Invitation for parents of adolescents (14-17years old) to participate in the study

Living with Primary Ciliary Dyskinesia (PCD)

Dear parent,

Thank you for considering taking part in this online study which describes health, health care, and psychosocial aspects of **children and adults who have PCD**. Participation in the study is entirely voluntary. All data collected as part of this research project will be stored safely as we explain in detail in this information sheet.

The chief investigator of this project is Prof. Claudia Kuehni at the Institute of Social and Preventive Medicine in Bern (Switzerland).

What is the study about and why do we do it?

The study aims to increase knowledge about PCD in order to improve the health and quality of life of people with PCD. The study started in 2020 when PCD patient support groups asked for a study that finds out what happens to people with PCD during the COVID-19 pandemic. After the pandemic, with the continuous encouragement of PCD patient support groups, we want to continue to learn more about other important topics for people living with PCD, such as lung health, mental health, or treatment burden by obtaining regular updates via online questionnaires.

Who can participate?

Everybody with a confirmed diagnosis of PCD or a clinical suspicion of PCD can take part. Patient support groups from all over the world support the study. Parents of a child with PCD can take part in the study and fill in the study questionnaires with their child.

Are there any benefits or risk for me taking part?

Benefits

- There are no direct benefits for you if you and your child to take part, but people with PCD may profit in the future.
- You and your child have easy access to our study website where we will regularly publish updates on our results using simple language so that you will be informed first hand.
- You and your child can also suggest topics to be investigated in the future.

Risks and inconveniences

- There is no risk nor major inconveniences of taking part in this study. This means that there is no risk to your child in participating in the study.

Goal and general information

Living with PCD is an international online study hosted in Bern, Switzerland. The goal of the study is to increase knowledge about PCD to improve the health and quality of life such as lung health, mental health and treatment burden. Our current research priorities include physical symptom evolution over time, seasonal changes in symptoms, mental health and social functioning, treatment burden, nutrition, fertility concerns and subsequent reproductive success rates. Every person with a confirmed or suspected diagnosis of PCD or a parent of a child with PCD is invited to participate.

This research project is conducted in compliance with Swiss legislation and international guidelines. The research project has been reviewed and authorised by the competent ethics committee.

What data will be collected?

We need an email address to send you a link to access the online questionnaires. The email address is stored separately and will never be given out.

Adolescents aged 14 to 17 years are invited to fill in the questionnaires themselves. When adolescents register to the study, you (parents) receive an email with a link to a short form that informs you about the study and asks for your consent. The following emails with links to questionnaires will then be sent to the adolescents directly. We encourage parents to help their adolescent children complete the questionnaires. Parents can always contact the study team with questions.

- **At the start we will send your child the link to a baseline questionnaire** which asks about the disease of your child, your child’s “normal” symptoms, treatments, and health-related behaviours (e.g. exercise), and some general information about your family. This comprehensive questionnaire allows us to gain a clear overall understanding of your situation.
- **Then we will send your child follow-up questionnaires** which ask again about your child’s current symptoms and treatments (planned 1x per year). This helps us understand how PCD changes over time.
- **Extra questionnaires**, from time to time (approximately two times a year), will deal with **special topics**. For instance: physical activity, mental health, or nutrition. You can also suggest topics to be included in extra questionnaires and thus help to shape the study.

For all questionnaires, your child is encouraged to reply all questions, but the adolescent child can also select to skip some if you would not like to answer.

How long does the study last?

The study has a provisional end date at the end of 2030. However, this date might be extended, depending on funding and interest by the participants. If so, you will be informed. But you and your child can withdraw at any time and tell us that you don’t want to receive more emails.

Are there any benefits for my child if they participate in the study, and are there any risks?

There are no direct personal benefits from participating in the study, but your child´s participation will help to better understanding of PCD and may benefit others with the condition in the future. You and your child will have direct access to our study website with the latest results and will be informed first-hand. You and your child can also suggest topics to be explored in a future questionnaire. There are no direct risks or physical procedures involved in this study.

What happens with the data that my child and I provide for this study, and when will I get information about the results?

