Jefferson Medical College

Department of Dermatology and Cutaneous Biology

Jouni Uitto, MD, PhD
Chair and Professor

T 215.503.5785 F 215.503.5788

jouni.uitto@jefferson.edu

Dear Patient,

Enclosed are two forms for the Pityriasis Rubra Pilaris (PRP) study. Please take your time to complete all questions. We will use your answers, anonymously, to advance medicine's understanding of this rare disease. Answers will be analyzed as combined data (along with those from other patients in the study). Your name will not be associated with any published information. Only IRB approved research physicians of the Department of Dermatology and Cutaneous Biology at Thomas Jefferson University will review these forms.

The **first form** is a survey regarding PRP symptoms and treatments. Our research team will study these in order to describe the variety of PRP presentations, associated symptoms and treatments tried. Your protected health information will be kept confidential.

The **second form** is a consent document that requests your permission for a member of our research team to acquire biopsy results and clinical records from your treating physician, who diagnosed your PRP. Our goal is to make sure that your diagnoses is correct for study purposes only. These documents will be kept confidential.

PLEASE RETURN completed forms to our office either by
Regular Mail (preferred)
Department of Dermatology and Cutaneous Biology,
Thomas Jefferson University Hospital, Attn: Nick Ross,
833 Chestnut Street, Suite 740, Philadelphia, PA 19107, USA

Email: Nicholas.Ross@jefferson.edu

HIPAA-certified fax machine: (215) 503-3333

Do not hesitate to contact a member of the research team with any questions. Your participation is most helpful. We thank you for your time and commitment to the advancement of science towards better understanding of PRP and its treatment.

Sincerely,

Jouni Uitto, MD PhD
Professor and Chair
Department of Dermatology and Cutaneous Biology
Thomas Jefferson University, Philadelphia, PA 19107

Study CONTACT INFORMATION

Study Member	Position	Contact Information
Nick Ross, BA**	Clinical Research Fellow	Tel: (215) 503-3787; Email:Nicholas.Ross@jefferson.edu
Hye Jin Chung, MD	Co-Investigator	Email: HyeJin.Chung@jefferson.edu
Jouni Uitto, MD, PhD	Principal Investigator	Email: Jouni.Uitto@jefferson.edu

** Please, use this contact FIRST for all questions and assistance needed.

END OF STUDY

Molecular Diagnostics Laboratory
Department of Dermatology and Cutaneous Biology
Thomas Jefferson University

PITYRIASIS RUBRA PILARIS (PRP) PATIENT HISTORY

This information is being collected by the THOMAS JEFFERSON UNIVERSITY HOSPITAL DEPARTMENT OF DERMATOLOGY AND CUTANEOUS BIOLOGY, IRB APPROVED RESAERCH TEAM. Answers will be kept strictly confidential as outlined by your consent to participate in this study. No identifiable information will be published; all answers will be combined with answers from other patients to keep your identity concealed.

YOUR DOCTOR(S)' NAME (who diagnosed your PRP): _____

DOCTOR'S TELEPHONE NUMBER (who diagnosed your PRP): _____

PATIENT NAME: _____ DATE OF BIRTH: ____/____/_____ (mm/dd/yyyy)

PATIENT MAILING ADDRESS: _____

_____

PATIENT TELEPHONE (confidential; for acquisition of PRP research information): _____

GENDER: ☐ Male ☐ Female RACE/ETHNICITY: _____

AGE AT ONSET OF SYMPTOMS: _____ (years) AGE AT DIAGNOSIS: _____(years)

WAS PRP CORRECTLY DIAGNOSED AT THE BEGINNING?

☐ Yes
☐ No; If NO, HOW LONG DID IT TAKE to identify the correct diagnosis? _____(years)

If NO, what was the INITIAL DIAGNOSIS? _____

CURRENT HEIGHT: _____(cm) or (in) CURRENT WEIGHT: _____(kg) or (lbs)

SKIN FINDINGS (please *check all* that apply):

☐ WIDESPREAD RED-ORANGE PLAQUES
DISTRIBUTION/LOCATION: _____
☐ LOCALIZED RED PLAQUES ON THE KNEES AND ELBOWS
☐ THICKENING/TIGHTENING OF SKIN ON HANDS/PALMS AND FEET/SOLES
☐ THICKENING/TIGHTENING/FLAKING OF SKIN ON ELBOWS/KNEES
☐ FLAKING OF SKIN
☐ REDNESS AND FLAKES AROUND HAIR (scalp or body hair)
☐ HAIR LOSS
☐ ECZEMA
☐ ITCHING
☐ BURNING SENSATION
☐ NAIL CHANGES: _____

CONTINUED→

SKIN BIOPSY (a sample of your skin taken/removed by a healthcare provider to examine further):

☐ NOT DONE

☐ DONE

If YES, BIOPSY DATE(S): ____/____/_____; ____/____/_____; ____/____/_____

If YES, was Pityriasis Rubra Pilaris (PRP) CONFIRMED BY SKIN BIOPSY?

