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

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.

Why have we asked you to take part?

You are being asked to take part because you have suspected or confirmed COVID-19 and you have consented to participate in the STH-Obs study and have given consent to be contacted for additional, optional research tests. We would like to invite you to participate in some additional 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. Details of these tests are below. Once you have given consent to any additional tests the research team will speak to you with more details of the sub-studies involving these tests and what we would like you to do. You may choose not to have any additional tests at any time.

OPTIONAL ADDITIONAL TESTS

Exercise Tests

You may have these as part of your normal clinical assessment. This involves performing a series of walking tasks in a measured corridor, under the guidance of a Respiratory Physiologist or Nurse. We may ask you to perform a Cardiopulmonary Exercise Test (CPET) on an exercise bike. These tests take up to 30 minutes. We will only ask if you agree to these tests and do them if we think it is safe for you to do so. We will not ask pregnant participants to undertake strenuous exercise tests.

Magnetic Resonance Imaging

MRI is one way of obtaining pictures of lungs and other areas of the body. Some patients with respiratory diseases will have MRI scans as part of their normal clinical assessment but we may ask you to have one of these as part of our research. The scan takes approximately 60 minutes. You lie in a tunnel which holds a large magnet. Short bursts of radio waves allow the images to be created. You will hear some loud banging noises during the scan which are made by the magnet.

There are only minor risks associated with MRI, and no x-rays or radiation are required. Some patients may experience claustrophobia, and if the patient becomes uncomfortable the procedure can be easily stopped. During the scan we may inject a “contrast agent” into a cannula inserted into a vein in your arm, which improves the image quality, This is used commonly in the NHS when performing MRI. The needle for this will feel like a sharp scratch. Sometimes the contrast agent can cause dizziness and light-headedness, but usually people are not aware of the contrast injection. Rarely, blood pressure can fall, which can be treated immediately with a drip. Very rarely (less than one in 1000 people) an allergic reaction to the contrast is seen. This usually includes skin rash and itchy eyes for a short time. In the unlikely event of a severe reaction, medical staff are on site and will be able to deal with this quickly.

Another type of MRI scanning that we might wish to perform involves the patient breathing in gas which improves the image quality. We may ask you to hold your breath for 15 seconds. The gas, which could be helium or xenon, is inert and harmless, and has been shown to be safe and well tolerated in people with lung disease. However you may become light-headed, drowsy or feel sick for a few seconds. We will closely monitor your oxygen levels throughout the study. We will not ask pregnant participants to undertake MRI.

Breath analysis
Using new breath analysis equipment (which is similar to a breathalyser test), we can analyse the different compounds in your breath. The results may yield information about health and disease which is relevant in our research. If you do this test it requires you to breathe in and out of the Breath Analyser, for up to fifteen minutes.

Mobile and Home Activity Data
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. 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 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.

No one other than the STH clinical team and the STH-Obs research team will have access to your clinical data.

Health-related questionnaires, interviews and applications
Questionnaires are standard tools used in clinical practice and research. We may ask you to complete questionnaires that are used to understand how well you are feeling, physically as well as mentally. The results will be analysed and related to the other measurements of your health and activity.

If you agree to be contacted for this purpose, we may want to contact you for a short interview to understand your experience of your health and symptoms, healthcare and research in further detail. Any interview scripts and themes will be approved by the ethics committee and taking part in this is completely optional.

We may ask you to participate in other studies which collect health related data through a smartphone application, if you choose to do this we can link this data to STH-Obs using your unique ID.

USE OF SAMPLES AND DATA IN RESEARCH

All data generated by these additional tests will be stored and used as described in the main participant information sheet.

Research Tissue Bank Study ID: _____

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The Sheffield Teaching Hospitals Observational Study of Patients with Pulmonary Hypertension, Cardiovascular and other Respiratory Disease (STH-ObS) COVID-19: Additional Tests 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: Patient Information Sheet for Additional Tests, version 2 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**

OPTIONAL ADDITIONAL TESTS

2. I agree to undertake additional exercise tests for the purpose of research, including walking tests or cardiopulmonary exercise tests, if it is safe for me to do so. I understand that I can choose to not undertake these tests at any time.

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

3. I agree to undertake additional Magnetic Resonance Imaging scans for the purpose of research. I understand that I can choose to not undertake these tests at any time.

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

4. I agree to undertake additional Breath Analysis tests for the purpose of research. I understand that I can choose to not undertake these tests at any time.

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

5. I agree to undertake health-related questionnaires for the purpose of research. I understand that I can choose to not undertake these at any time.

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

6. I agree that I may be contacted to have an interview to share my experience of health-care, symptoms and research. I understand that I can choose to not undertake these at any time.

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

Please proceed to sign this form on the next page.

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.