

Informed Consent

Before collecting any more information, we would like to tell you more about the Pulmonary Fibrosis Foundation (PFF) Community Registry, how much data we are collecting, and how we will protect your data. We will also cover what it means to take part in a research study. This process is called informed consent.

Please read the informed consent document below. After you have had time to review it, you will be asked to sign electronically before enrolling. If anything changes about the project in the future, such as what type of data is collected or who it might be shared with, we will contact you to verify that you are still interested in being in the PFF Community Registry. As with all research, you may stop participating at any time.

----- INFORMED CONSENT DOCUMENT v1.1 -----

Participant Information and Informed Consent Form

Protocol Title	PFF Community Registry
Protocol #	PFF-002A
Sponsor	Pulmonary Fibrosis Foundation
Principal Investigator	Kevin Flaherty, MD Chair, PFF Registry Steering Committee
Address	230 East Ohio Street, Suite 500, Chicago, Illinois 60611
Phone	(844) 825-5733 (844.TalkPFF)
Email	registry@pulmonaryfibrosis.org

Key Information Statement

The purpose of the PFF Community Registry is to determine the effect of pulmonary fibrosis (PF) or interstitial lung disease (ILD) on individuals with the disease, individuals who have received lung transplants, caregivers, and family members over time. Participants will be asked to complete a short set of surveys online every six months to help provide a better understanding of PF and ILD, and their effect on individuals with the disease, individuals who have received lung transplants, caregivers, and family members.

Participation in the PFF Community Registry is completely voluntary. While every effort will be made to keep your information confidential, there is the risk of loss of confidentiality of your medical and personal information collected for this study.

If you are interested in learning more about this study, please continue to read below, where you will find additional information related to this study such as the risks, benefits, procedures, alternatives, and contact information.

Key Information about this Research Study

Purpose	<p>The goal of the PFF Community Registry is to build a national, large-scale registry of individuals with PF or ILD—including lung transplant recipients—as well as the caregivers and family members affected by PF or ILD to:</p> <ul style="list-style-type: none"> • Collect information to better understand how PF and ILD affect the lives of people with PF, caregivers, and family members, • Build a base of PF community members willing to share their thoughts and participate in future research, and • Work together with researchers and learn how we can improve the lives of those impacted by PF and ILD.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	At this time, the PFF Community Registry is funded to collect data for 3 years, but that may be extended.
Procedures	Individuals with PF or ILD, individuals who have received lung transplants, caregivers, and family members will be asked to complete a short set of surveys online every six months. We estimate that it will take 45 – 60 minutes or less to complete the surveys each time.
Risks	There are no physical risks to participating in the PFF Community Registry. While every effort will be made to keep your information confidential, there is the risk of loss of confidentiality of your medical and personal information collected for this study.
Benefit	You may not receive any medical benefits from being in this study. However, you may receive information and participate in study measures that ultimately may help you become more informed, activated, and engaged in your health care. Additionally, this study may benefit future patients who have PF or ILD.
Alternatives to Study Participation	You do not have to take part in the PFF Community Registry. If you are interested in finding other ways to support people affected by PF or researchers studying it, please visit https://www.pulmonaryfibrosis.org/ .
Financial Costs	There is no financial cost to take part in the PFF Community Registry.
Confidentiality	If you choose to take part in the PFF Community Registry, information will be entered via a secure, HIPAA-compliant portal. While efforts will be made to protect your confidentiality, there is still a risk in loss of confidentiality.

This overview does not include all the information you need to know before deciding whether to take part. Additional detail is given in the full consent document, which can be found on the

pages that follow below. Be sure to review the rest of this consent form before deciding about participation.

Informed Consent Document

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve, and the risks and benefits. The PFF Community Registry team can be contacted at registry@pulmonaryfibrosis.org if you have additional questions after reviewing this consent form or if you want more information.

Please take time to read this form carefully. Feel free to discuss it with your relatives, friends, or your primary care physician. If you agree to take part in this research study, you must sign this consent form.

Disclosure of Financial Interests

The PFF is a non-profit organization and the sponsor of this study. Together with contributions from industry sponsors and individual donors, the PFF is providing funding to support the PFF Community Registry.

Purpose of the Study

The purpose of this study is to collect information from individuals with PF or ILD including lung transplant recipients, as well as their caregivers and family members. By collecting information over time, we are hoping to build a database of information, which can then be used by researchers working to understand how this disease progresses over time and responds to treatments.

Number of Subjects and Length of Study Participation

Up to 100,000 individuals in the United States will be invited to participate in this study online via a secure web portal. There is no physical location associated with this research study, and there is no cap on enrollment.

Your participation in this study is expected to continue for at least 3 years. We will ask if you can complete a set of surveys every six months, as long as the PFF Community Registry is running. The project is funded for at least 3 years with the potential to continue. You may withdraw at any time.

