SARS-CoV-2 **A**cquisition in **F**rontline Health Care Workers – **E**valuation to Inform **R**esponse (**SAFER**)

You are being invited to take part in a research study about your risk of catching the novel coronavirus SARS-CoV-2 which causes COVID-19, at work. This information sheet will explain the purpose of the study and what your involvement will be. Please read this information sheet before you decide to participate. You may want to discuss with colleagues, who may also have been invited to participate, before taking part. Please ask us anything that requires further explanation or anything that is not clear. Take time to decide whether or not to participate.

What is the purpose of the study?

Patients in hospital are at risk of catching SARS-CoV-2 during their admission since they often share open bays with other patients who have the virus before they are isolated. Since patients are often immunocompromised or immunosuppressed or at extremes of age, they are more likely to have a severe illness and even die from SARS-CoV-2. We know that some people have SARS-CoV-2 and are asymptomatic. What is not clear, is whether they can pass this infection on to others.

Health care workers who work during a pandemic are at risk in two ways. They are at risk of catching the infection from their patients, many of whom may be infected but not suspected or isolated. They are also at risk of carrying the infection during work and passing it to their patients. It is not clear which staff are more at risk; those in A/E or those who work in cohort wards.

This study aims to assess whether staff working during a novel coronavirus pandemic are at risk of catching SARS-CoV-2 at work.

Since viral infections can be asymptomatic, we will do this by two ways. Firstly, by testing for the virus in the nose and throat, and secondly by taking blood samples to see if there are antibodies in blood to the virus, indicating possible recent infection.

We are also interested to know whether the presence of nasal bacteria (specifically a bacterial called *Streptococcus pneumoniae*) is associated with increased risk of SARS-CoV-2 infection and Covid-19 disease and to better understand the role of host immune responses. Therefore, if you are taking part in the study in **Liverpool**, we will also ask you to provide samples of saliva and samples from the nose using nasosorption papers. We provide you with small piece of paper to place inside your nostril for two minutes and store in a designated tube. We will provide the equipment to enable you to do this and store the samples for a period of time at home. We will provide an information sheet to explain this in more detail (see Liverpool participant information sheet 2). At enrolment, we may ask to take an extra sample of blood to study immune cells and their responses to stimulation.

You and your data

Participation is voluntary. In this research study we will use information from you. This information will include your:

- Initials
- Name
- Contact details
- NHS number (optional).

Those working on this trial will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number (study code) instead.

We will keep all information about you safe and secure.

Nasal swab samples and blood samples will be stored in freezers in the Virology Department of UCLH or at Liverpool School of Tropical Medicine for participants in Liverpool. To make full use of your samples, we ask that you "gift" your samples to UCLH and Liverpool School of Tropical Medicine. We will store them so that we may use them in the future or send to collaborators involved in infection research globally (universities, NHS organisations or companies involved in health and care research in this country or abroad). We would not send your personal details (see above).

Once we have finished the study, we will keep some of the data so we can check the results and for future research. This data will be kept for 10 years (which is similar to other COVID 19 studies). We will write our reports in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.
All of this information would allow us to better inform staff of risks from working during a viral pandemic and potentially how best to protect themselves. Additionally, we hope it will help to identify ways of reducing the risk of transmission of coronavirus to inpatients.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, by asking one of the research team or by sending an email to Naomi.Walker@lstmed.ac.uk or Catherine.houlihan5@nhs.net.

Taking part in the study:

We aim to recruit at least 100 staff members from various wards in Royal Liverpool University Hospital (Liverpool University Hospitals NHS Foundation Trust) and at least 100 staff members at University College Hospital. Since we know staff are busy when at work and require undisturbed break times, we will provide swabs which can be used at a convenient time. We will also text you (if you consent to this option) or come onto the ward frequently to remind staff to participate and offer swabs. Each interaction should take 1-2 minutes.

If you decide to take part in the study, you will be asked to sign a consent form and be given a copy of this in addition to this information sheet to keep. Once you have signed the consent form, the researcher will ask you to complete a short questionnaire and then instruct you on how to collect your nose and throat swab yourself and observe the first swab sample. This sample will then be labelled with your study code and then stored for processing after the study period. Samples will be stored for up to 10 years.

