e., light therapy) on skin microbes. A description of NB-UVB phototherapy is included below.

If you agree to participate in this study, and if your dermatologist and/or the study doctor think that phototherapy is an appropriate treatment option for you, we will measure the number and type of microbes on your skin before and after you have received 8 weeks of phototherapy.

As an optional part of the study, we would also like to obtain two additional skin samples (one each of normal and affected skin) at the start of the study in order to measure the levels of potential markers of psoriasis to help us better understand how psoriasis develops.

How long will I be in the study? How many other people will be in the study?

You will first be screened to determine if you are eligible to be a part of the study. If you agree to participate in the study, your involvement will last anywhere from 58 days (just over 2 months) to a maximum of 35 weeks (just under 9 months). This study is only being conducted at The University of Pennsylvania. The total number of subjects expected to enroll in this study is 34. The total length of time that it is expected to take in order to enroll subjects and complete the study is 2 years.

What am I being asked to do?

You will be seen at a scheduled research appointment at the study clinic located on the 1st floor of the Perelman Center for Advanced Medicine (3400 Civic Center Boulevard, Philadelphia, PA 19014). During this visit a member of the research team will explain the study to you. If you decide to participate you will need to be interviewed and examined to find out if you can be in the study. If you decide to participate, you will not be allowed to use any prescription psoriasis medications or other phototherapy (i.e., light treatment), other than NB-UVB phototherapy, low potency steroid creams or ointments (i.e., hydrocortisone 2.5% or less, ointment or cream) up to twice daily to the face, groin or underarm areas, and non-prescription shampoos and moisturizers. Prior to study visits, you will be asked to avoid applying anything to the skin (including moisturizers) in order for the study dermatologist to be able to accurately assess the severity of your psoriasis and for skin sampling.

Screening Visit:

- You will have a discussion about this study and this consent form.
- You will be asked to sign this consent form.
- You will be asked about your medical and surgical history, including a review of all current medications or supplements and particularly prior or current medications or therapies you have used or are using to treat your psoriasis. You will be asked to stop taking any prior or current medications or therapies for psoriasis. The washout period (length of

time between stopping current medication and starting the study treatment) is detailed below.

- **Requirements for Medication/Therapy Washout Periods:** In order to be eligible for this study, in addition to meeting all of the other screening requirements, you must agree to stop using all current psoriasis medications and/or therapies. The length of time you must wait between stopping your current medication and beginning the new study therapy is as follows according to your current treatment:
    - Topical treatments – 2 weeks
    - NB-UVB phototherapy or Excimer laser - 2 weeks

If you are taking a psoriasis medication or receiving other therapy that is not listed above, then you will not be eligible for this study.

- You will be asked about your routine personal hygiene and skin care habits.
- You will have a full skin physical examination.
- The type and severity of your psoriasis will be evaluated.
- After completing the screening process, your doctor will determine whether you are eligible to participate in the study. If you are eligible, you will be enrolled in the study and will enter the treatment period (see below).

Baseline Visit and Treatment Period:

Baseline Visit:

- You will be asked to do the following prior to your baseline visit:
    - Avoid swimming in a chlorinated pool or using a hot tub for 48 hours.
    - Avoid using saunas or steam baths for 48 hours
    - Avoid using a tanning bed for 48 hours
    - Avoid showering and body lotion for 24 hours

- The study team will review and update your medical history and any changes in medications or treatments.

- The study team will monitor your alcohol and tobacco use.

- You will have a physical examination including measurement of your blood pressure, pulse, temperature, weight and height.

- The type and severity of your psoriasis will be evaluated.

- Photographs will be taken of select areas of your body that are affected with psoriasis and that will be sampled. Photographs will not show any identifiable features.

- Samples will be collected from your skin. To collect the samples we will swab an approximately 4 centimeter square area (2 by 2 centimeter square) of skin in up to 4 different places on your arms or legs and in 1 place on your back. The swabs will then be placed in a solution to be sent to the lab to look for microbes.

- OPTIONAL: Two skin biopsies will be taken, one each from an area that is affected and unaffected by psoriasis. A skin biopsy involves removal of a small piece of skin measuring 4mm (about the size of a pencil eraser) under local anesthesia. The areas to be biopsied will first be cleaned with an alcohol wipe. The biopsy areas will then be anesthetized (made numb) by injecting a medicine called Lidocaine into the skin with a small needle. The Lidocaine will also be mixed with a medication called Epinephrine to help minimize bleeding. We will ask you if you are allergic to or have had a bad reaction to either of these medications before performing the skin biopsies. Skin will be removed using an instrument that looks like a small cookie cutter. You will receive 1 to 2 stitches at each biopsy site, and a small dry sterile dressing will be applied over the biopsy area and kept in place for 24 hours. The stitches will need to be removed after 10-14 days. You will be provided with written wound care instructions.

- **Treatment:** You will start NB-UVB phototherapy.

    - **About NB-UVB Phototherapy:** NB-UVB phototherapy is a therapy which uses ultraviolet B (UVB) light directed at the skin. This type of light therapy is given through the use of phototherapy booths which contain fluorescent tubes that emit UVB light. Booths used for phototherapy look similar to commercial tanning booths. NB-UVB phototherapy affects psoriasis by causing changes to the cells of the skin and producing a local effect by reducing the number of certain types of skin cells which have an impact on psoriasis formation. More information about UVB light can be found under the risks section of this consent form.

    - **Treatment Period:** You will return to the clinic 3 times a week for 8 weeks for phototherapy sessions.

    - **Response to Therapy:** On average, it will take 15 to 20 phototherapy sessions (about 5 to 7 weeks) in order to clear your skin. If you either become unable to tolerate your symptoms or display signs of a potentially serious psoriasis flare, you will be removed from the study.

Weeks 1 through 8:

- You will receive NB-UVB phototherapy 3 times per week.
    - On phototherapy days, please avoid using body lotion before treatment

Week 8 (on the day of your last phototherapy session):

- You will be asked to do the following prior to this visit:
    - Avoid swimming in a chlorinated pool or using a hot tub for 48 hours.
    - Avoid using saunas or steam baths for 48 hours
    - Avoid using a tanning bed for 48 hours
    - Avoid showering and body lotion for 24 hours

- The study team will review and update your medical history and any changes you have had to medications or treatments.

- The study team will monitor your alcohol and tobacco use.

- You will have a physical examination including measurement of your blood pressure, pulse, temperature, and weight.

- The type and severity of your psoriasis will be evaluated.

- Photographs will be taken of select areas of your body that are affected with psoriasis and that will be sampled. Photographs will not show any identifiable features.

- Samples will be collected from your skin. To collect the samples we will swab an approximately 4 centimeter square area (2 by 2 centimeter square) of skin in up to 4 different places on your arms or legs and in 1 place on your back; these will be the same places that were sampled during your baseline visit. The swabs will then be placed in a solution to be sent to the lab to look for microbes.

Week 9 (2 to 7 days after your last phototherapy session; this is your last study visit):

- You will be asked to do the following prior to this visit:
    - Avoid swimming in a chlorinated pool or using a hot tub for 48 hours.
    - Avoid using saunas or steam baths for 48 hours
    - Avoid using a tanning bed for 48 hours
    - Avoid showering and body lotion for 24 hours

- The study team will review and update your medical history and any changes you have had to medications or treatments.

- The study team will monitor your alcohol and tobacco use.

- You will have a physical examination including measurement of your blood pressure, pulse, temperature, and weight.

- The type and severity of your psoriasis will be evaluated.

- Photographs will be taken of select areas of your body that are affected with psoriasis and that will be sampled. Photographs will not show any identifiable features.

- Samples will be collected from your skin. To collect the samples we will swab an approximately 4 centimeter square area (2 by 2 centimeter square) of skin in up to 4 different places on your arms or legs and in 1 place on your back; these will be the same places that were sampled during your baseline visit. The swabs will then be placed in a solution to be sent to the lab to look for microbes.

How much time will the study visit take?

The screening, baseline, week 8, and final study visits will each last up to 1 hour. All visits in which you are only receiving phototherapy will last about 30 minutes.

What are the possible risks or discomforts?

You may experience one or more of the side effects or risks described below due to the therapies or procedures used in this study, and they will vary from person to person. In addition to what is listed, there may be other unknown risks, or risks that we did not anticipated, associated with being in this study. Everyone taking part in the study will be watched carefully for any side effects. The potential risks are included below:

Potential Discomforts, Side Effects and Risks Associated with Medication/Therapy Washout

You will be asked to stop your current psoriasis therapies for a maximum of 2 weeks. This is standard practice for many clinical trials for psoriasis. Based on extensive data from psoriasis clinical trials, no significant risks have been identified for going without treatment for this period of time. Rarely, patients who are not on active therapy for psoriasis will experience disease flares. During any washout period you may need to complete and throughout the study, the study doctor will monitor you and remove you from the study if you either become unable to tolerate your symptoms or display signs of a potentially serious flare. If you are removed from the study for either of these reasons, you may receive alternative treatment for your psoriasis per your primary dermatologist or other medical provider, or you may establish care with any dermatologist, including at the University of Pennsylvania, per your preference.

Potential Discomforts, Side Effects and Risks Associated with Phototherapy

Common Risks: risk occurs in 10% - 30% of patients

- Redness
- Itching
- Burning
- Stinging
- Tanning of the skin

Risks that may occur with prolonged use of phototherapy (more than 200 treatments): (risk was not experienced with short-term use)

- Premature aging
- Wrinkles
- Theoretical increased risk of skin cancers

Potential Discomforts, Side Effects and Risks Associated with Skin Swabs

- Mild discomfort from swabbing the skin
- You may feel uncomfortable or embarrassed because of the sites that we will be swabbing.

Potential Discomforts, Side Effects and Risks Associated with Optional Skin Biopsies

- Local discomfort from local anesthesia injection
- Bruising
- Bleeding
- Scarring
- Fainting
- Nerve damage
- Rare side effects include:
    - Serious bleeding complication that required medical attention (risk is less than 1%)

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

A potential benefits from your participation in this study includes NB-UVB phototherapy at no cost to you for 8 weeks. There is also a chance that you may not get any benefit from being in this research study.

