Supported by NIHR

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The Sheffield Teaching Hospitals Observational Study of Patients with Pulmonary Hypertension, Cardiovascular and other Respiratory Disease (STH-ObS): Participant Information Sheet – COVID-19

STH-ObS is a research study that has been established within Sheffield Teaching Hospitals (STH) since 2008. A central element of the study is a Biobank, a facility for the safe and secure long term storage of samples from patients with pulmonary hypertension, and other respiratory disease, cardiovascular disease and connective tissue disease, and a database to store information about these samples and other tests you undergo. We also collect samples from healthy volunteers for comparison. The aim of this research is to increase our understanding of the causes of these conditions, how they cause symptoms and illness, and help us to develop new ways to diagnose, treat, and prevent diseases. In some cases we may ask if you wish to participate in a study to collect activity or health and symptom related data via your mobile device (e.g. iPhone) or fill in some questionnaires. With your permission, data will be collected to help researchers understand patterns in your activity and information about your cardiovascular health. We may also notify you of other linked research projects, taking part in these are completely up to you.

Why have we asked you to take part?

You are being asked to take part because you have suspected or confirmed COVID-19, have had suspected or confirmed COVID-19 in the past, or are deemed to be at risk of severe COVID-19. We wish to obtain samples and data from these groups of patients for research. We wish to obtain samples and data from those who have had, are suspected to have or currently have COVID-19 for research. Samples will be used to study the coronavirus, its effects on the body and your immune system including looking in detail at the ways in which your body may have responded to, and built up defences against, the COVID-19 virus in order to try and protect you from being infected in the future. Your blood sample may also be used to develop tests, and set reference standards for blood tests, and to make products, including commercial products.

What are we asking you to do?

1. We would like to ask your permission to obtain the data from tests you will have, or have had as part of your routine clinical care and from other research studies you may have been involved in. All data that we collect will be stored in a secure database for use in research.

2. We may ask you to give blood, saliva, nasal and throat swab samples to help our research, we may also ask for urine samples.

3. Some patients may have another illness compatible with COVID-19 in the future. If this happens, we would like to ask permission to obtain a swab from your nose or throat at the time.

4. There are no fixed timescales for you participating in the study. We will aim to collect samples and data from you each time you return to the hospital for a clinical follow-up visit, for as long as you are willing to be involved. If you are not attending hospital clinics, we may contact you to arrange specific research visits.

5. We will ask if you are willing to be approached for additional research tests (described briefly below), more detail will be provided if we get in touch to ask you this but you do not have to do these test if you do not want to.

6. We may contact you ask you for additional consent to participate in studies linked to this research, this is optional.

What will happen if you agree to participate?

The first thing you will be asked to do is give your written consent by signing the form attached to this information sheet. Please keep this information sheet to remind you of what you were asked to do. Once you have agreed to take part, the following will happen:

DATA COLLECTION

- We will ask your permission to obtain data that is collected during your normal clinical care and other research projects that you have been involved in (where ethical approval allows this). This will include information about your condition, other diseases, previous assessments and treatments, test results, and images (such as X-ray, CT or MRI scans). The research team will collect this data from your medical records, and store it in a secure research database at the Royal Hallamshire Hospital. We will use this data in research.

- We would like you to give permission for regulatory authorities or officials from STH or University of Sheffield to have access to your medical notes and any data we collect for monitoring purposes.

BLOOD SAMPLES

- We may collect blood samples from you over the course of your illness, during your recovery and into the future, this is to understand more about your body's defences against COVID-19 and whether there is any long term effects of the COVID-19 virus. Wherever possible, if you are coming into hospital for clinical follow-up, we will collect blood for research at these visits. This will be like any other blood donation and should not harm you. You are free to refuse to give a repeat sample and your clinical care will not be affected. If you are not coming into hospital routinely, we may contact you to ask you to come in to donate blood. You are free to say no to this at any time, this will not affect your involvement in other parts of the study.

- No more than 100ml (6 tablespoons) of blood will be taken for research at any one time and no more than 100ml (6 tablespoons) will be taken for research in any 24 hours. This will be in addition to any blood that you have to give for clinical purposes.

SALIVA SAMPLES

- We may collect a sample of saliva from your mouth using a swab each time you have a follow-up or research visit.

NOSE OR THROAT SWABS

- We may ask you for a nose or throat swab at your visits. For example, if in future if you have another illness related to COVID-19 we will ask to take another swab to test for the virus.

URINE SAMPLES

- We may collect urine samples while you are in hospital and may request additional samples each time you have a clinical follow-up or research visit.

All blood, urine and saliva samples will be stored in the Sheffield Biorepository at the Royal Hallamshire Hospital, which is a secure storage facility licensed by the Human Tissue Authority.

MOBILE AND HOME ACTIVITY DATA (OPTIONAL)

We are interested in determining whether everyday activity data measured by 'smart' devices and sensors are helpful in assessing disease. We are currently working with expert partners including Stanford University, Samsung and colleagues at the University of Sheffield. A member of the STH-Obs research team will inform you about this research taking place at Stanford University, USA called "My Heart Counts" which uses a mobile App. If you are interested in taking part, you can download the app for free onto your iPhone or other mobile device. If you agree to participate in the MyHeartCounts study you will be given a unique MyHeartCounts study identification number. The app will collect data about your levels of daily activity. The STH-Obs research team in Sheffield will then be able to use the MyHeartCounts activity data to link it to the STH-Obs study data and make direct comparisons between hospital exercise tests and your daily activity. The Stanford University researchers will not have access to any of your clinical data.

We have similar arrangements with PAI Health to obtain heart rate data, Samsung for their ACTIVAGE programme, and investigators at the University of Sheffield for their Aequora programme. Agreement to participate in either of these studies may involve the receipt of smart devices and home sensors which would be installed in your home (with your consent) by authorised specialist installers.

If you agree to participate in home or activity sensing tests, the study team will contact you provide you with further information about these studies and how to get involved.

If you are interested in being contacted please provide your email address on the consent form. This will be stored securely by the STH-ObS study team. No one other than the STH clinical team and the STH-Obs research team will have access to your clinical data.

OPTIONAL ADDITIONAL RESEARCH TESTS

There are several different tests we may want to perform and you can give your permission to have all, some, or none of these performed. Your clinical care will not be affected in any way. If you agree to be contacted for this purpose, we will send you an additional information sheet with more details of these tests if there is an opportunity to take part in STH-ObS sub-studies involving these. These optional additional tests may be:

- Exercise Tests
- Magnetic Resonance Imaging
- Breath analysis
- Mobile and Home Activity Data
- Health-related questionnaires
- Interviews

If you give your permission to take part in these additional tests the study team will provide you with detailed further information about what these tests involved.

USE OF SAMPLES AND DATA IN RESEARCH

The samples and data that you donate will be stored indefinitely, for as long as we have the required ethics and research governance approval to undertake this research.

Researchers may request access to the samples and data that we have collected from you and other participants. A Scientific Advisory Board will review applications for samples and data to ensure the research meets appropriate standards. If the request is approved, we will provide the samples and data to the researchers. We may share samples and data with clinical, academic, or commercial institutions, from inside or outside the UK.

No readily identifiable information will be given to the researchers, meaning that you nor other participants cannot be identified from the information given. When the STH-Obs provides samples to researchers they are obliged to only use the samples for the research they said they would do. Researchers will be bound by a Material Transfer Agreement reviewed by the Sponsor R&D Department.

Data Protection Information

The University of Sheffield (TUOS) is the sponsor for this study and will act as the data controller. This means that TUOS is responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.sheffield.ac.uk/govern/data-protection

Staff from the Sheffield Clinical Research Facility, as well as research team members from the University of Sheffield, may use your name and contact details to contact you about the study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from TUOS and regulatory organisations may look at your medical and research records to check the accuracy of the research. The only people in TUOS who will have access to information that identifies you will be people who need to contact you about the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. TUOS will keep identifiable information about you for 15 years after the study has finished.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

What will happen if you say no?

You are free to decline to participate in this research. Your decision will NOT affect the care you receive from the hospital or doctor, now or in the future. If you say no, we will not take samples or data from you other than for normal clinical care. We may ask you to help us understand why you said no – but you do not have to tell us.

What happens if you agree to participate but then wish to withdraw from participation?

You can withdraw from the study at any time by contacting the research team (details given below). We will ask you to sign a "Withdrawal of Consent Form" so we can keep a record of anyone who has withdrawn. If you request that you no longer want any of the samples you have previously donated to be used in research, all samples in remaining in storage will be destroyed. If you wish to withdraw your consent, it is possible that some or all of the samples may have already been used by researchers.

What are the benefits to you?

The samples and information that you give will be treated as gifts that could help research to benefit those affected by disease in the future. It is unlikely you will benefit directly from the research as it usually takes many years for research to produce medical advances. The results of research tests involving you as an individual will NOT be put in your health records or told to you, your relatives or your doctors because the researchers cannot identify who you are. However we will publicise the research findings from the tissue bank as a whole on the websites www.lungsheffield.org, the University of Sheffield website https://medicine.dept.shef.ac.uk/news/index.php/2015/07/21/the-pulmonary-hypertension-blood-biobank/ , and the Donald Heath Research Programme website (https://donaldheath.org/home/research/). Findings will also be publicised at research conferences and via publications in academic journals.

What are the risks to you?

There are NO significant risks to donating samples for this research. There are no more risks of giving blood for research than there are for being a blood donor or giving a routine blood sample.

Your clinical and research teams will take every precaution to prevent researchers from obtaining information that identifies you. The only people who will know your identity are the hospital staff and trained research staff dealing with patient records who are bound by a professional duty to protect your privacy.

Other things you should consider

The samples and information you have gifted will be made available to researchers in the UK or overseas, in universities, hospitals or private companies that do medical research. This research will always be relevant to understanding how the body works, which may help us understand COVID-19 in more detail. You will not receive any personal financial reward for making your gift.
Sometimes samples are used for genetic research about diseases that are passed on in families. However any genetic results about an individual will not be revealed to that individual. Your samples will not be used for research involving animals or reproductive cloning.

What if I have any questions or concerns?

If you have questions about this research, please ask a member of the study team by emailing sth.obs@nhs.net, research nurse, or your consultant:

Local Consultants:
Prof David Kiely, Pulmonary Vascular Disease Unit, M Floor, Royal Hallamshire Hospital, Sheffield, S10 2JF
Tel 0114 271 2132

Dr Thushan de Silva, Senior Clinical Lecturer and Honorary Consultant Physician in Infectious Diseases, University of Sheffield Medical School. Tel 0114 2159532

What if there is a problem or if I wish to make a complaint?

If there is a problem, please contact the study team (details above).
If wish to complain formally, you can write to:
Professor Christopher Newman, Dean of the Medical School, University of Sheffield Medical School, Beech Hill Rd, Sheffield S10 2RX.

If you are harmed during the course of the study and this is due to someone's negligence, you may have grounds for a legal action for compensation against the employing NHS Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

The Sheffield Teaching Hospitals Observational Study of Patients with Pulmonary Hypertension, Cardiovascular and other Respiratory Disease (STH-ObS) COVID-19: Patient Consent Form

Thank you for reading the STH-Obs Patient Information Sheet. If you would like to take part, please give your consent by putting your initials in the box labelled "Yes" after the questions below. Then sign and date the form and have this witnessed by a member of the research team.

1. I have read and understand the document "*The Sheffield Teaching Hospitals Observational Study of Patients with Pulmonary Hypertension, Cardiovascular and other Respiratory Disease (STH-ObS) - COVID-19: Participant Information Sheet, version 5 dated 11/12/2020*", and have had the opportunity to ask questions. These questions have been answered satisfactorily and I understand the risks and benefits of giving my samples and clinical information to STH-ObS.

   Yes ☐ **Initials** **No** ☐ **Initials**

2. I give permission to the STH-Obs study team to collect blood, saliva, nose and throat swab and urine samples from me to be used for research.

   Yes ☐ **Initials** **No** ☐ **Initials**

3. I understand that my blood and tissue samples may be used for DNA analysis in this research, and that only the research team will have access to personal data linked to DNA analysis.

   Yes ☐ **Initials** **No** ☐ **Initials**

4. I give permission for information about me found in my clinical, medical, other health-related records or other data from other research studies I am participating in (where the relevant approvals are in place), to be supplied to the STH-ObS study team and stored on a secure study database for research purposes. I understand this includes test results and information that has been collected previously, or will be collected in the future, as part of my normal clinical care or research.

   Yes ☐ **Initials** **No** ☐ **Initials**

5. I agree that samples taken from me, or materials or data derived from those samples, can be used to manufacture tests, treatments or other products, including commercial products.

   Yes ☐ **Initials** **No** ☐ **Initials**

6. I give permission for STH-ObS to store the samples, the clinical information collected during my normal care, and any additional information obtained during additional research tests, and distribute them to researchers whose work has ethical approval and is deemed by the STH-Obs Scientific Advisory Board to be high quality appropriate medical research. STH-ObS will keep my information confidential at all times, researchers will not be able to identify me from any of the samples or information that they receive.

   Yes ☐ **Initials** **No** ☐ **Initials**

7. I understand that giving samples and information for research is voluntary, and that I am free to withdraw my approval for use of the samples or information at any time without giving a reason, without my medical treatment or legal rights being affected.

   Yes ☐ **Initials** **No** ☐ **Initials**

8. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my records.

   Yes ☐ **Initials** **No** ☐ **Initials**

9. I understand that I will not personally benefit, financially or otherwise, from my gift of samples or clinical data.

Yes ☐ **Initials** **No** ☐ **Initials**

10. I am interested in being contacted about mobile and health activity tracking applications *(optional)*.

Yes ☐ **Initials** **No** ☐ **Initials**

11. I agree to be approached by the study team with more details of optional additional tests that may be performed as part of this study *(optional)*.

Yes ☐ **Initials** **No** ☐ **Initials**

12. I agree to be approached by the study team for other research studies *(optional)*.

Yes ☐ **Initials** **No** ☐ **Initials**

Preferred email address for contact by the study team: _____

Name of Participant	**Date**	**Signature**	**Biobank ID**
Name of Person Witnessing Consent (if applicable)	**Date**	**Signature**	**Role**
Name of Study Team Member Taking Consent	**Date**	**Signature**	**Role**

Thank you for agreeing to make this gift to help research.

Create 3 copies - One for patient notes, one for participant, one for site file.