Study Procedures

If you agree to take part in the PFF Community Registry, you will be asked to log in from your personal computer or device onto a secure web portal every six months and complete a set of surveys. If you are a person with PF or ILD, or if you received a lung transplant due to PF or ILD, these surveys will ask questions about your health history, treatments you may be taking, symptoms experienced, and your lifestyle. If you are a caregiver or family member, these surveys will ask about the health history of the person you care for, treatments they may be taking, symptoms experienced, and their lifestyle. On average, this will take 45 – 60 minutes or less to complete each time. These questions are like those commonly asked in a health care setting, but if you are uncomfortable answering any question, you are welcome to skip over it.

You also will be asked if you are interested in being contacted for other research projects in the future and/or if you would like to be notified of PF support and educational events in your area

from time to time. You do not have to agree to be contacted for future research or about support/educational events to take part in the main PFF Community Registry.

Risks and Discomforts

There are no physical risks anticipated with completing surveys online. As with any research study and providing information online, there is a risk of breach of confidentiality. To minimize this risk, participants will be asked to log into a web portal, using a user ID and password, before providing any information. The same regulations that govern how a doctor's office stores your electronic health record are utilized in the PFF Community Registry. Additionally, the PFF Community Registry will operate under a Certificate of Confidentiality from the National Institutes of Health (NIH). For more information about privacy and data sharing, please see the "Confidentiality" and "Authorization to Use and Disclose Personal Health Information" sections below.

New Information

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

This is not a research study looking into a particular treatment such as a drug or device. Information is being gathered to promote additional research and may not result in any clinically relevant research results in and of itself. There are no specific plans at this time to share information back with participants regarding insights generated from this research. However, the PFF regularly posts updates on research activities coming from the PFF Community Registry, including publications, on their website.

Benefits

You may not receive any medical benefits from being in this study. However, you may receive information and participate in study measures that ultimately may help you become more informed, activated, and engaged in your health care. Additionally, this study may benefit future patients who have PF or ILD.

Alternatives to Study Participation

This is not a therapeutic study. Participating in the PFF Community Registry, or not participating, will have no effect on the condition of treatment for you, the person for whom you provide care, or your family member.

You do not have to take part in the PFF Community Registry. If you are interested in finding other ways to support people affected by PF or researchers, please visit <https://www.pulmonaryfibrosis.org/>.

Costs of Participation

There is no cost to you to participate in the PFF Community Registry.

Reimbursement

You will not receive any reimbursement for taking part in the PFF Community Registry. Researchers using information gathered by the PFF Community Registry may make novel discoveries. However, you would not be entitled to any compensation from them.

Confidentiality

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and their representatives. Other regulatory agencies, such as the Institutional Review Board, Biomedical Research Alliance of New York (BRANY), may review information provided to make sure the study is being conducted ethically. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications. However, you will not be identified in these presentations and/or publications.

A description of this research study will be available on <https://clinicaltrials.gov/>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Authorization to Use and Disclose Personal Health Information

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. You will choose how much information to share with the PFF Community Registry by entering information directly into the web portal.

Information you report about your health during and after the study, may be used by the study sponsor and given to other researchers. “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:

- Department of Health and Human Services agencies
- Governmental agencies
- The Biomedical Research Alliance of New York (BRANY) Institutional Review Board (IRB)
- Accrediting agencies
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you take part in additional research studies)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. 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.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

Collection of Identifiable Private Information

Identifiers might be removed from your identifiable private information. After such removal, the information may be used for future research studies or distributed to another investigator for

future research studies without your additional informed consent (or consent from your legally authorized representative).

NIH Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Voluntary Authorization to Use and Disclose Personal 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. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. 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 may not be allowed to look at or copy your information until after the research is completed.

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 PFF at the mailing or email address at the beginning of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. 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.

Voluntary Participation and Withdrawal from the Study

Your participation in this study overall is voluntary. You may decide not to participate, or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the PFF by sending written notice to the mailing or email address at the beginning of this informed consent form.

Your participation in this study may be stopped without your consent at any time and for any reason by the sponsor or regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you do not follow the study instructions, the study is stopped, or for other administrative reasons.

Contacts for Questions, Complaints, Concerns

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, you may contact the PFF at (844) 825-5733 or registry@pulmonaryfibrosis.org.

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns, or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

Optional Research and Educational Information

From time to time, researchers may also wish to reach out and ask if you would be willing to participate in an additional survey or project. Participating in these extra research projects are completely optional. You may choose not to partake and remain in the main PFF Community Registry.

Would you be willing to allow researchers to contact you about future research projects?

- Yes, you may contact me about future research projects.
- No, do not contact me about future research projects.

Would you be interested in finding out more about upcoming educational events or experiences sponsored by the Pulmonary Fibrosis Foundation? This may include information about fund raising events or activities.

- Yes, you may contact me about future education events.
- No, do not contact me about future education events.

Statement of Consent – Signatures

By signing this form, I confirm the following:

- I have read all this consent form.
- All my questions have been answered to my satisfaction.

- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)

Signature

Date

Submit Consent Signature