We will analyse data regularly, publish it online on our study website, and make it available to people with PCD, doctors, and policy makers. The data will also be published in scientific journals and via the PCD support groups.

Will the data of my child be kept confidential?

With the exception of e-mails (compulsory), we will not collect any personal or identifying data. Only members of the research team will see your email address, and only to perform tasks related to the project. All data is saved using the secure, web-based application, Research Electronic Data Capture (REDCap), which is a tool to collect and save data for research. The database is run by the SwissRDL, a centre for medical registries and data linkage at the University of Bern. The health-related data of your child can be given to other research groups, also abroad, but always encrypted, so that it is not possible to identify you or your child. Encryption means that all data that can identify you or your child (email address) is deleted and replaced with an encryption code. No data in any publication will be traceable to you or your child as an individual. All research personnel who have access to your data as part of this project are subject to confidentiality. The requirements of data protection are complied with and you and your child as a participant have the right to inspect your child´s data at any time.

Does my child have to take part in the study and what happens if I change my mind?

It is your free decision whether you and your child want to take part in the study. Your child may choose to skip certain extra questionnaires that the child does not want to complete. You and your child can also change your minds and withdraw at any time without giving a reason. To withdraw your consent and step out of the study, you can write an email to pcd.ispm@unibe.ch. We will then no longer send your child questionnaires and you choose if you want us to anonymise or delete your already collected data.

Who has reviewed this study?

The patient support groups that are supporting the study have contributed to the design of this study and have approved it, and the ethics committee of the canton of Bern, Switzerland has reviewed and approved this study (**2025-00807**).

This project may be reviewed by the responsible ethics committee (if needed) and by the organisation that is funding or supporting the study. If that happens, the researcher may need to share the stored data. Everyone involved is required to keep your information strictly confidential.

Financing

The study is supported by grants from the Swiss National Science Foundation (10001934, 320030B_192804). We have also received funding from the Swiss Lung League, and from various PCD patient support groups (PCD Support UK, PCD Foundation, PCD Australia, Kartagener Syndrom und Primäre Ciliäre Dyskinesie e. V.).

Where can I get more information?

More information and first results are available on the study website www.pcd.ispm.ch. You can also contact the PCD support group in your country, and the research team at the Institute of Social and Preventive Medicine, University of Bern, Switzerland by phone +41 31 684 68 55 or by email to pcd.ispm@unibe.ch. Dr. Myrofora Goutaki, and Prof. Claudia Kuehni will answer your questions.

You can also watch a video with the study information available on the study website.

Consent form for parents of adolescents (14-17 years old)

Please read this form carefully. Don’t hesitate to contact us if there is anything you do not understand or if you have questions about the study. By selecting yes for checkboxes below, you confirm your child’s voluntary participation and that you have read and understood the information provided in this document. Your informed consent to all points below is required for your child’s participation.

	Yes	No
• I confirm that I have read the study information for the study Living with PCD (2025-00807).	☐	☐
• I understand that the participation of my child is voluntary and that I am free to withdraw my child from the study at any time, without giving any reason. If I withdraw my child from the study, I will get no more links to questionnaires and I can choose if the data will be anonymised or deleted, after the data has been analysed.	☐	☐
• I understand that data collected from this study may be accessed by research staff from the Institute of Social and Preventive Medicine, University of Bern, Switzerland.	☐	☐
• I understand that data collected from this study will be analysed and published using encrypted data and results can be shared with other researchers, regulatory bodies, or public health agencies. The health-related data can be given to other research groups, also abroad, but always encrypted, so that it is not possible to identify my child or me.	☐	☐
• I agree that emails with a weblink to questionnaires will be sent to the email address that I provided until the study ends or I request to withdraw from the study. I will be free to skip some questionnaires if I don’t have time or prefer not to answer.	☐	☐
• I understand that the data collected will be held and maintained by the Institute of Social and Preventive Medicine, University of Bern, for a minimum of 15 years.	☐	☐
• I agree that my child takes part in this study.	☐	☐

Date: