Sirens Study Procedure Scarborough

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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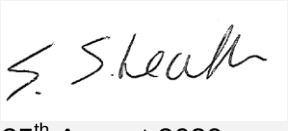
	Signature:	
	Date:	25th August 2020

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	25th August 2020	

Contents

1 Introduction, Background and Purpose

This SIRENS study aims to find out whether healthcare workers who have evidence of prior COVID-19, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection.

We will recruit healthcare workers to be followed for at least a year and study their immune response to the virus causing COVID-19, called SARS CoV2. We will do this by collecting data on their history of COVID-19 infection and any new symptoms. All NHS staff who deliver care to patients are being asked to have a nose and throat swab every other week in order to detect mild cases or cases who do not have symptoms (For more information see Patient Information leaflet in Appendix A)

This SOP will outline the planned procedure for recruitment and follow up at the Scarborough site.

2 Who Should Use This SOP

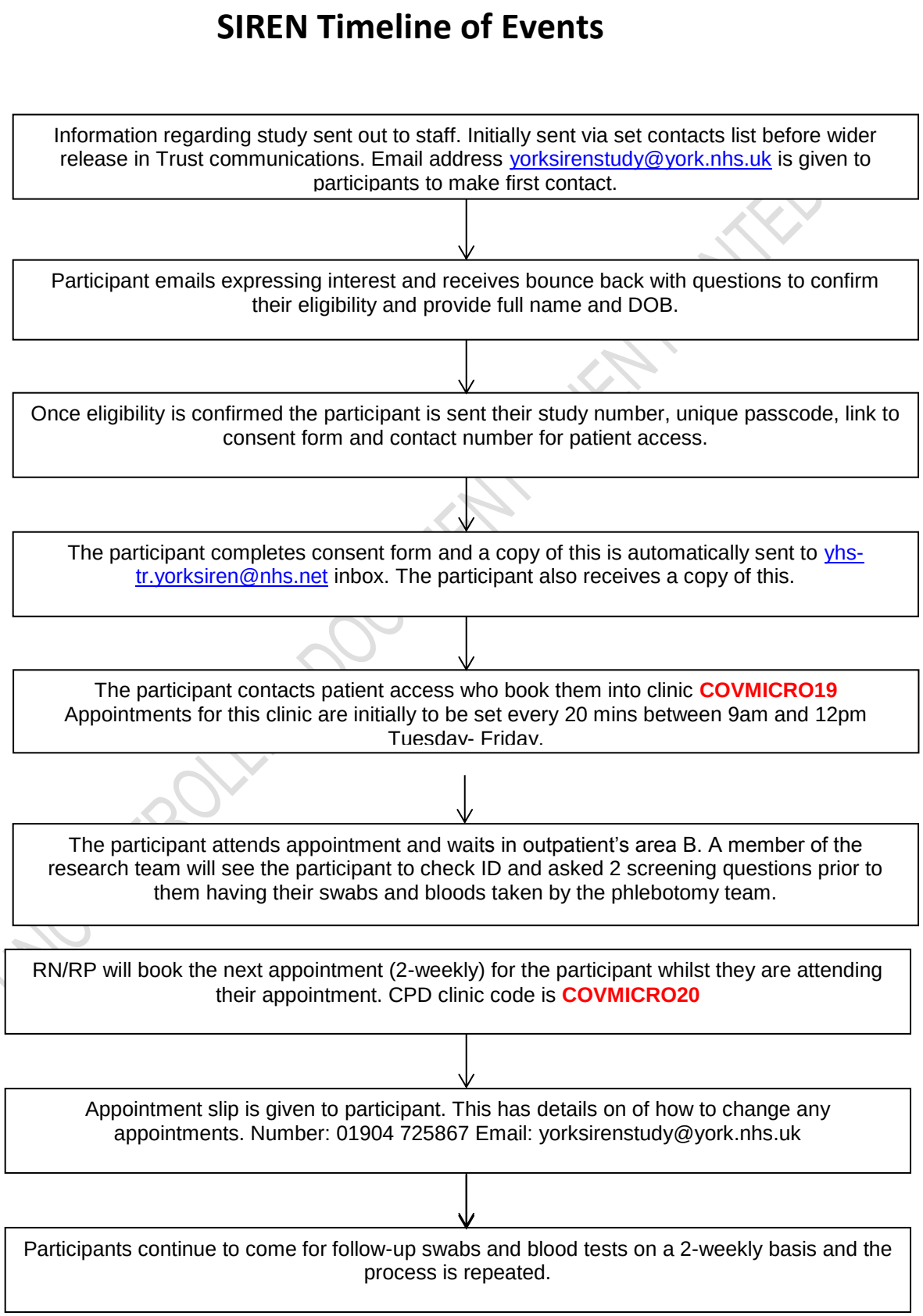
This SOP applies to all investigators, research team members, phlebotomists, administrative and clinical staff involved in running of the SIRENS study at Scarborough.