Important information may be learned from this study that will help us better understand how psoriasis develops and, therefore, impact the future of psoriasis treatment.

What other choices do I have if I do not participate?

- You may choose not to participate in this study.
- You may receive psoriasis treatment outside of the setting of this study and not participate in this study.
- You may choose to not treat your psoriasis.
- You may choose to take part in another study.

You may discuss any alternative to being in this study with the study doctor.

Will I be paid for being in this study?

You will be provided a total of $90 ($30 per visit requiring physical examination) to offset travel and other indirect costs to you for study participation. You will be paid at study completion and not at the end of each individual study visit. After your last study visit you will receive cash payment of your total reimbursement for all study visits. If you do not complete all study visits the amount you receive will be pro-rated to reflect the number and type of visits you have completed. In addition you will need to complete a W-9 form which is required by the IRS when you receive payment for participating in a research study; this form will be provided to you.

Will I have to pay for anything?

The study therapy (NB-UVB phototherapy) will be provided to you free of charge while you are participating in this study. Also, all procedures that are required only for this study and that are not part of your regular medical care will be provided to you free of charge.

You or your health plan will need to pay for any medicines and any clinic, hospital, and doctors' services that are part of your regular medical care. The study sponsor will only pay for the specific procedures listed for each visit under

the screening period and treatment period sections of this consent form. Any procedure or visit outside of what is listed under those sections will need to be paid for by you or your health plan.

Financial Disclosure:

This research study is supported by money from Pfizer, Inc. In addition, Dr. Joel Gelfand, a member of the study team, receives extra money from Pfizer and other companies making psoriasis products for work that is not a part of this study. These activities may include other research studies, consulting, advisory boards, or writing reports. If you would like more information, please ask the researchers or the study coordinator.

What happens if I am injured from being in the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the study doctor listed on page one of this form. If you have an illness or injury during this research trial that is <u>not</u> directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

It is important that you tell your study doctor, Dr. Junko Takeshita, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 215-349-5551.

Your doctor will explain the treatment options to you and tell you where you can get treatment. You and/or your health plan will be charged for this treatment. The study sponsor or doctor will not pay for this medical treatment, and you will not receive any other kind of payment. You do not give up your legal rights by signing this form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The study Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and of the reason for this decision.

- You have not followed study instructions.

- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care. If you decide that you want to leave the study, please notify your study doctor at the number on the front of this consent (215-349-5551) immediately so that a final visit can be performed. Your study doctor will also discuss with you what follow up care would be important for you.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out 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.

It is a requirement that your involvement in this study be noted in your medical records. Medical records also include electronic medical records or EMR (a detailed explanation of EMR is included below). If your primary care physician is different from the study doctor for this study, he/she may also be notified. Direct access to your records may be required by authorized representatives of Pfizer, Inc. to check the information collected for the study. Your medical records may also be reviewed and copies made by members of either the institutional review board/independent ethics committee responsible for this study, a regulatory agency, or an authorized Pfizer, Inc. representative. These individuals will see your name, other personal information such as date of birth and gender, and your medical information, but shall not disclose your name to anyone else.

Clinical procedures (i.e., phototherapy) will be placed in your medical record and may be accessible to employees of the health system that are not part of the research team. This information may also be viewed by your insurance company during routine audits.

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.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e., clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have).

Results of research procedures performed as part of your participation in the study (i.e., clinical procedures) may be placed in this EMR. Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g., health insurance company, disability provider, etc.).

Health Insurance Portability & Accountability Act (HIPAA) Information

What information about me may be collected, used or shared with others?

The following subject information may be collected:

- Name
- Social Security Number
- Street address, city, county, precinct, zip code, and equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual and all ages over 89

- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Current and past medications or therapies
- Results of tests and procedures subjects will undergo during this research study as described in the informed consent form.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- To see if the research was done right.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator (Study Doctor) and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of the School of Medicine, might receive my information?

As part of the study, the Principal Investigator (Study Doctor), the study team and others listed above, may disclose subject personal health information, including the results of the research study tests and procedures. Whenever possible, the Study Doctor and staff will provide this information in a way that does not identify you directly. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- The funding source for the study, Pfizer, Inc., and organizations supporting the company, and its authorized representatives.

Once your personal health information is disclosed to others outside of UPHS and the School of Medicine, it may no longer be covered by federal privacy protection regulations.

If you sign this form, you allow the Study Doctor or the funding sponsor, Pfizer, Inc., to use some facts about your study participation in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.

The Principal Investigator (Study Doctor) or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You may do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject Informed Consent Form and HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting UPHS and the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

Please indicate your choice below regarding the optional collection of skin biopsies:

☐ I would like to participate in the optional skin biopsies to study psoriasis markers in the skin.

☐ I would **NOT** like to participate in the optional skin biopsies.

A copy of this consent form will be given to you.

_____ _____

Name of Subject (Please Print) Signature of Subject Date

Name of Person Obtaining Consent (Please Print)	Signature	Date