

## National PAP Registry Written Informed Consent • Parental Permission • Assent

We invite you to join the National PAP Registry. This is a program of the PAP Foundation and Rare Lung Diseases Consortium (RLDC). The person in charge is Bruce Trapnell, a doctor at Cincinnati Children's Hospital Medical Center (CCHMC).

### Purpose

This Registry is for people interested in helping evaluate new lab tests for PAP, in receiving information about PAP, and possibly participating in other PAP research. Before you decide about joining, you should know some facts. **1)** Your participation is voluntary. **2)** If you choose to join, you may withdraw at any time and for any reason. **3)** You will not receive any payment for participating. **4)** You will not receive any specific treatment for PAP as part of your participation in this Registry (This is not a treatment trial). **5)** It will not cost you (or your insurance company) anything to participate. **6)** Participation in this Registry will not affect your rights to treatment unrelated to this study, payment for services, and enrollment in a health plan or eligibility of benefits.

### Confidentiality

No personal information about you will be given to any other researcher(s), the PAP Foundation, or included in any publication(s). Only Dr. Trapnell and the Registry Staff managing the database at CCHMC and institutional/federal auditors will have access to your personal information. It will be up to you to choose whether or not to contact any researcher(s) seeking volunteers from the Registry.

### What Will Happen In This Study

Before you can participate, we must inform you about the Registry. We must also have your written permission. You can give permission by signing, dating, and returning this form to us. We encourage you to ask questions at any time and to take enough time to decide. If you agree to join, we will ask you to do the following things. **1)** Complete a 'Release of Medical Information' form giving us permission to use your health information. **2)** Complete a Registry Questionnaire. **3)** Collect several drops of blood from your finger using a new test kit – PAPKit™. This test is an accurate new way to identify diseases that cause PAP. We may need to do a genetic test on your blood. We will use your test results and health information to identify the disease that caused PAP (if you have PAP). We will keep your leftover blood and DNA for future PAP research studies. We plan to have 500 people join the Registry over five years.

### Risks, Discomforts, Inconveniences, and Benefits

**Risks, Discomforts, and Inconveniences:** The physical risks of participating relate to collecting several drops of blood. These include minor pain, and rarely, minor infection or scarring. Completing the Questionnaire may seem tiring or some questions too personal. Please, take as long as you need to complete it and skip any questions if you think you should. Responding to requests to join future research studies may seem inconvenient. You may elect not to receive such requests. We will make all reasonable efforts to keep your information confidential. However, we cannot guarantee that errors in protecting this information will not occur.

**Benefits:** You may learn what disease caused PAP (if you have PAP). We will give you information about PAP and other research studies to test new treatment approaches. Knowledge gained from your participation in this Registry may help other people with PAP.

### HIPAA Authorization

HIPAA is a federal law requiring protection of your health information. To be in this research study you must also give your permission to use and share your protected health information (PHI). PHI is information about your past, present, and future physical and mental health conditions or the provision of health care. Your written authorization is required.

**What PHI will be used and shared during this study?** Your PHI will be obtained from your medical records, medications, information you share on the questionnaires, lab tests, diagnostic reports (e.g. x-rays, CT scans, MRI scans), consultation reports and pathology reports, slides, tissue blocks, and discarded clinical specimens.

**Who will share, receive and/or use your protected health information in this study?** Dr. Trapnell and the study staff, personnel who provide services to you as part of this study, other individuals and organizations that need to use your PHI in connection with the research, including people at the organizations that the sponsor may use to oversee or conduct the study. Federal law requires the CCHMC Institutional Review Board (IRB), the staff of the Office of Research Compliance and Regulatory Affairs, and the federal Office of Human Research Protection have access to any research data, if needed, to protect participants in human research studies.

**How will you know that your PHI is not misused?** People that receive your PHI as part of the research are generally limited in how they can use it. Federal privacy laws require most people who receive your PHI to protect it. However, some people may be allowed to share your information with others, if permitted by the laws that apply to them.

**Will this permission expire?** This study involves the maintenance of a research database repository, this authorization will not expire.

**Can you change your mind?** You may choose to withdraw your permission at any time. Withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

**Will your other medical care be impacted?** By signing this form you are agreeing to be in this study and give permission to CCHMC to use and share your PHI for the purpose of this study. If you do not sign this document you cannot be in this study. Your rights about treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

**Data Handling**

We will remove any personal information that could identify you. The ‘de-identified’ data will be kept in a secure electronic database at the Data Management and Coordinating Center (DMCC) at the University of South Florida in Tampa, FL and also sent to a Federal data repository. The DMCC will maintain this database and will follow local and federal security requirements for research datacenters. The data repository provides a way for researchers to store the information collected during the research study for future use. A description of the National PAP Registry study and de-identified database is located at <http://www.ClinicalTrials.gov>.

**Financial Support**

Support for the National PAP Registry comes from the PAP Foundation, the Translational Pulmonary Science Center at CCHMC, and the RLDC. The RLDC is part of the RDCRN, an initiative of the National Institutes of Health Office of Rare Diseases Research and the National Center for Advancing Translational Science (NCATS). Support for the RLDC comes from a grant from NIH (U54HL127672) through collaboration between NCATS and the National Heart, Lung and Blood Institute (NHLBI).

**Who to Contact with Questions**

To ask questions about this study, please contact Dr. Bruce Trapnell, by mail, e-mail, or phone using the contact information shown on the right. If you want to talk to someone who is not part of the study, about your rights as a participant, or if you have questions, concerns, or complaints about the study, you can speak with a member of the CCHMC IRB at 513-636-8039.

**Professor Bruce Trapnell, MD**  
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**Consent (for Participants 18 years and older) • Parental Permission (for Participants under 18 years old\*)**

By my signature below, I agree (or for my child\*) to participate in the National PAP Registry.

Name of Participant: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 (Print) (mmm/dd/yyyy)

\*Name of legal guardian: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 (Print) (mmm/dd/yyyy)

Relationship of parent/legal guardian to Participant:  Mother  Father  Other (Specify): \_\_\_\_\_

**Agreement to participate in certain parts of the research study**

My initials/date below indicate my agreement to participate in the indicated parts of this study.	Yes, I agree to participate	
	Initials	Date
My (or my child’s) DNA (from blood spot) may be used for genetic tests for PAP –	/	/
My (or my child’s) samples may be kept in the “Lung Disease Tissue Repository” for future studies –	/	/
The research team may contact me about possible participation in future research studies –	/	/

**Assent (for Participants 7 to 17 years old – written for 7-year-old people ☺)**

- We invite you to join our research study. Dr. Trapnell is in charge. He works at Cincinnati Children’s Hospital.
- It is your choice to join or not. If you decide to join, you can quit at any time.
- Before you decide to join, you may ask us questions about the study. We like to answer questions ☺
- Joining will not change any help you get from your doctors.
- By joining, you will help us learn about diseases that make breathing difficult. You will also be helping other sick people.
- It will not cost you or your parents anything to join. You will not get any money for joining.
- If you join, we will ask you to do several things. These include:
  - You and your parents will answer a list of short questions.
  - We will read what other doctors wrote about your health. We will keep information about you private.
  - You and your parents will help get three drops of your blood. We will use your blood to check a new lab test.
  - We will keep a little bit of your blood for other tests.

I agree to join this research study.

My Name: \_\_\_\_\_ My Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
 (Print your name) (Write your name) (month / day / year)