

COVID-19 health professional impact study (CHIP)

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and if you have any queries, please discuss them with friends, relatives, work colleagues or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The COVID-19 pandemic has had a huge impact on healthcare resources and staff in the UK. Understanding the key risk factors associated with infection amongst healthcare workers is essential for future pandemic response plans. Currently there are scarce data relating to the infection rates and associated factors amongst healthcare workers in the UK.

Studies of infection rates in healthcare workers have largely relied on the real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test to date and it appears that Healthcare workers are twice as likely to succumb to Coronavirus infection, when compared to the general population and those from Black and minority ethnic (BAME) backgrounds appear to be particularly at risk.

Currently there is no evidence that the presence of SARS-CoV-2 antibodies provides seasonal or long term immunity to future infection.

Therefore, this study aims to understand the current level of SARS-CoV-2 antibody positivity and try to determine the likely risk to healthcare workers in the UK to COVID-19 infection. We hope to find out whether certain individual characteristics will have an impact on likelihood of infection susceptibility and antibody response and determine the impact of the presence of antibodies on the likelihood of future clinical infection over a 12 month period.

Chairman: Professor Steve Field CBE
Chief Executive: David Loughton CBE
Preventing Infection - Protecting Patients

A Teaching Trust of the University of Birmingham

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The study involves an initial online survey and linkage to your recent antibody test, then a further online survey in 6 and 12 months' time. The data obtained will be linked to data that the HR holds about you.

You also have the option whereby another antibody test will be conducted at 6 and 12 months' time and linked to the data collected. This is optional and if you choose not to participate in the additional blood tests for antibody testing, you can still participate in the survey.

Why have I been invited?

You can take part in the study if you are a member of staff of RWT and have undergone an antibody test as part of standard protocol.

Do I have to take part?

No. Participation is voluntary, and it is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you are still free to withdraw (come out of the study) at any time and without giving a reason.

Also, you can still take part in the main study if you do not want to take part in the optional additional antibody testing.

What will taking part involve?

If you decide to take part, you can access the study via the link given which will direct you to the first online survey.

We will then contact you again in 6 and 12 months' time to complete the online survey again.

Your survey answers will be linked to the results of your antibody test by your mobile and ESR Number. We will also link your answers and results to data held about you by the HR Department.

The survey will take approximately 15 minutes to complete and will include questions on the following: profession; work-line type; demographics and behavioural factors; ethnicity; and symptoms (if COVID 19 was manifested).

The optional antibody testing will involve you attending for another blood test to detect any presence of antibodies at 6 and 12 months which will again be linked to your survey and HR data. We will also require your NHS number in order to link the optional antibody test results to the study data.

What happens if I don't want to carry on with the study?

If you decide you do not wish to take part in the study survey, you can withdraw at any time by pressing the 'Exit' button or by closing your browser window without giving a reason. Any information you have provided prior to your decision to exit the survey will be kept and analysed with your antibody test result if you have provided us with your personal details. If you wish for your data to be removed, you can do so by contacting the research team.

What are the benefits of taking part in this study?

You will not benefit directly from participating in this research but by sharing your information and agreeing to link your antibody test results, you are helping us to determine the likely risk to healthcare workers in the UK to COVID-19 infection, and this information will then help us make recommendations on how to best support NHS staff during this crisis and any future outbreaks.

If you test positive or negative to any of the antibody tests, then you would know if you have had COVID-19 at some point in the preceding 6 months and have antibodies for it. At this moment in time, there is too little information known as to whether this will be of benefit as we do not know how long you would have antibodies for and whether you could catch COVID-19 again.

What are the risks of taking part?

It is possible that you may find answering some questions upsetting in light of the current situation. However, we will provide you with information about available support and relevant resources.

There is a chance of bruising and slight discomfort from the site of blood sampling for the antibody test.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the Trust will have your personal details removed so that you cannot be recognised from it.

How will we use information about you?