We will ask you to complete a brief baseline questionnaire, providing information about yourself, your role in the hospital and baseline health status. If you prefer not to share health data, you will be able to indicate that on the form. We will give you training on nose and throat sample collection. We will take a blood sample at enrolment (up to 40ml) and at four-week intervals (10mls) for the duration of the study – 4 blood samples in total.

During the study we will ask you to record any known Covid-19 contact. If you are unwell with symptoms compatible with Covid-19, we ask you to report your illness to the study team and record the number of days you remain away from work and whether you receive a Covid-19 diagnosis as the result of routine clinical testing. If you are self-isolating, we may arrange for a sample kit to be delivered to you and arrangements for its storage and collection will be made. **You should continue to follow national and trust guidance about how to report and manage your illness and you should be assessed and treated by routine clinical services as required through the duration of your participation in the study.** We request your permission to seek information about any Covid-19 diagnosis (if this occurs) from your clinical records. This is optional and not essential for participation.

This sample will be tested for SARS-CoV-2 at the end of the study. Whilst you are at work during the study period, the researcher will visit the ward frequently and request that you take a nasal swab or remind you to take one twice per week. The researcher can send you a reminder text message if you provide your mobile phone details. The researcher will also ask you to complete the brief questions on the form.

At the end of the study period, or your time on the selected ward, the one final nasal swab will be requested 3 days after you have left. This can be posted to your house. All samples will be stored in the freezer and tested at the end of the study, so you will not be able to know if you have caught novel coronavirus at the time. If you become ill with symptoms of Covid-19 and self-isolate, swabs may be collected from your home. Again, these will not be tested until the end of the study.

Some participants will be asked to undergo a longer interview about their experiences of working on Covid/haematology/acute medical wards, ITU and/or A&E during the study. This should take less than 30 minutes and participation is an additional voluntary option.

Potential harms or risks to participants:

The collection of weekly nose and throat samples and monthly blood samples is considered to be minimally arduous for participants. Potential harms:

Venepuncture: taking blood samples may cause some discomfort and occasionally result in a bruise.

Throat swab: participants may gag a little when the sample is taken**.**
Nasosorption: (similar to a paper swab) this can tickle but is not painful.

As the study analysis is retrospective, there is no anticipated impact on your ability to provide clinical care during or after the study. You should continue to follow National and Trust guidance on assessment of your symptoms and testing for Covid-19.

During the study, samples will be stored in freezers in the Virology Department of UCLH or Liverpool School of Tropical Medicine. Sample testing will be arranged by the research team at the host institutions.

The overall findings from the study will be shared with participants and published in peer-reviewed literature. No results from staff members will be linked to their personal medical records at any point. Specifically, participant's SARS-CoV-2 results will not be seen by their GP, employers, supervisors, colleagues, occupational health team or infection control.

Organisation and funding of the study

The research study is being carried out by staff at the Department of Virology, The Farr Institute, (part of University College London), the Centre for Research in Infection and Sexual Health (part of University College London), Liverpool University Hospitals NHS Foundation Trust and Liverpool School of Tropical Medicine.

Time to Consider

You can decide to participate after reading this information form and completing the consent form, or you can take time to decide whether to participate.

Who Should You Contact with Questions?

You will be given a copy of this information sheet and the signed consent form to keep.
If you have any problems or questions about this study or your rights as a patient in clinical research you should contact:

Study doctors: Dr Catherine Houlihan (UCLH) Catherine.houlihan5@nhs.net
Dr Naomi Walker (RLUH) Naomi.walker@lstmed.ac.uk
Dr Nina Vora (UCL) nina.vora@ucl.ac.uk

Telephone contact (between 0900 and 1700 Monday-Friday): Rebecca (UCL): 07557289967 or Abby (UCL): 07506922239 and in Liverpool (the study team on **07740 410 290**).

Thank you for reading the Patient information sheet and for considering taking part in this study. If you have any further questions, please talk to the study doctor or nurse.

Liverpool email: **2volresearch@lstmed.ac.uk**