

# Pandemic tracking of healthcare workers cohort and questionnaire study

<b>Submission date</b> 19/01/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/02/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The WHO characterised COVID-19 as a pandemic after 118,000 cases and 4,291 deaths. Cases have continued to rise and now 400,000 deaths have been reported. National guidance has recommended physical distancing to reduce transmission of the virus, although healthcare workers are expected to continue with normal patterns of working in order to care for those with the virus. There is early evidence that there is up to a 12-fold increased risk of SARS-CoV-2 infection in healthcare workers, and there have been 245 reported fatalities in UK healthcare workers.

In an environment where there is increased exposure, it is important to understand the occupational, personal, medical and genetics factors which predispose healthcare workers to contracting the virus and make individuals at risk of poor outcomes. There have been a number of epidemiological and serological studies which have identified risk factors such as age, gender and certain pre-existing conditions, but there is less evidence looking evidence in the healthcare worker population.

We set up a study under the Human Tissue Authority licence at the Nottingham Tissue Bank (PANTHER Tissue study) to allow healthcare workers (and their household contacts) to donate samples for testing for research purposes. As of June 2020, 640 participants have consented to donate tissue and over 3000 samples have been collected. This tissue will be subjected to antibody testing, and genetic sequencing to help understand the prevalence of COVID-19 in the healthcare worker population and genetic factors which influence COVID-19.

We would now like to contact participants to invite them to take part in a linked questionnaire study to enrich the human tissue authority study date by providing details about whether they experienced COVID-19 symptoms, their general health and wellbeing (including comorbidities), health related quality of life, and personal and occupational exposure along with questions related to their home circumstances.

### Who can participate?

Healthcare workers and their household contacts who have donated blood to the Nottingham Tissue Bank for use in COVID research

What does the study involve?

Participants will complete sets of questionnaires at baseline and 12 weeks later.

What are the possible benefits and risks of participating?

None

Where is the study run from?

1. University of Nottingham (UK)
2. Nottingham University Hospitals (UK)

When is the study starting and how long is it expected to run for?

April 2020 to November 2021

Who is funding the study?

1. The Medical Research Council (UK)
2. UK Research and Innovation
3. Nottingham Biomedical Research Centre (UK)

Who is the main contact?

1. Jessica Nightingale, [jessica.nightingale@nuh.nhs.uk](mailto:jessica.nightingale@nuh.nhs.uk).
2. Professor Ana Valdes, [ana.valdes@nottingham.ac.uk](mailto:ana.valdes@nottingham.ac.uk)
3. Professor Ben Ollivere, [benjamin.ollivere@nottingham.ac.uk](mailto:benjamin.ollivere@nottingham.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Miss Jess Nightingale

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

285436

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CPMS 47035, IRAS 285436

## Study information

**Scientific Title**

PANdemic Tracking of HEalthcare woRKers Cohort and Questionnaire study

**Acronym**

PANTHER Cohort

**Study objectives**

Healthcare workers are more likely to develop COVID than non-healthcare workers. It is anticipated that certain characteristics (age, gender, ethnicity, occupational exposure) confer an increased risk of infection, and severe disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 27/10/2020 North West - Greater Manchester South Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), ref: 20/NW/0395

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

COVID-19 (SARS-CoV-2 infection)

**Interventions**

We set up a study under the Human Tissue Authority licence at the Nottingham Tissue Bank (Licence holder: Nottingham University Hospitals Trust, Licenced Tissue Bank (no. 11035)) to allow healthcare workers (and their household contacts) to donate blood samples for COVID research. We would now like to contact participants to invite them to take part in a linked questionnaire study to enrich the data collected under the human tissue authority licence by providing details about whether they experienced COVID symptoms, their general health and wellbeing (including comorbidities), health related quality of life, and personal and occupational exposure.

Participants will be asked to complete two questionnaires to provide health and wellbeing information. The first questionnaire will ask about their health and behaviour prior to lockdown and their health and behaviour during lockdown to the point of the first questionnaire. The second questionnaire will be sent at 12 weeks after recruitment and will ask participants to reflect on their health and behaviours in the previous 12 weeks. The questionnaire will ask the individual to provide details of their general health and wellbeing (including PHQ-9 and comorbidities), health related quality of life (EQ-5D-5L), and personal and occupational exposure (These questionnaires and questions are included in the questionnaire attached to the checklist). It will also ask individuals whether they have experienced COVID symptoms, had a positive COVID test or episodes of self-isolation. Participants will initially be sent the questionnaire by post. The postal communication will include a covering letter, participant information sheet, CRF and SAE. Individuals who fail to respond on the 1st attempt will be sent a reminder letter and second copy of the questionnaire.

**Intervention Type**

Other

**Primary outcome(s)**

Health-related quality of life (EQ-5D) at baseline and 12 weeks

**Key secondary outcome(s)**

1. Development of COVID symptoms and antibodies during COVID pandemic, based on self-reporting and blood serology. This was measured during the first national lockdown, at the end of the first national lockdown, and in April 2021
2. Mood assessment measured using PHQ9 during the first national lockdown, at the end of the first national lockdown, and in April 2021

**Completion date**

01/11/2021

**Eligibility****Key inclusion criteria**

1. Healthcare workers and their household contacts who have donated blood to the Nottingham Tissue Bank for use in COVID research
2. Capacity to consent
3. Speak English
4. Minimum age 16 years, no upper age limit

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Declined to be contacted for future research

**Date of first enrolment**

01/12/2020

**Date of final enrolment**

01/08/2021

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Queen's Medical Centre**

Nottingham University Hospitals NHS Trust

Derby Road

Nottingham

United Kingdom

NG7 2UH

**Study participating centre****Nottingham University Hospital**

The Queen's Medical Centre Campus

Derby Road

Nottingham

United Kingdom

NG7 2UH

**Sponsor information****Organisation**

University of Nottingham

**ROR**

<https://ror.org/01ee9ar58>

**Funder(s)**

**Funder type**

Government

**Funder Name**

UK Research and Innovation; Grant Codes: MR/V027883/1

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Nottingham Biomedical Research Centre

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

**IPD sharing plan summary**

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		14/02/2022	15/02/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes