SARS-CoV-2 Acquisition in Frontline fill in this Health Care Workers – Evaluation to Inform Response-PLUS (SAFER-PLUS)

IRAS: 290628

University College London Hospitals
NHS Foundation Trust

Movement tracking Study

Participant Information Sheet (PIS) and Informed Consent Form (ICF)

WHY are we doing this?

- As part of the wider SAFER–PLUS study that you are currently participating in, we are conducting an investigation into the movements and interactions between healthcare workers and patients within the hospital to better understand virus transmission.
- By quantifying the movements and interactions of individuals, and combining it with virus testing data, we will build a better understanding of the contexts and locations in which virus transmission occurs.
- These insights will feed into models of virus transmission, and allow us to better target infection control policy interventions to reduce the future risk of virus transmission.

WHO can get involved?

- Anyone who is currently taking part in the wider SAFER–PLUS study

WHAT do I need to do?

- If you are interested in taking part please progress to the next screen of this questionnaire and complete the consent form on the last page.
- You will be asked to provide some identification data that will allow us to link your anonymised SAFER–PLUS responses to existing data collected by the hospital.
- You will be asked to download an app to your mobile device.
- This survey will take 5 minutes to complete.
- Participation is strictly confidential and only anonymised data will be disseminated.

More detail about the study is available below.

If you have any questions or would like further information please contact:
Prof Ed Manley: e.j.manley@leeds.ac.uk

UCLH Telephone contact (between 0900 and 1700 Monday-Friday): 07790972176

SAFER-PLUS study email: uclh.saferstudy@nhs.net

Thank you for taking the time to consider taking part in this study.

INVITATION TO TAKE PART IN A RESEARCH STUDY

We would like to invite you to take part in the above research study. Before you decide if you want to take part or not, we would like to tell you why this study is being done, and what you can expect if you do take part. Please read what we have to say carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

WHAT IS THE PURPOSE OF THE STUDY?

Working in the context of an outbreak of a novel pathogen will likely present risks and unique challenges to healthcare workers who continue to work in hospitals during an epidemic. This is a research study about healthcare workers' risk of catching the novel coronavirus SARS-CoV-2, which causes COVID-19, at work. 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.

There are a number of behaviours and measures that can be taken to reduce the risk of acquiring and transmitting COVID-19. These include for instance, use of personal protective equipment (PPE), hand washing, disinfecting objects and surfaces, distancing, etc. There is a lack of evidence regarding the extent to which these measures are used in the context of the current outbreak of COVID-19, and what factors make it easier or more challenging to use these measures.

This study is part of our research programme called 'SARS-CoV-2 Acquisition in Frontline Health Care Workers – Evaluation to Inform Response–PLUS,' or SAFER-PLUS.

This part of the study aims to:

- establish measures of interactions between staff and patients within the hospital, based on proximity and clinical engagement;
- identify virus transmission pathways between staff and patients, and vice versa;
- establish the clinical scenarios, spatial locations, staffing patterns, and broader conditions under which there is a higher risk of virus transmission.

To achieve these aims, we are asking healthcare workers who are currently taking part in the SAFER-PLUS study to download an app that will track their movements within the hospital, and to provide identification data that enables their information and responses to be linked to routinely collected data at the hospital.

If the hospital can accommodate devices then you will also be provided with a wearable Bluetooth device that can be placed on a lanyard or put in a pocket. The device will track your location around the hospital by using Bluetooth to communicate with beacons set up around the hospital.

By enabling us to collect this data, you will help us improve infection prevention control, pandemic preparedness and response.

DO I HAVE TO TAKE PART IN THE STUDY?

No. The decision on whether you take part in the study or not is entirely yours. You can still participate in the wider SAFER-PLUS study without taking part in this study. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. Your line managers and/or colleagues will not be notified of your decision of whether or not you take part.

WHAT WILL HAPPEN IF I DO TAKE PART?

You will be asked to download an app to your mobile device which will track your movements around the hospital. The app will use Bluetooth to communicate with beacons set up around the hospital. If the hospital can accommodate devices then you will also be provided with a wearable Bluetooth device that can be placed on a lanyard or put in a pocket. The device will track your location around the hospital.

We will use the identifiers you provide us with to link together data held by the hospital relating to your interactions with patients and your movement around the hospital. These data include electronic patient records (from the 'EPIC' records system), the staff rota dataset, and card access logs. We will link these data with other responses (including your COVID-19 test results) you have provided on the SAFER-PLUS study, to build a wider picture of your interactions at the hospital.

At all times within this analysis your identity will remain anonymous. We will use your participant identifier (assigned to you as part of the wider SAFER-PLUS study) to link together these responses and maintain your anonymity.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

We do not anticipate that there are any risks associated with your participation, but you have the right to withdraw your consent and involvement in this study at any time by contacting any of the study team.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Your data will help us to better understand the situations and contexts that lead to greater risk of virus transmission. We hope this information will help identify ways of reducing the risk of transmission of coronavirus, strategies to help healthcare workers best to protect themselves, strengthen infection control practices, and future pandemic preparedness and responses.

