

## RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE:** International Pachyonychia Congenita Research Registry (IPCRR)

**PROTOCOL NO.:** WIRB® Protocol #20040468

**SPONSOR:** PC Project  
Salt Lake City, Utah  
United States

**INVESTIGATOR:** Mary E. Schwartz  
PC Project  
Suite B  
2386 East Heritage Way  
Salt Lake City, Utah 84109  
United States

**SITE(S):** PC Project  
Suite B  
2386 East Heritage Way  
Salt Lake City, Utah 84109  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** 877-628-7300 (24 Hour)  
801-272-9716 (24 Hour)

In this consent form, “you” always refers to the subject. If you are a legally authorized representative, please remember that “you” refers to the study subject.

### STATEMENT

We are asking you to participate in the International Pachyonychia Congenita Research Registry (IPCRR). The purpose of the IPCRR is to gather information about PC patients in a useable research registry, which may be used to assist researchers in understanding PC in order to find treatments and a cure for PC. So that qualified doctors, scientists and researchers are able to use information in the registry, PC Project must follow specific laws of the U.S. government regarding medical registries and the IPCRR must be approved by an Institutional Review Board (IRB).

The purpose of this consent form is to give you the information you will need to help you decide whether or not to be in the IPCRR. You may ask questions about the purpose of the IPCRR, what you will be asked to do, any possible risks or benefits, your rights as a volunteer participant, and anything else about the IPCRR or this consent form that is not clear. This is called informed consent. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Please keep one signed copy of this consent form for your records. Please return one signed copy to the principal investigator listed above. The consent form may be sent by email, fax or mail.

**Who is being asked to participate in the IPCRR?**

All persons with PC in all countries are being invited to register. It is not known how many persons have PC although it is known it is a very rare disease.

**For how long will the IPCRR maintain your information?**

The information contained in the IPCRR will be maintained for an indefinite period of time unless you withdraw your permission for participation in the registry.

**What will your participation in the IPCRR involve?**

If you agree to participate in the IPCRR you are asked:

- to complete a questionnaire providing detailed information about you, your family history, your PC condition and how PC affects your life
- to have a consultation (in person or by telephone) with a Board Certified Dermatologist to review and validate your responses to the Questionnaire. There will be no cost to you or your insurance carrier for this consultation.
- to ask other family members who also have PC to contact the investigator
- to give permission for PC project to contact you about once a year to update your information
- to give permission for PC Project to contact you if you are eligible for participation in a future research study concerning PC. If you qualify for any future research studies, you will be asked to sign a separate consent form that outlines that study in detail. There is no obligation to participate in future studies.
- to indicate whether or not you wish genetic tests, if the Dermatologist recommends this option. There is no cost to you or your insurance carrier for the genetic tests. There is no obligation to participate in genetic tests.

**What are the possible risks of my participation in the IPCRR?**

Participation in the IPCRR does involve the possible risk that information about you might become known to individuals outside of PC Project. We will assign a research code number to your information stored in the IPCRR, and we will separate personal identifiers (for example, your name, social security number, address). Access to personal identifiers will be password protected. Further, information linking the research code number to your name and other personal identifiers will be stored in a separate secure location.

If you request genetic testing, a small blood sample will be needed. Drawing blood from your arm may cause pain, bruising, lightheadedness, and, on rare occasions, infection.

**What are the possible benefits of my participation in the IPCRR?**

You will receive no direct benefit from participation in this study. However, information contained in the IPCRR will be available for research studies directed at improving knowledge, treatment and cure for PC.

It is anticipated that the IPCRR will assist study doctors in two ways:

- (a) allow researchers to review and study information on many individuals with PC
- (b) help researchers identify and recruit patients who may be eligible for participation in future research studies. There is no obligation to participate in any future study. There are no current research studies for PC.

**Will I be paid for my participation in the IPCRR?**

No. You will not receive any payment for participating in the IPCRR.

**Will I or my insurance provider be charged for my participation in the IPCRR?**

There will be no costs to you or your insurance provider to participate in the IPCRR. Any costs will be paid by PC Project (which is funded by PC Fund, a 501(c)3 charity.)

**Is there any alternate registry for PC patients?**

PC Project is aware of no other registry specifically for PC patients. Your alternative is not to participate in this study.

### **Who will have access to my identifiable information in the IPCRR?**

Access to your identifiable information contained within the IPCRR will be limited to the PC Project principal investigator and those serving on the Medical Advisory Board of PC Project. A current, complete listing of these individuals is posted on the PC Project website ([www.PC-Project.org](http://www.PC-Project.org)) and will be provided to you upon your written request.

### **AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

### **What information may be used and given to others?**

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Questionnaires

### **Who may use and give out information about you?**

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

### **Who might get this information?**

Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health, which might identify you, may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The Western Institutional Review Board<sup>®</sup> (WIRB<sup>®</sup>)

**Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB<sup>®</sup>. WIRB is a group of people who perform independent review of research as required by regulations.

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

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission will not stop automatically.

