DEPARTMENT OF RESPIRATORY MEDICINE, ST. VINCENT'S UNIVERSITY HOSPITAL, DUBLIN

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: IPF/PPF Apple Study

NAME OF PRINCIPAL INVESTIGATOR: Dr Cormac McCarthy

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to monitor participants with a diagnosis of Idiopathic Pulmonary Fibrosis or Progressive Pulmonary Fibrosis. Participants will be given an Apple smartwatch series 6 or above, and an iPhone series 8 (if they do not have one) with an App to answer questions about their symptoms this information will be updated to a research database. The results of this study will be used to better understand the symptoms and trajectory of the disease, as well as develop prediction models for clinical outcomes.

WHY HAVE I BEEN CHOSEN?

You have been chosen for this study as you have a diagnosis of Idiopathic Pulmonary Fibrosis or Progressive Pulmonary Fibrosis and the specialist team providing your care have deemed you to be a suitable candidate for the study.

WHAT WILL HAPPEN IF I VOLUNTEER?

Your participation is entirely voluntary. If you initially decide to take part you can subsequently change your mind without any adverse consequences. This will not affect your future treatment in any way. Furthermore, your doctor may decide to withdraw you from this study if they feel it is in your best interest.
If you agree to participate, you will be requested to wear an Apple watch for at least 20 hours per day, and to complete electronic questionnaires on a mobile application on an iPhone about your symptoms. Weekly questionnaires consist of a breathlessness and cough rating which take less than 1 minute to complete. Monthly fatigue and cough questionnaires take approximately 15 minutes in total to complete. Every three months a health-related quality of life questionnaire will take approximately 10 minutes to complete.

You will also come to your usual outpatient clinic appointments where you will have routine lung function tests, radiology tests and give blood samples where they are necessary for your care.

Study visits, apart from the baseline visit, will happen on clinic days. The baseline visit will require additional time spent with the study research team member for initial training on the use of the Apple watch and iPhone App. Once participants are on-board the study

subsequent study visits will be routine as per usual outpatient clinic visits and standard care with the specialist rare lung disease team. Before you leave your clinic visit Apple watch data will be exported from your iPhone Health App to our research system. It is important to understand that an Apple Watch is not a medical device, the data gathered from the Apple watch will not be monitored by hospital staff real-time but will be used to update our research system every four months when you come to clinic. You should follow your doctor's advice on the use of approved medical devices for monitoring your blood oxygen levels to adjust your supplemental oxygen requirements.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

It is hoped the study information we will obtain may provide further knowledge of this condition, and can be used to inform treatment in future.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no increased risks associated with this study above standard care at outpatient clinics, which will include minimal risks associated with taking blood samples and radiology images. It is an observational study to collect real-time participant data.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

If you decide not to participate in this study your treatment will not be affected in any way.

CONFIDENTIALITY

Your identity will remain confidential. A study number will identify you. Your name will not be published or disclosed to anyone. Anonymised results will be published in medical journals and presented at peer groups.

COMPENSATION

Your doctors are adequately insured by virtue of their participation in the Clinical Indemnity Scheme.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised and funded by HRB-Trials Methodology Research Network, UCD Clinical Research Centre, Prof Michael Keane & Prof Peter Doran Research funds.

Will, I be paid for taking part in this study? No

Will my expenses be covered for taking part in this study? Travel costs related to attending the baseline visit will be reimbursed.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

The St. Vincent's Healthcare Group, Ethics and Medical Research Committee have reviewed and approved this study.

CONTACT DETAILS

Principal Investigator: Dr Cormac McCarthy (01) 221 3702

RESEARCH PARTICIPANT'S RIGHTS

If you have any questions about your rights as a research participant, then you may contact the Hospital's Quality & Patient Safety Department 01 2214013

CONFIDENTIALITY & DATA PROTECTION

1. INTRODUCTION

1.1 This Participant Information and Consent Form provides guidance and information to IPF/PPF Apple study research participants regarding the processing of the research participants' personal data. St. Vincent's University Hospital is committed to protecting and respecting your privacy. This Participant Information and Consent Form together sets out the basis on which any personal data we collect from you or that you provide to us will be processed by us an independent data controller. Please read this Participant Information and Consent Form carefully to understand our treatment and use of your personal data.

1.2 The processing of your personal data will be in compliance with the Data Protection Acts 1988 to 2018 (as amended) and the General Data Protection Regulation (the "Data Protection Legislation").

1.3 Please note that agreeing to participate in a research program with St. Vincent's University Hospital, you acknowledge that you have read, understood and agree to this Participant Information and Consent Form.

2. IDENTITY OF THE CONTROLLER OF PERSONAL INFORMATION

For the purposes of the Data Protection Legislation, St. Vincent's University Hospital is an independent data controller in the following circumstances:

1.	**SVUH – Facility Provider for patients and clinical care** **Company Type**: PLC **Company Registration number** : 338585 Having its registered office at: SVUH, Elm Park, Dublin 4 **Dr Cormac McCarthy – Principal Investigator and clinical care** **Company Type:** SVUH Employee**,** **Company registration number -** NA Having its registered office at: SVUH, Elm Park, Dublin 4

3. CONTACT DETAILS OF THE DATA PROTECTION OFFICER*

3.1

The data protection officer for SVUH and PI is: Sean Gibney, SVUH, Elm Park, Dublin 4, Contact 01 221 3591 Email: dataprotection@svuh.ie

4. PROCESSING OF YOUR PERSONAL DATA

St Vincent's University Hospital will process your personal data for the following purposes on the basis of your consent:

Personal data	Purpose of processing[1]
1. **Identification e.g. name, address, DOB (please note this and subsequent information will be anonymised/coded once leaving SVUH)**	1. **(a)Originally captured as part of medical care (b) used for purpose of carrying out research**
2. **Test results**	2. **Research outcome analysis**
3. **Clinical History**	3. **PMH relevant to study research outcome analysis**
4. **Real-time biometric data collected by wearable device Apple watch**	4. **Statistical analysis , to build prediction models for clinical outcomes**
5. **Questionnaire (PROMS) data collected by iPhone App**	5. **PROMS to measure disease progression also for statistical analysis , to build prediction models for clinical outcomes**

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4.1 Where does St. Vincent's University Hospital obtain my personal data from?

Most of the personal data we process is obtained from you directly but we also obtain personal data about you from your

- medical notes,
- lab test results,
- radiology results,
- lung function tests
- wearable Apple device,
- iPhone App questionnaire responses,

5. SHARING OF PERSONAL DATA

Your personal data will in particular be shared with:

*NOTE: These parties will either be acting as Processors of your information as part of this research study e.g. CROs, non-SVUH employees supporting research process or Controllers in their own right.

Person/Company/institute	**Requirement for sharing**
Research Study team Sinead Holden (UCD) Emer Gunne (UCD)	Data analysis and Prediction modelling - UCD Clinical Research Centre

5.1 Service Providers

We use third party service providers who provide services including financial services, occupational health and IT services. In providing the services, your personal data will, where applicable, be processed by the service provider on our behalf.

We will check any third party that we use to ensure that they can provide sufficient guarantees regarding the confidentiality and security of your personal data. We will have written contracts with them which provide assurances regarding the protections that they will give to your personal data and their compliance with our data security standards and international transfer restrictions.

5.2 Disclosures to Third Parties

In certain circumstances, we share and/or are obliged to share your personal data with third parties outside St. Vincent's Hospital, for the purposes described above and in accordance with Data Protection Legislation.

These third parties include but are not limited to:

- the Health Products Regulatory Authority;
- the Health Service Executive;
- the Joint Commission International;
- relevant industry bodies;
- external professional advisors; and
- others, where it is permitted by law, or where we have your consent.

6. TRANSFERS OUTSIDE THE EUROPEAN ECONOMIC AREA[2]

6.1a We will not transfer, store or process your personal data outside the European Economic Area.

6.1 If you would like to see a copy of any relevant provisions, please contact your data protection officer (see "Contact Us" section below).

7. HOW IS MY PERSONAL DATA SECURED

7.1 St. Vincent's University Hospital operates and uses appropriate technical and physical security measures to protect your personal data.

7.2 We have in particular taken appropriate security measures to protect your personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access, in connection with this research study. Access is only granted on a need-to-know basis to those people whose roles require them to process your personal data. In addition, our service providers are also selected carefully and required to use appropriate protective measures.

8. STORAGE OF PERSONAL DATA

We will keep your personal data for 10 years. This may mean that some Information is held for longer than other information.