WILL TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes, all the information that is collected about you during the study will be kept strictly confidential and secure in line with the law as set out in the General Data Protection Regulation (GDPR). We will only use information that we need for the research study and will also follow all privacy rules, and we will make sure no-one can work out who you are from the reports we write.

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 (please see contact details below), and the UCLH Data Controller contact: UCLH.IGQueries@nhs.net

HOW WILL WE USE INFORMATION ABOUT YOU?

We will use the data on your interactions with patients and other staff members to identify and understand the activities and conditions under which virus transmission is more likely. These conditions will relate to the clinical scenarios, hospital arrangement, and staffing patterns that influence interaction between staff and patients, and thus risk of virus transmission. These findings will help inform infection control interventions that reduce future transmission risk. As part of the wider SAFER-PLUS study you will have been assigned a participant ID number so that you cannot be personally identified from the data during analysis and reporting of study findings. We will use this identifier when analysing your data held within the hospital datasets and SAFER study responses.

Anonymised data will be shared with the SAFER research team to enable the analysis to be carried out.

WHAT IF THERE IS A PROBLEM?

If at any stage, you have concerns about the study or the way it has been carried out, you should contact the research team (see contact details below). Taking part in the study does not alter your legal rights in any way if you have grounds for legal action. You can withdraw your involvement in this study at any time.

Any complaints should be dealt with in the usual way through the NHS Complaints Procedure. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital's

Site: University College London Hospitals NHS Foundation Trust

Address: Ground Floor Atrium, University College Hospital, 235 Euston Road, London NW1 2BU

Tel: 020 3447 3042

Email:

When contacting them, please quote the UCLH study / Sponsor reference number: **136676**.

WHAT WILL HAPPEN TO THE RESULTS OF THE TRACKING RESEARCH STUDY?

At the end of the study, we will analyse results and publish in research journals and present in other reports and presentations.

WHO IS ORGANISING THE RESEARCH?

The research is funded by the Medical Research Council (MRC) UKRI: MC_PC_19082, and UCLH Charity. It is Sponsored by University College London Hospitals (UCLH) Foundation Trust and carried out by a research team from the Department of Virology (UCLH) and the University College London Farr Institute, Centre for Behaviour Change and departments of Population, Policy and Practice, Infection and Population Health, Epidemiology and Public Health, Infection and Immunity and Science and Technology Studies, and the University of Leeds

WHO HAS REVIEWED THE STUDY?

This study has been reviewed and given a favourable opinion by the Health Research Authority NHS Research Ethics committee (Cambridgeshire and Hertfordshire IRAS: 290628, Approval ID TBC).

WHO SHOULD I CONTACT FOR FURTHER INFORMATION?

If, at any time during the study, you have questions or concerns regarding the study you can contact the Research Team: -

University of Leeds: Prof Ed Manley: e.j.manley@leeds.ac.uk

UCLH Telephone contact (between 0900 and 1700 Monday-Friday): 07790972176
Study contact email: uclh.saferstudy@nhs.net
Camden and Islington Highgate Mental Health Care Trust:

Harry Clark: researchteam@candi.nhs.uk

Thank you for taking the time to consider taking part in this study.

SARS-CoV-2 Acquisition in Frontline fill in this Health Care Workers – Evaluation to Inform Response-PLUS (SAFER-PLUS)

IRAS: 290628

University College London Hospitals
NHS Foundation Trust

Movement Tracking Study

Informed Consent Form (ICF)

IRAS: 290628; REC reference: 20/EE/0298

SAFER PLUS Study ID:	[user text input]	
No.	**Statement**	**Please Initial Box Below**
1	I confirm that I have read the participant information sheet dated....., version..... for the above study.	[radio button]
2	I have had the opportunity to consider the participant information, ask questions on the above study, and these questions have been answered satisfactorily.	[radio button]
3	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care, legal rights or participation in the wider SAFER PLUS study being affected.	[radio button]
4	I understand that information collected will be anonymised and held and maintained by the study investigators at the host institutions.	[radio button]
5	I agree to allow the use of Bluetooth tracking technology to record my location and interactions within the hospital.	[radio button]
6	I agree to allow the linkage between my SAFER PLUS responses to existing data collected by the hospital.	[radio button]
7	I understand that records of my location within the hospital environment, and interactions with other healthcare workers and patients will be used to study activity patterns, contact patterns and risk factors for COVID-19.	[radio button]
8	I understand that any individual research results from this study will not enter my medical records, nor will they be shared with my employer or anyone else within the host organisation with the exception of the necessary study team members.	[radio button]
9	I understand that the information collected may be used to support other research in the future, and may be shared anonymously with other researchers, and that I will not be able to be identified. .	[radio button]

10	I understand that data collected during the study, may be looked at by individuals from University College London Hospitals, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records"	[radio button]
11	I agree to take part in the above movement tracking study.	[radio button]

Name of Participant:			
Date:		Signature:	

Participants and study researchers will receive a signed copy of this consent form via email

Thank you for taking the time to consider taking part in this study.