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

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

**Who should I contact if I have questions about the IPCRR or about my rights?**

If you have questions about the IPCRR, you may contact the principal investigator:

Mary Schwartz at 877-628-7300 or 801-272-9716 (24 Hours).

If you have questions about the IPCRR, which you feel you cannot discuss with the principal investigator or questions about your rights as a participant, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, Washington 98502  
Telephone: 1-800-562-4789.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**Is my participation in the IPCRR voluntary?**

Your participation in the IPCRR for the purposes described above is completely voluntary. You may choose to participate or refuse to participate. Whether or not you participate in the IPCRR will have no affect on your association with PC Project.

**May I withdraw, at a future date, my consent for participation in the IPCRR?**

You may withdraw, at any time, your consent for participation in the IPCRR and no further information will be gathered or distributed from your submission. However, any research use of your information before the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in the IPCRR, you should provide a written and dated notice of this decision to the PC Project principal investigator at the address listed on the first page of this consent form.

**Can the IPCRR refuse my participation?**

Your participation in the IPCRR may be ended by the PC Project principal investigator or by the sponsor, PC Project, for any reason, without your consent. However, if this situation arises, PC Project will advise you of this decision.

**Who will provide the source of funding?**

Funding for this research study will be provided by PC Project.

**How will I know about significant new findings or future research studies?**

The PC Project website ([www.PC-Project.org](http://www.PC-Project.org)) will describe progress of the IPCRR and will list any future research studies that are developed using the IPCRR information.

If you participate in the IPCRR, you will be contacted if you qualify for participation in any future study. You will then be able to request information on that study. Once you have received information, you will decide whether or not you wish to participate in that study. There is no obligation to participate in future studies and your decision will not change your participation in IPCRR.

**May PC Project contact you?**

If you agree to participate in the IPCRR, you will receive a copy of this signed and dated consent form.

In addition to listing with the IPCRR for research purposes, do you give PC Project permission to use your contact information to provide you with information on PC Patient Retreats, news about PC, or other activities of PC Project which may be of interest?

Please initial your choice                      Yes\_\_\_\_\_                      No\_\_\_\_\_

**Consent and Assent Instructions:**

*Consent: Subjects 18 years and older must sign on the subject line below  
 For subjects under 18, consent is provided by the Legally Authorized Representative*  
*Assent: Is not required for subjects 11 years and younger  
 Is required for subjects ages 12 through 17 years using the Assent Section below*

**OPTIONAL PARTICIPATION IN GENETIC TESTS**

PC Project is providing genetic testing at no cost to registry enrollees. The results of these tests will be given to each patient in a confidential consultation with a physician and/or genetic counselor. The results will be kept for review in the research studies conducted on PC. After my questionnaire is submitted and if recommended by the dermatologist:

I request genetic testing to verify my specific genetic mutation.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I agree the results of the tests can be released to PC Project for the IPCRR	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I agree the DNA can be stored by the laboratory for possible further tests or study. If DNA is to be used for any tests other than genetic studies, PC Project will contact me to obtain consent before using my DNA in that future study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I agree that if the laboratory cannot store the DNA, PC Project can arrange for storage at another fully-qualified facility.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

**CONSENT**

I have read this consent form (or it has been read to me). I have had the opportunity to ask questions. All of my current questions have been answered to my satisfaction. I voluntarily consent to participate (to allow my child to participate) in the IPCRR.

I authorize the use and disclosure of my (my child's) health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of the legal rights, which I (or my child) otherwise would have as a subject in a research study.

\_\_\_\_\_  
Subject's printed name

\_\_\_\_\_  
Subject's Signature (18 years and older)

\_\_\_\_\_  
Date

**OR**

\_\_\_\_\_  
Signature of Legally Authorized Representative  
(when applicable)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority of Subject's Legally Authorized Representative or Relationship to Subject

### **CERTIFICATION OF INFORMED CONSENT**

I certify that I have explained the nature and purpose of the IPCRR to the above-named individual. I have discussed the possible risks and potential benefits of participation in this research registry. Any questions the individual has about the IPCRR have been answered, and I (or a member of PC Project Advisory Council) will be available to address future questions as they arise.

Mary E. Schwartz

\_\_\_\_\_  
Printed Name of Person Conducting Informed Consent  
Discussion

\_\_\_\_\_  
Signature of Person Conducting Informed Consent  
Discussion

\_\_\_\_\_  
Date

**ASSENT SIGNATURES, For Subjects Ages 12 through 17 years:**

Assent:

This research study has been explained to me and I agree to be in this study.

\_\_\_\_\_

Subject's Signature for Assent

\_\_\_\_\_

Date

\_\_\_\_\_

Age (years)

I confirm that I have explained the study to the extent compatible with the subject's understanding, and that the subject has agreed to be in the study.

\_\_\_\_\_

Signature of Person Conducting Assent Discussion

\_\_\_\_\_

Date

-----**Use the following only if applicable**-----

*If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:*

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

\_\_\_\_\_

Signature of Impartial Witness

\_\_\_\_\_

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.