☐ Yes

☐ No

PLEASE SUBMIT A COPY OF THE SKIN BIOPSY REPORT, IF AVAILABLE.

DO YOU STILL HAVE SKIN FINDINGS/SYMPTOMS?

☐ Yes; If YES: HOW LONG have you had skin FINDINGS/SYMPTOMS? _____(years)

☐ No; If NO: HOW LONG did your skin FINDINGS/SYMPTOMS last for? _____(years)

HAS YOUR DOCTOR TOLD YOU WHAT TYPE YOUR PRP IS?

☐ Yes; If YES, TYPE: _____

☐ No

IS THERE A FAMILY HISTORY OF PRP-RELATED FINDINGS OR PSORIASIS?

☐ Yes; If YES, WHO has it?_____ AND is it PRP or PSORIASIS?_____

☐ No

TREATMENTS TRIED FOR PRP

☐ NONE

TOPICAL TREATMENT (please *check all* treatments tried)	WAS THIS HELPFUL?
☐ MOISTURIZERS	☐ Yes ☐ No
☐ TOPICAL STEROIDS	☐ Yes ☐ No
☐ UREA CREAM	☐ Yes ☐ No
☐ SALICYLIC ACID	☐ Yes ☐ No
☐ RETINOIDS	☐ Yes ☐ No
☐ CALCIPOTRIENE (CALCIPOTRIOL)	☐ Yes ☐ No
☐ PIMECROLIMUS	☐ Yes ☐ No
SYSTEMIC TREATMENT (please *check all* treatment tried)	WAS THIS HELPFUL?
☐ RETINOIDS (ACITRETIN or ETRETINATE or ISOTRETINOIN)	☐ Yes ☐ No
☐ METHOTREXATE	☐ Yes ☐ No
☐ TNF α INHIBITORS	☐ Yes ☐ No
☐ LIGHT THERAPY	☐ Yes ☐ No

OTHER(S), including over the counter remedies (please *list all* other treatment(s) tried):

_____

_____

_____

CONTINUED→

END OF STUDY

MEDICAL HISTORY: (please *check all* that apply)

- ☐ SKIN DISEASE: If so, what disease(s): _____
- ☐ MYASTHENIA GRAVIS
- ☐ CELIAC SPRUE ("celiac disease")
- ☐ MYOSITIS ("inflammation" of muscles)
- ☐ HYPOthyroidism ("low" thyroid function)
- ☐ CANCER/MALIGNANCY; Type: _____ YEAR DIAGNOSED: _____
- ☐ HIV INFECTION
- ☐ DIABETES
- ☐ DYSLIPIDEMIA (e.g. "high cholesterol," "high triglycerides," etc.)
- ☐ HEART DISEASE

OTHER SYMPTOMS related to PRP:

REGARDING YOUR MOOD, HOW OFTEN DO YOU FEEL DOWN OR DEPRESSED?

☐ Don't Know

☐ ALWAYS ☐ OFTEN ☐ SOMETIMES ☐ RARELY ☐ NEVER

IN YOUR OPINION, WHAT PERCENT OF YOUR DEPRESSION IS RELATED TO YOUR PRP?

☐ Don't Know

☐ 0% (Not at all related) ☐ 1-25% ☐ 26-50% ☐ 51-75% ☐ 76-100% (Extremely related)

PLEASE LIST WHAT ABOUT YOUR PRP MAKES YOU FEEL DEPRESSED/IS HARD TO DEAL WITH:

☐ Don't Know

-example: people stare at me in public

-example: I am not allowed in the public pool because of my rash

END OF PATIENT SURVEY

PLEASE RETURN this form and the **new research consent form** via:

1. **Mail** (preferred):
   Department of Dermatology & Cutaneous Biology, Attn: Nick Ross, 833 Chestnut St., Ste. 740, Philadelphia PA 19107. (If you require a stamped envelope, please contact (215) 503-3787).

OR

2. **Fax**:
   (215) 503-3333 (Jefferson Dermatology Associates)

OR

3. **Scanned email attachment**:
   Nicholas.Ross@jefferson.edu (data-secure email address)

Thank you for taking the time to complete this form. Your information is very helpful and will be used to advance dermatology's understanding of Pityriasis Rubra Pilaris (PRP).