3 When this SOP Should be Used

This SOP should be used when setting up and planning recruitment to the SIREN's study in Scarborough.

4 Procedure(s)

4.1 Flow chart of process



4.2 Procedure for Research Staff:

(SM – Refers to Staff Member)

1. Ensure request forms are correctly labelled with Barcode and study number
2. RN/RP access clinic appointments via CPD- clinic code: **COVMICRO19** or **COVMICRO20**
3. Start up Edge, CPD & OH spreadsheet
4. Check copy of SM original online consent has been received- helpful to check these before clinics start (**beware:** SM can get a clinic appointment even if they haven't completed the consent form!)
5. SM attends Phlebotomy in Outpatients B. To sit in waiting and then is called through to booked room.

RN/RP to:

i. Confirm SM consent- for new participant access CF and confirm with SM. If follow up appointment reconfirm consent verbally

ii. For new participant- confirm their Tel. No. on OH spreadsheet. For FU confirm it has not changed since previous appointment.

iii. For new participant confirm and record on Edge questions related to previous PCR/antibody tests

iv. Give SM time/date for next follow up (normally 2/52) via CPD- see SOP for guidance. Ensure entry also includes study ID number

v. Copy appointment to Edge- make sure to tick 'global event' so visible in Edge calendars

vi. SM sent through to phlebotomist for samples to be taken

vii. Clean room/workspace as per Trust guidance- all direct contact areas to be cleaned with clinical wipes between participants

- SM receives results of swabs by text from Occupational Health. They are not to look up their own results or request a colleague to look up their results.

Please Note: If there are times when the waiting rooms become overcrowded staff will be asked to wait in their relevant workplace and called to return when appropriate.

4.3 A note on appointment timeframes

We are aware that due to shift patterns, annual leave etc, participants may not be able to get their swabs and bloods exactly every 14 days. However if they are more than 5 days out, please count that as a missed blood/swab and bring them for their next one. If they are delayed or early for their swab you can either start them on a new 14 day test cycle or return them to their old one. Unless there is a clinical reason to do so, please do not test participant more than once in a 7 day period.

4.4 Recruitment and follow up appointments

For the first 2 weeks all the appointment will be recruitment slots (**COVMICRO19).** At the end of the second week we will review capacity with the view to increasing the appointments to 18 per day (one appointment every 10 minutes between 9am and 12pm Tuesday-Friday). Half of these slots will remain recruitment (**COVMICRO19)** and the other half will be follow-up **(COVMICRO20).** Once we hit a total of 144 recruited staff members recruitment will have to stop to allow all follow ups to be completed with the slots available

4.5 Protocol deviations and adverse events/incidents

Participants' safety and quality of study data remains a priority for this project. Protocol deviations (i.e. unable to access participant's blood, bruising from blood sampling or any risk of harm) must be reported via DATIX as per the Trust AIRS Policy.

Please mark the incident as 'occurred on a research study'.

4.6 PPE

As per the Trusts guidance (COVID-19 PPE requirements in non-ward clinical areas (e.g. outpatients, radiology, antenatal clinic v 3.1)
all staff will wear FFP2 (Gloves, Plastic Aprons, Fluid Resistant Surgical Mask, eye protection).

5 Related SOPs and Documents

SIRENS Participant Information Sheet V3.1

COVID-19 PPE requirements in non-ward clinical areas
(e.g. outpatients, radiology, antenatal clinic) v 3.1

6 Appendix A

6.4

6.5 SIREN- SARS-COV2 immunity and reinfection evaluation

6.6 Impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers

INFORMATION LEAFLET FOR PARTICIPANTS

We would like you to invite you to take part in this study to understand whether prior infection with SARS-CoV2 (the virus that causes COVID-19) protects against future infection with the same virus. *Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish.* Please also ask the research nurse if there is anything that is not clear.

Why are we doing this study?

The coronavirus (COVID-19) pandemic is having a major impact across the UK.

COVID-19 is caused by a virus, called SARS-CoV2, and the main way we can diagnose infection with it is to take a swab from a person's nose or throat and look for presence of genetic material from the virus. Once someone has recovered from the infection, the virus is no longer present in the nose or throat. But one way the body fights infections like COVID-19 is by producing small particles in the blood called "antibodies". It takes 2-3 weeks for the body to make enough of these antibodies to fight the infection. When someone gets better, these antibodies can still stay in their blood at low levels – this may help protect against future infections with the same virus.

