

Sample Collection for Research into the Immune Response to COVID-19 Infection

Lead investigator: Prof. F. Kern, Brighton and Sussex Medical School

INFORMATION SHEET FOR VOLUNTEERS

You have been invited to participate in a research sample collection, but before you decide, it is important for you to understand why the sample collection is being compiled and what it would involve for you. Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is not clear or if you would like more information and time to decide. Your decision is completely voluntary. You do not have to give reason if you do not wish to participate.

Please note that we are using the services of One Research Ltd for the recruitment of participants and the initial telephone interview only. One Research is a professional recruitment company (located at Science Park Square, Falmer, Brighton, BN1 9SB) and not otherwise involved in the conduct of this sample collection or the use of the samples for research.

What is the study about?

We are undertaking a research sample collection from people who have recovered from COVID-19 infection. This infection currently affects over 1 million people around the world. Most cases are mild, but some people become very unwell. This sample collection will help researchers gain a better understanding about various aspects of COVID-19 infection, in particular relating to the body's defence against COVID-19. We are not collecting the samples for one specific project, but for a variety of projects each of which will be evaluated carefully before access to samples is granted. This is more efficient than collecting samples for individual projects. Projects may be funded directly or indirectly by the UK governments's public funding agencies, other public UK or non UK funders, charities, private donations, or by industry on the basis of a research collaboration or contract research. All research projects will require approval by an ethics committee. The aim of all projects using these samples will be to help find better ways to manage and treat COVID-19 infection in the future.

Why have I been invited?

You have been invited, because responded to one of our advertisements and told us that you tested positive for COVID-19 within the last 4 months but have now fully recovered. You have given us the date when you tested positive and also when your symptoms related to the acute illness had entirely disappeared. We have checked the current guidance on self-isolation and concluded that it is now safe for us to invite you to give a blood sample for research at our University of Sussex location. The time since your infection and full recovery is also important to us in a different way, because we need to leave at least 2-3 weeks since the infection for the body's defences to form a mature response to the virus.

What will happen if I take part in this sample collection?

If you agree, we will collect information from you about the severity of the symptoms that you have experienced during the course of your COVID-19 infection as well as some personal information that will help us better understand the results, for example your age, any medications that you are on, or underlying health issues. Also, a blood sample of about 55 ml (equivalent to about 2 table spoons, for comparison) will be taken from a vein in your arm.

We will also ask you, if we may access clinical information about your infection that is available in the NHS (that could be in the hospital where you were treated or at your GP practice). This is however, not a requirement for your participation. We would like to access clinical records only in order to confirm some of the information that we have gathered from you in relation to your COVID-19 infection and in order to assess the severity of the clinical course that you have experienced in more detail. If you do not agree with us accessing your clinical information, you can indicate this on the consent form.

What if the COVID-19 lockdown is still in effect when I travel to the university campus for my scheduled appointment?

If you agree to participate and your appointment is scheduled at a time when the COVID-19 lockdown has not been lifted yet, we will provide you with a letter (sent by e-mail preferably) that you can show in the event that you get stopped by police enforcing lockdown rules. The letter will be in PDF-format so that you can print it off, or have it on your mobile phone or tablet. Brighton and Hove City Council have been informed of our study so that we anticipate no problems.

What will happen to my samples?

We will carefully process your samples, label them and store them. Your samples will be held in facilities registered under a Human Tissues Authority licence (12561). Researchers will use your blood samples to look at how the body fights COVID-19 infection. They may also use your samples to analyse your DNA and RNA in relation to genes involved in immunity and inflammation. They may examine your DNA and RNA to try to find out what makes some people more likely to get an infection or develop severe inflammation.

What will happen to my information?

All information about you will be kept confidential at all times. Only the principal investigator (who is the guardian of all of the information provided) and the team immediately involved in organizing the sample collection will have access to your personal information. Researchers working with your sample will not have access to your name or any other personal information that would allow them to find out who you are. All samples will be labelled with a sample code made up of letters and numbers (e.g. 'MRBCOV19-001-20200501') and will not be able to be directly linked to you personally. No personal information will be used in any reports using samples from this collection for research. The results of any studies done with samples from this collection will be shared as quickly as possible with health authorities, and doctors to help them treat patients with COVID-19 infection.

We will store clinically relevant information about you and your sample in an electronic file under the sample code. Any information that would allow anyone to find out who you are, like your contact details, will be kept in a separate file. The two files are linked by the sample code.

We will only keep the minimum personally identifiable information about you and for a maximum of 10 years. This information will be held securely by the scientists running this study under the control of the University of Sussex. Your consent form will be retained for 10 years. The University of Sussex is responsible for looking after your information and using it properly.

The participant recruitment company, One Research, who passed your contact details on to us along with the information provided by you on the telephone will delete all information about you once we have received it safely.

The data and samples collected during this study may be looked at by regulatory authorities, authorised individuals from the University of Sussex, your hospital, or public health agencies.

Your primary care doctor will not be informed that you are taking part in this study, however, you are welcome to mention it to them if you wish.

Are there any benefits to taking part in this study?

There is no benefit to you personally. The information we learn may help in caring for other patients infected with COVID-19 or other, similar viruses in the future.

What are the risks of being in the study?

If you take part in the study all information will be used anonymously in reports and publications and nobody will know that this information relates to you.

There is a small risk of pain or discomfort when samples are taken. As with any blood draw there is a small risk of bruising, pain, or local infection.

Will I be told about the results obtained with my samples?

We will not be able to inform you of any of the results that researchers may obtain with your samples.

Who is responsible and what if something goes wrong?

The research is organised by Brighton and Sussex Medical School. BSMS has arrangements in place to provide for harm arising from participation in the study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the University of Sussex Research Governance Office, which can be contacted via:

rgoffice@sussex.ac.uk

Can I request that I be withdrawn from the study at any point?

Yes, you can withdraw at any time without giving a reason. Any samples that have not already been analysed can be destroyed anytime you request it. Please contact us using the contact details at the end of this information sheet.

What about future research?

With your consent, we would like to keep your contact details so we may inform you of opportunities to participate in future research led by the same team or collaborative researchers from the University of Sussex concerning different aspects of COVID-19 infection or, more generally, the immune system in infection and inflammation. There is a specific question on the consent form regarding future contact about further research. Agreeing to be contacted does not oblige you to take part in any future research. There is no problem if you do not want to be contacted again and it will not affect your participation in this sample collection or have any other negative consequences for you. You can ask us to have your contact details removed from our database at any time.

Who has approved this study?

This study has received ethical approval from the Brighton and Sussex Medical School Research Governance and Ethics Committee (BSMS RGEC).

Contact details and further information about the study

If you would like more information about the study you can contact Prof. F. Kern, Brighton and Sussex Medical School, MRB, Biology Road, T. 01273/877671, e-mail: f.kern@bsms.ac.uk.

Thank you for taking the time to read this information sheet.