The Royal Wolverhampton NHS Trust is acting as Sponsor for this study.

We will need to use information from you provided by completion of the survey and the antibody test you had and from data held by HR for this research project.

This information will include your employee number and your mobile number along with your NHS number (if you participate in the optional additional antibody tests) in order to link the data and we will collect your postcode. People 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 personal details. Your data will have a code number instead.

We will keep all information about you safe and secure.

The separate personal data and research study data we collect for the study will be stored for the length of the study on Trust secure servers under password protection.

Then when the study has finished, the data will be stored for 5 years in a safe and secure archiving facility of which only named personnel have access. Research data results will be kept separate from the personal information collected.

Abbott and Abbott's representatives from Abbott Laboratories Ltd who are funding this study will receive copies of de-identified Study results.

Antibody test samples:

A CHIP study request will be set up on the ICE system (this will capture visit number and participant number) which will link to the laboratory information system (LIMS). The antibody test will be analysed upon receipt of the blood sample into the lab. A specific location or a code within the LIMS will be used to do an automated daily gather to pull the results and these will be imported into an Excel sample log which the lab will maintain and will also enable identification of the samples through a participant number label to facilitate storage of serum at -80oC in the lab. The antibody results will be reported back to the ICE system. The samples will be stored for the full length of the study until the results are analysed which we would envisage being for 1.5 years and then destroyed at the end of the study in accordance with the Human Tissue Authority's Code of Practice.

The results of the optional antibody testing will be kept on the ICE computer system of the Trust and then transferred to an anonymised database with the other research study data we keep on the secure Trust server.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

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 unless you tell us otherwise.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to opt-in to future research using your data saved from this study. The more we know about COVID 19 the more future research will be favourable to prevent future pandemic and benefit the NHS staff and patients.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to andy.smallwood@nhs.net
- by ringing us on 01902 695065 (new ext. 865065)
- by sending an email to Information Governance to rwh-tr.IG-Enquiries@nhs.net or in addition please refer to your Trust policies on GDPR.
- Or the following link: www.hra.nhs.uk/patientdataandresearch

What will happen to the results of the research study?

We will prioritise the dissemination of findings that have the highest potential to guide ongoing support strategies for NHS workers and will share our findings with NHS colleagues responsible for provision of initiative / programmes to support staff. We will also hope to publish the results in a research journal. You will not be identified in any report/publication.

Who is organising and funding the research?

The Royal Wolverhampton NHS Trust and The University of Wolverhampton are organising and running the study with part support from the Local Clinical Research Network and funding from Abbott Laboratories Ltd.

The study has been reviewed by the Cambridge South Research Ethics Committee and a favourable opinion has been given.

Who should I contact for further information?

Whenever you want to get more information about this study please contact:

Prof S Basu
Consultant Haematologist

New Cross Hospital Ext 85271

OR

Andy Smallwood

Research & Development

New Cross Hospital Ext 8648 (new ext. 88648)

If you have any concerns or complaints, then please contact:

Research & Development Directorate Manager

Address Research & Development Directorate, The Chestnuts, New Cross Hospital

Telephone number 01902 695065

If you need any further support, please find below further details:

- [Practical Help](https://www.rwt.nhs.uk/wellbeing/Practical-Help.html) - <https://www.rwt.nhs.uk/wellbeing/Practical-Help.html>
- [Access](https://www.rwt.nhs.uk/wellbeing/Psychological.html) to Peer Listeners and the Serenity Room via this link - <https://www.rwt.nhs.uk/wellbeing/Psychological.html> – contact Amy Steadman amy.steadman4@nhs.net
- National support is available via this [link](https://people.nhs.uk/help/) - <https://people.nhs.uk/help/> and you can download apps to help you by clicking [here](https://people.nhs.uk/help/support-apps/) - <https://people.nhs.uk/help/support-apps/> .
- RWT Safeguarding Team- call 01902 695163.

Thank you for taking the time to read this information.