

**Affected Adults, Parents/Guardians, Legally Authorized Representatives  
Informed Consent to Participate in the PFIC Network Patient Registry (PNPR)  
for Affected Adults/Affected Minors**

**Registry Name:** PFIC Network Patient Registry (PNPR)  
**Principal Investigator:** Melissa Kochanowsky  
**Email:** melissa@pfic.org  
**Contact Address:** PO Box 551, Stanton KY 40380

***NOTE: In this consent form, “you” always refers to the research participant. If you are a legally authorized representative, please remember that “you” refers to the study participant. If you are a parent or legal guardian, please remember that “you” refers to the child study participant.***

**About this consent form**

You are invited to participate in a research registry. **It is important that you carefully think about whether participating in this registry is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to participate in this registry. **Please ask the PFIC Network (PN) staff to explain any information in this consent document that is not clear to you.** You can download an unsigned copy of this consent form from <https://www.pfic.org> to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide to not participate. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**Overview of Participation in the PNPR**

To advance science, it is helpful for researchers to share information. They do this by putting data into one or more scientific databases (called registries or repositories), where it is stored, possibly along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more.

- This consent form asks for permission to store and share your information in a research registry to help research studies in the future.
- The purpose of this registry is to collect and store health and wellbeing related information along with your name, phone, email, and other personal information you may provide.
  - The information will be available for any research question, such as research to understand what causes PFIC and PFIC-related diseases, development of new scientific methods or treatments.

- Your information will be protected, but there is always a possibility that information could be accessed by individuals without authorization.
- Your participation in this registry will not give you any known benefit at this time. We do not anticipate learning any information that could clinically benefit you personally. It is hoped that the knowledge gained from research studies conducted using this registry will benefit people in the future.
- There is no limit on the length of time we will store your information.
- Identifiers might be removed from the information you provide in this study, and after that removal, the de-identified information could be used for other research studies by this study team or another researcher without asking you for additional consent.

### **Why is the registry being created?**

PFIC Network (PN) is a registered non-profit patient advocacy organization focused on Progressive Familial Intrahepatic Cholestasis (PFIC) and PFIC-related diseases such as Benign Recurrent Intrahepatic Cholestasis (BRIC) and Intrahepatic Cholestasis of Pregnancy (IPC). The purpose of the PFIC Network Patient Registry (PNPR) is to establish an international registry for PFIC and PFIC related diseases. PN's goal is to collect and provide a valuable resource of information, and to facilitate patient recruitment into research studies and clinical trials.

### **What will happen if I participate?**

If you decide to participate, you will be asked to do the following things:

1. Take surveys and answer questions about your disease (e.g., symptoms, medications, surgeries), your general health and wellbeing, and the impact of the disease on quality of life.
2. Consider to upload your medical records regarding diagnosis, treatment and surgeries.
3. Sometimes, it is important for researchers to know how many members of a family are affected by a given condition and how diseases are inherited within a family. You will have an option to link your account with other family members who are enrolled in the PNPR. By linking your account to a family member's account, you are agreeing to have your name, date of birth, city/state residence, and family relation shown to the family member to which you would like to be linked. You will not be able to look at or edit each other accounts. Researchers will not be able to identify who the individuals are; rather they will only know that you are related to the family member you have linked to.

Your information will be stored on a secure server at Amazon Web Services in one or more scientific databases. De-identified information may be shared with other researchers. The information will be available for any research question, such as research to understand what causes PFIC or other diseases, development of new scientific methods, or development or assessment of new treatments.

### **Will I be contacted by other researchers in the future?**

Future research studies involving this registry may only use the information stored in this

registry, and therefore will not require further involvement or additional informed consent of participants. However, information from this registry may be used to identify people who may be eligible to participate in future research studies that relate to PFIC and PFIC-related diseases for which additional information is needed that is not in the registry.

If you would like to be contacted for future studies, **please initial the optional consent** to contact below to authorize the registry to give out your contact information to the relevant study team so they may contact you. The researchers would fully explain the new research study and you would have to give your informed consent to that study before you could participate

If you participate in this registry, you are not required to participate in any future research study. You can also remove permission for the PNPR to contact you about future studies at any time by contacting the Principal Investigator identified at the top of this document.

*Optional Permission:* I give permission for the registry staff to share my contact information with other researchers who need additional information or are conducting research that might interest me.

YES \_\_\_\_\_ NO \_\_\_\_\_

### **How long will I be in the registry?**

Your active participation in this study while contributing information will last until you decide to cancel your participation, and your information will be stored in the registry for the duration of your participation and used for research studies. An unlimited number of subjects may participate in the PNPR.

If you enroll your child in the PNPR and your child reaches age 18, we will try to contact them to ask whether they want to continue to participate in this research registry. If we cannot find your child, we will remove all identifying information, and continue to use their health information in research.

Your alternatives are to not participate in the PNPR or to participate in a different registry if one is available. You do not have to participate in this registry to be treated for PFIC or PFIC-related diseases.

If you prefer to fill out a paper copy of the surveys you can contact the Principal Investigator mentioned at the top of this document.

### **What are the risks of participation on the PNPR?**

- Participation in research might involve some loss of privacy or confidentiality. There is a small risk that someone outside the research study could see and misuse information about you.
- Questionnaires may contain questions that are personal in nature. You may refuse to answer any question that makes you feel uncomfortable.