9. YOUR RIGHTS

9.1 You may have various rights under Data Protection Legislation. However, in certain circumstances, these rights may be restricted[3]. In particular, your rights may be restricted where this is necessary: (i) for the prevention, detection, investigation and prosecution of criminal offences; (ii) in contemplation of or for the establishment, exercise or defence of a legal claim or legal proceedings (whether before a court, tribunal, statutory body or an administrative or out-of-court procedure); and/or

(iii) for the performance of a task carried out in the public interest or in the exercise of official authority vested in St. Vincent's University Hospital.

These rights may include (as relevant):

(i) **The right of access** enables you to check what type of personal data we hold about you and what we do with that personal data and to receive a copy of this personal data;

(ii) **The right to object** to processing of your personal data where that processing is carried out on the basis of our legitimate interests. We will stop using your personal data unless we can demonstrate an overriding legitimate ground for the continued processing of this personal data;

(iii) **The right to rectification** enables you to correct any inaccurate or incomplete personal data that we hold about you;

(iv) **The right to erasure** enables you to request that we erase personal data held about you in certain circumstances;

(v) **The right to restrict processing** of your personal data by us in certain cases, including if you believe that the personal data held about you is inaccurate or our use of the personal data is unlawful; and

(vi) **The right to data portability** enables you to receive your personal data in a structured, commonly used and machine readable format and to have that personal data transmitted to another data controller

10. YOUR RIGHT TO LODGE A COMPLAINT WITH A SUPERVISORY AUTHORITY

10.1 Without prejudice to any other administrative or judicial remedy you might have, you may have the right under data protection legislation in your country (where applicable) to lodge a complaint with the relevant data protection supervisory authority in your country (i.e. the Office of the Data Protection Commissioner in Ireland) if you consider that we have infringed applicable data protection legislation when processing your personal data. This means the country where you are habitually resident, where you work or where the alleged infringement took place.

11. CHANGES TO THIS INFORMATION

11.1 We may decide to make changes to this Participant Information and Consent Form. If a change is made, we will notify you in person of such changes. An updated Participant Information and Consent Form will be provided to you in advance of any change actually taking effect.

12. CONTACT US

12.1 For further information or if you have any questions or queries about this Participant Information and Consent Form, please contact:

Sean Gibney, Data Protection Officer, St Vincent's University Hospital
Elm Park, Dublin 4
By email: dataprotection@st-vincents.ie
By telephone: (01) 221 3591

CONSENT FORM

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information and Consent Form YES □ NO □
- I have had the opportunity to ask questions and discuss the study YES □ NO □
- I have received satisfactory answers to all my questions YES □ NO □
- I have received enough information about this study YES □ NO □
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES □ NO □
- I am aware of the potential risks, benefits and alternatives of this research study. YES □ NO □
- I consent to take part in this research study having been fully informed of the risks, benefits and alternatives. YES □ NO □
- I give informed consent to have my data processed as part of this research study. YES □ NO □

STORAGE & FUTURE USE OF INFORMATION:

- I give permission for material/data to be stored for possible future research related to the current study only if consent is obtained at the time of the future research but only if the research is approved by a Research Ethics Committee. YES □ NO □
- I give permission for material/data to be stored for possible future research related to the current study without further consent being required but only if the research is approved by a Research Ethics Committee. YES □ NO □
- I give permission for material/data to be stored for possible future research unrelated to the current study only if consent is obtained at the time of the future research but only if the research is approved by a Research Ethics Committee. YES □ NO □
- I give permission for material/data to be stored for possible future research unrelated to the current study without further consent being required but only if the research is approved by a Research Ethics Committee. YES □ NO □

- I agree that some future research projects may be carried out by researchers working for commercial/pharmaceutical companies. YES ☐ NO ☐

- I understand I will not be entitled to a share of any profits that may arise from the future use of my material/data or products derived from it. YES ☐ NO ☐

Participant's Signature: _____
Date: _____
Participant's Name (block capitals): _____

Research Team Member's Signature: _____
Date: _____
Research Team Member's Name (block capitals): _____

Translator's Signature: _____
Date: _____
Translator's Name (block capitals): _____

Legal Rep./Guardian's Signature: _____
Date: _____
Legal Rep./Guardian's Name (block capitals): _____