As per University guidelines - [illegible] consent form date

END OF STUDY

Thomas Jefferson University
Informed Consent Document for Human Subjects Research – OHR-8 (v.12/11/13)

Principal Investigator: Jouni Uitto, MD, PhD **Telephone**: (215) 503-5785
Co-Investigator(s):Hye Jin Chung, MD; Qiaoli Li, PhD **Telephone**: (215) 955-6680/(215) 503-5713
Key Personnel: Nicholas A. Ross, BA **Telephone**: (215) 503-3787
Medical Title: Investigation of Potential Genetic Causes of Pityriasis Rubra Pilaris (PRP) by Mutation Analysis of Patient Tissues
Lay Title: Researching a genetic cause of Pityriasis Rubra Pilaris (PRP) through gene studies of patient samples

What Is Informed Consent?

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans. Before a knowledgeable decision about whether to participate in a research study can be made, the possible risks and benefits related to the study should be understood. This process of learning and thinking about a study before deciding to participate is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form once the nature of the study is understood and a decision is made to participate. If there is anything about the study you don't understand or if there are questions, you should ask for explanations before signing this form;
- Being given a copy of the signed and dated consent form to keep.

What is the purpose of this study?

This study has two phases:

During Phase I, our research team searched for a genetic link of PRP by collecting blood and/or buccal swabs (saliva genetic sample kits) from patients who enrolled and participated in this phase.

During Phase II (this current phase) of this study, there are no tests. Our aim is to gather clinical information from patients regarding their experience, symptoms and treatment of PRP. A second signature page (attached to this informed consent document) requests your permission to allow study team members (listed above) to contact your diagnosing/treating physician(s) to acquire medical records (clinical and/or pathologic) and/or skin biopsy slides. Specifically, we seek your permission to contact your physician in order to confirm your diagnosis of PRP. We also request permission for study personnel to contact you, strictly for the purpose of obtaining these documents and information related to the PRP study. Through this research, we hope to establish a possible genetic link of the disease that can enable further research that may improve diagnosis and treatment options.

How many individuals will participate in the study and how long will the study last?
Currently, 152 PRP patients, just like you, are participating in this research study. We plan to enroll any patient diagnosed with PRP, world-wide, whether active or in remission.
Your participation in this phase of the study will last only as long as it takes you to complete the documents followed by the time it takes our study team to obtain clinical records from your diagnosing/treating physician(s) (approximately six months to one year). Once information has been gathered, you will have "completed" your enrollment in the study. Your participation, of course, is voluntary and can be terminated at any time at your request or at the discretion of the principal investigator.

What will happen during the study?
In this non-interventional (no-test) phase of the study there are three steps:

1) You will receive information regarding the study (Patient Study Packet), which you may review at your own pace.
2) If interested in participating, you will complete the Patient Study Packet and mail (preferred) completed forms to our clinical research office (other options/details are listed in the study packet).
3) Our study team will use information provided in the study packet to contact your physician(s) and gather your clinical and/or biopsy records in order to review and confirm your diagnosis of PRP. We seek medical records containing clinical (doctor's notes) and/or pathologic (biopsy) reports and/or biopsy slides that will allow us to definitively establish your diagnosis of PRP through pre-defined study criteria. The goal is to collect this information and allow the physicians associated with this study at Thomas Jefferson University's Department of Dermatology and Cutaneous Biology to review the diagnosis for study purposes.

Are there benefits from being in this study?
There may be no personal benefit from participating in this research, but we hope to learn valuable information about this rare disease. This may help patients just like you in the future or society in general.

What is the risk of releasing my medical record?
By releasing your medical records, there is always a risk of a breach in confidentiality. By following preventative privacy measures outlined in the study protocol, we hope to minimize this risk. All information we obtain will be kept confidential and protected in a secure on-campus office within a locked file cabinet. Your name will not be linked to any published data. There are no tests associated with this part of the research protocol.

Are there alternatives to being in the study?
The alternative is not enrolling in the study. You do not have to complete the study survey nor do you have to provide permission for our study team to contact your treating/diagnosing physician. If, however, you are interested in participating, please complete the Patient Study Packet enclosed.

How will privacy and confidentiality (identity) be protected?

Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies an individual personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that people may see and review their medical records at any time. However, in a research study, people may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

- The following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of Thomas Jefferson University, Jefferson University Physicians, and Thomas Jefferson University Hospitals, Inc. involved in this specific study, the University's Division of Human Subjects Protection and the Institutional Review Board (IRB).

PHI collected during this study may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- A Data and Safety Monitoring Committee (DSMC),
- Any person or agency required by law.