By doing both swab and blood tests regularly together over time we will be assessing whether prior infection (measured through an antibody test) protects against future infection (detection of virus on a swab).

We will also be trying to improve our understanding of other important areas:

- The blood tests will allow us to understand the number of healthcare workers infected by COVID in the last few months and allow us to understand whether there are differences related to age, ethnicity and other factors.

- By taking regular samples (both swabs and blood), we can measure what proportion of frontline NHS staff that are exposed to SARS-CoV-2 and improve our understanding on how quickly it spreads over the coming months
- By taking blood samples we will understand how the antibody levels change over time and the different types of antibodies that may be present.
- We will also attempt to see how viruses from different individuals relate to each other by comparing the genetic make-up of the viruses.
- If individuals are admitted to hospital, we will explore how individual and virus factors may impact on the illness that people suffer.

Why have I been asked to take part?

You are being asked to take part because you are a healthcare worker and are being offered swabs and blood tests for COVID-19. This study allows us to collect more details about your personal history and symptoms of COVID-19 which allows us to understand the results of the test in more detail. Taking part is voluntary and you should not be placed under any pressure - it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What do you want me to do?

If you decide to take part, you will be asked to complete a registration questionnaire and provide an updated symptom review, nose and throat swabs, blood samples regularly (usually once every 2 or 4 weeks) for up to 12 months. The frequency of the samples will vary related to the amount of virus circulating in the population.
If you have fever, cough or any other respiratory symptoms or you are a contact of a confirmed case of COVID-19 are currently being asked to self-isolate at home, then please access swabbing and complete as you would normally within your organisation. If that is the case, please reschedule your appointment for a later date when you are well and back at work.

What will happen to my sample?

You will be given all your results as they are performed at your local laboratory and the results will be shared with PHE who are conducting the study and also monitor the number of infections in the country. Your sample will be processed as normal to look for active virus from nose and throat swabs; if these samples are positive then you will be asked to follow the public health and government advice and stay at home for at least seven days. The blood samples will be processed in a laboratory to collect the serum and the part containing the majority of cells will be discarded. Your blood samples will be tested for antibodies against SARS-CoV-2. Testing will be done at your local hospital, or a PHE lab. Any remaining serum sample at the end of the survey will be anonymised and incorporated into the PHE Seroepidemiology Unit (SEU) collection, unless you ask us to destroy your sample as soon as it has been tested. Samples stored at the PHE SEU will be used to perform a range of different national serosurveys in the future. If you do not want us to transfer your sample to the PHE SEU collection, this will not prevent your taking part in the surveillance, this is

marked on the consent from. Your personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The donated samples will be treated as a gift meaning that we will not be able to return them to you.

What are the benefits to me?

The study will not benefit you directly, but your participation will help provide important information about SARS-CoV-2 re-infection among clinical NHS healthcare staff and provide a stronger evidence base to inform national guidance and policy. You will be informed of you swab test and blood test results from the hospital as soon as they are available. At the end of the surveillance, the overall results will be published in national reports.

What are the disadvantages?

For some, blood sampling may cause momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of lightheadedness when the blood is drawn, and rarely, an infection at the site of blood draw

What if I change my mind?

If you no longer want to be involved, you can withdraw from the survey at any time by contacting us at SIREN@phe.gov.uk

Will I be given my results?

Yes, you can be given your results according to your local Trust procedures. If you have SARS-COV2 detected on your nose/throat swab, you must follow the self-isolation guidance as you would usually. If you have SARS-COV2 antibody detected in your serological test, you should remember that this does not necessarily protect you against future infection, and you should not change your behaviour. You should take all usual precautions against COVID-19 at home and at work.

What should I do now?

If you would like to volunteer, please go online https://snapsurvey.phe.org.uk/siren/ and complete the online consent form and initial questionnaire. If you have any questions regarding the study, please contact us (contact details below)

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by Berkshire Research Ethics Committee.

How have healthcare workers been involved in the study?

This study has been reviewed by healthcare workers who have participated in other PHE studies (including swab and blood test studies for COVID-19)

What should I do if I have any concerns?

Public Health England as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Susan Hopkins (study email address SIREN@phe.gov.uk) or if you are still unhappy, you can contact the Complaints Manager, Strategy Directorate, Wellington House, 133-155 Waterloo Road, London, SE1 8UG *or email:* complaints@phe.gov.uk

Who is funding the study?

The Department of Health is funding the study through COVID-19 grant in aid monies to Public Health England.

Thank you for reading this information and considering taking part.

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