

PARTICIPANT INFORMATION SHEET

COVID-19 research cohort, part of the NIHR BioResource

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We are inviting adults (aged 16 years or older) who may or may not have symptoms of COVID-19 infection to join the COVID-19 research cohort, which is part of the NIHR BioResource. This form gives information about the study; feel free to ask questions or request more information.

1) Why is this research being done?

The 2019 novel coronavirus pandemic (COVID-19) is affecting the lives of people all over the world. The NIHR BioResource COVID-19 research team will look at immune responses, genetic, microbial and other tests, to increase our understanding of the COVID-19 virus and to help develop diagnostic or prognostic tests, treatments or vaccines for it. Research will also involve analysing health-related information for the above aims and to help predict disease outcomes and inform public health policy.

2) Who is doing this study and who is sponsoring and funding it?

The NIHR BioResource, working with NHS Trusts and researchers across the UK is conducting this study. Cambridge University Hospitals NHS Foundation Trust is the establishment responsible for managing the NIHR BioResource and this study.

3) Who can join this study?

Anyone who is over 16 years of age can join, whether they have symptoms of COVID-19 infection and may have been admitted to hospital for it, or not. The NIHR BioResource COVID-19 research cohort is a group of volunteers from all over the country who have agreed that biological samples (including repeat samples) and information about their health may be collected, analysed and stored for research related to COVID-19.

4) Do I have to join the NIHR BioResource COVID-19 research cohort?

It is completely up to you to decide whether or not you wish to join. If you decide not to join your decision will not affect the healthcare you receive in any way.

5) What happens next if I agree to join this study?

If you decide to join, you will be asked to read and sign the consent form. If you are seen in hospital, your personal details (e.g. name, NHS number) and contact details will be retrieved from your medical records; if you are not a patient we will ask you to provide your personal and contact details (including email and mobile phone if available) in a form and allow us to store them.

Next, we will ask you to donate a blood sample (3-4 tablespoons) and/or other biological samples (e.g. nose/mouth swabs, saliva) at the point of joining the study. We may ask you to donate repeat biological samples, at regular intervals where possible. DNA may be isolated from your sample and will be used to determine your genetic make-up. We will collect, store and analyse health information about you, and this includes accessing your medical or other health-related records (e.g. your GP, hospital, central NHS records).

In the future we will invite you to join the general NIHR BioResource and may invite you to other COVID-19 related research studies (academic or industry-led); you are free to accept or reject these invitations. To protect healthy volunteers from exposure to COVID-19, their recruitment will be undertaken by research staff who have not had contact with patients with known or suspected COVID-19 infection, and in facilities that have not been used for the screening or care of patients with known or suspected COVID-19 infection.

6) What will happen to the samples I give?

Your biological samples will be stored and used in a variety of tests to help understand how our bodies respond to COVID-19. These will include e.g. microbiology, immunology and haematology tests among others.

In addition, we want to know how genes (which are made of DNA) influence disease and we will analyse your DNA and test other components of your blood such as cells, RNA, protein and metabolites. Other researchers may seek access to your samples and related data for COVID-19-related research, but your personal details will never be released to researchers without your knowledge. Your samples will be kept in secure locations.

7) Will my details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all your information will be handled in confidence. Your samples will be labelled with a unique sample study number and information from genetic and other tests will be stored separately from your personal details in secure databases. Access to your personal details will only be available to necessary members of NIHR BioResource, its COVID-19 research team and regulatory authorities who check that this study is being carried out correctly. Our privacy notice is on the <https://bioresource.nihr.ac.uk/> website. De-personalised data about you may be stored in an electronic archive and made available to researchers (academic or commercial) for COVID-19-related research. Researchers will have to make a request to access this data and explain how they will use it. You will not be identified personally in any report or publication arising from the analysis of your samples and/or data.

8) How often will I be contacted?

The NIHR BioResource COVID-19 research team may approach you at intervals in the future for repeat samples and updated information. The NIHR BioResource closely monitors the number of times you are approached.

9) What are the risks and disadvantages of joining the study?

The samples you donate (e.g. blood, mouth swabs) will be taken, where possible, at the same time as your clinical samples are taken for your healthcare. Qualified, experienced staff will collect these samples according to best clinical practice, but sampling can cause some discomfort or bruising.

10) What are the benefits of joining the study?

There will be no direct benefit to you but you will be making a contribution to science and there may be a benefit to the future development of healthcare provision, including related to COVID-19.

11) Can I know the results obtained from my study samples?

Your samples will be taken for research purposes and therefore there will be no feedback of genetic or other test results to you. However, if there are research results regarding COVID-19 that the NIHR BioResource COVID-19 research team feel could affect your care, they will be reported to your clinical care team and/or GP.

12) Are there any payments and what happens if an invention is made using my sample/data?

Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions, even in the event of your incapacity or death.

13) What if I no longer want to be in the study?

You are free to withdraw at any time without giving a reason. If you choose to withdraw, you can either ask us to stop further contact with you, but allow us to continue accessing your healthcare records and using your existing samples for COVID-19 – related research, or you can ask us to also stop further use of your data and destroy your remaining samples. Any research already done with your data and samples cannot be undone.

14) Who do I contact for further information?

If you would like more information or have any queries, contact the NIHR BioResource team on [0800 090 2233] or e-mail us on [nbr@bioresource.nihr.ac.uk], or visit our website [<https://bioresource.nihr.ac.uk/>]