PHI collected as part of this research may be used/disclosed indefinitely. All confidential patient information will be stored only in locked file cabinets within the secured research offices at the Department of Dermatology and Cutaneous Biology of Thomas Jefferson University.

You may revoke permission the study and revoke permission to use and share PHI at any time by contacting the principal investigator, in writing, at: Jouni Uitto, MD, PhD, Professor and Chair, Department of Dermatology & Cutaneous Biology, Thomas Jefferson University, 233 South 10th Street Bluemle Life Sciences Building, Room 450 Philadelphia, PA 19107. Further collection of PHI will be stopped on those who quit the study, but PHI that has already been collected will remain in the offices of the research team for study purposes only.

The information from this study may be published in scientific journals or presented at scientific meetings but no one will be personally identified in these publications and presentations. This is because we will be collecting information from hundreds of patients and combining all answers without names.

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, this Web site will include a summary of the results. You can search this Web site at any time.

Is there payment for being in this study?

There is no payment for participating in this study.

Are there costs related to being in this study?
The only cost to you with participating in this study is for postage to mail the forms. If you are unable to afford this cost, please contact the clinical research fellow (information in the patient study packet) who can assist you in finding alternative means of supplying the study team with your documents.

What if the research results in new findings?
Anything learned during the study, beneficial or not, that may affect your health or willingness to continue in the study, will be explained.

Can I be removed from the study or quit the study?
Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent for any reason that he feels is appropriate.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting the ability to receive medical care at Thomas Jefferson University. Should you decide to withdraw from the study, please be sure to inform the study doctor.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	The Jefferson Institutional Review Board	(215) 503-8966
For questions, concerns or complaints about the research	Nicholas Ross, BA, Clinical Research Fellow***	Nicholas.Ross@jefferson.edu; (215) 503-3787
Co-Investigator	Hye Jin Chung, MD	HyeJin.Chung@jefferson.edu
Co-Investigator	Qiaoli Li, PhD	Qioali.li@jefferson.edu
Principal Investigator	Jouni Uitto, MD, PhD	Jouni.Uitto@jefferson.edu
If you have difficulty contacting the study staff	Call the Jefferson Office of Human Research	(215) 503-0203

***Please use this as a primary contact for study questions or concerns (email preferred).

If you have questions about your rights as a research subject, contact the Thomas Jefferson University Office of Human Research at 215-503-8966. If you want more information about the Jefferson Institutional Review Board or Jefferson's Human Research Protection Program, please visit our website at http://www.jefferson.edu/human_research/irb/index.cfm.

Non-Waiver of Legal Rights Statement

- ✓ **By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.**
- ✓ **In order to be in this research study, you must sign this consent form.**
- ✓ **You affirm that you have read this consent form. You have been told that you will receive a copy.**

SIGNATURES (Page 1 of 2)

_____
Your Name

_____
Your Signature Date

_____
Witness Signature *(only required if subject understands and speaks English but cannot read English or if subject is blind or cannot physically sign the consent form)* Date

_____
Signature of Principal Investigator or Co-Investigator Date
(This line will be signed by Thomas Jefferson University research staff)

CONTINUE TO SIGNATURE PAGE 2 →

Jefferson
University Physicians

Department of Dermatology
and Cutaneous Biology
Jefferson Dermatology Associates

T 215.955.6680 F 215.503.3333

PHYSICIAN CONTACT INFORMATION & SIGNATURES

You are signing to give permission to your treating physician to release your medical record(s) to the individuals of this research protocol who will contact your doctor to acquire the medical records for the purposes of medical research.

******Please fill out the following **information about the physician** (e.g. dermatologist) who gave your diagnosis of Pityriasis Rubra Pilaris (PRP)******

******If there were **multiple physicians** involved in your diagnosis, please attach additional pages with their information as necessary******

1. **PHYSICIAN Name**: _____
2. **PHYSICIAN Contact Telephone**: _____
3. **PHYSICIAN Contact Fax**: _____
4. **PHYSICIAN Address**: Street: _____

_____

City _____ State/Province _____

Country _____

I hereby authorize the physician(s) listed above to release my medical records to the research personnel listed above at Thomas Jefferson University Hospital for the purposes of scientific study.

_____	___/___/___	_____
Print **YOUR** Name	**YOUR** Date of Birth	Print **YOUR** Telephone Number
_____	___/___/___	
Signature	Date	
_____	___/___/___	
Witness Signature	Date	

Thomas Jefferson University IRB
Approval Date 2/27/14
Expiration Date
Annual review due 4 weeks before expiration

END OF STUDY