**Genetic Risks:**

This registry or future research studies that use your information may involve genetic analysis. If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Unknown or Unforeseeable Risks**

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

**What are the benefits of participating in the PNPR?**

This registry is not likely to benefit you. However, we hope the information learned from this study will provide more information about PFIC and PFIC related diseases. By participating in the PNPR you may permit PN to contact you about research opportunities you qualify for and can decide at that time if you would like to participate (see above optional consent). However, PN cannot guarantee that a researcher will request to contact you.

In general, we will not give you any individual results from the study. We do not anticipate learning any information that could personally benefit you. However, if we or other researchers find something of medical importance to you, we will inform you. We will publish summary results regularly via online media.

**What are the costs?**

There are no costs involved in participating in the PNPR.

**Will I be paid for participating in the PNPR?**

You will not be paid for participating in the PNPR. You will not be paid for any future research studies that use the information in the registry. The information stored as part of this registry could lead to discoveries or inventions in the future that may be of value to PN or to other organizations. You will not receive any money or other compensation that may come from products that are developed from the information stored in the registry.

**Can I stop being in the registry?**

You can stop being in this research registry at any time. Leaving the registry will not affect your medical care, employment status, or relation with PN. Tell the study staff if you are thinking about stopping or decide to stop.

In the future, if you decide that you don't want to be part of this registry, you can request that your information be removed by contacting the Principal Investigator of this study. However, information that has already been shared with other researchers will continue to be used.

### **How will my information be protected?**

PN has established a secure server at Amazon Web Service to store information and to monitor and oversight research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks. Identifiable information in these databases are not released outside PN unless required by law or authorized by you in a separate consent. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

### **How will my health information be used and shared during this study?**

As part of this research study, we will ask you to consider to upload your health records related to diagnosis, treatments, and surgeries. This type of information is considered "Protected Health Information" that is protected by federal law.

### **What type of health information may be used or shared with others during this research?**

- Genetic diagnosis
- treatment codes
- Surgeries and age at surgery
- Discharge summaries

### **Who will use or share protected health information about me?**

PN and the PNPR are required by law to protect your identifiable health information. By signing this document, you authorize to use and/or share the health information that you have provided to the registry for the purpose of research studies. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

### **When will this authorization (permission) to use my protected health information expire?**

This authorization will expire when the registry is closed, or when you decide to end your participation.

### **Statement of Privacy Rights**

You may change your mind and revoke (take back) the right to use your protected health information at any time. To revoke this Authorization, you must write to the Principal Investigator at [melissa@pfic.org](mailto:melissa@pfic.org), or PO Box 551, Stanton KY 40380

### **If you live outside the United States**

The Registry is maintained on servers that are physically present in the United States. For persons living outside the United States who choose to share information about themselves and about a person for whom they serve as a Legally Authorized Representative, the same

protections for privacy and confidentiality are offered as in the United States; in addition, as explained below, residents of the European Union, Switzerland, and the United Kingdom have additional particular rights related to personal information. By signing this consent, you acknowledge that you are disclosing information that would otherwise be private. Privacy laws in your country may have different protections than those provided in the United States.

### **Whom should I contact with questions about this study?**

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**Melissa Kochanowsky** ([melissa@pfic.org](mailto:melissa@pfic.org)) or Emily Ventura ([Emily@pfic.org](mailto:Emily@pfic.org)). Both can also be contacted by mail at **PO Box 551, Stanton KY 40380**

An Institutional Review Board (IRB) has reviewed this Biobank to ensure that it meets ethical and regulatory standards for protecting your rights. An IRB is an independent group that reviews research proposals to make sure they properly protect participants. For questions about those protections and your rights as a participant in this Registry, or to discuss other related concerns or complaints, please contact North Star Review Board at 877-673-8439 (toll free) or [info@northstarreviewboard.org](mailto:info@northstarreviewboard.org). You may want to contact the IRB if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

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.

### **Statement of Consent (and/or Parent/Legal Guardian permission)**

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate and/or give permission for my child to participate in this research study. I will receive a copy of the consent form for my records.

**Signature Block for Enrolling Adult Participants**

\_\_\_\_\_  
Adult Participant Name (Printed)

\_\_\_\_\_  
Adult Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

**Signature Block for Enrolling Decisionally Impaired Adult Participants**

_____ Name of Adult Participant (Printed)	
_____ Name of Legally Authorized Representative (Printed)	_____ Relationship to Participant
_____ Legally Authorized Representative Signature	_____ Date

**STATEMENT OF ASSENT BY ADULT PARTICIPANT**

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

_____ Adult Participant's Signature	_____ Date
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_____ Principal Investigator Signature (if different from above)	_____ Date
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<b>Signature Block for Enrolling Child Participants (Ages 0-18) Parent/Guardian Permission</b>	
Name of Child/Youth Participant	
Name of First Parent/Legal Guardian (Printed)	
Required First Parent/Legal Guardian Signature	Date
Optional Second Parent /Legal Guardian's Signature	Date
Principal Investigator Signature	Date

<b>Signature Block for Enrolling Child Participants (Ages 10-18) – Assent by Child</b>	
<b>STATEMENT OF ASSENT BY CHILD PARTICIPANT</b>	
The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.	
Child Participant's Signature	Date
Principal Investigator Signature	Date