



# UK CIC - Characterisation of COVID-19

## long-term immunity – Participant information

We would like to invite you to take part in a new research study. We want to understand more about the immune response to COVID-19. An immune response is the reaction of our bodies to something it does not recognise. In this case the virus that causes COVID-19.

### What is the purpose of the research?

In March 2019 a new coronavirus (SARS-CoV-2) was identified that causes the disease COVID-19. This has caused a global pandemic, with millions of people infected. Many scientists are now working to develop vaccines and treatments to help slow the spread of the virus. A number of vaccines are now in use across the UK and the world. However, scientists still do not fully know what level of immune response provides protection against the virus, how long immunity persists following vaccination or the effectiveness of the vaccines against new variants of the virus

Reducing the infection rate and finding effective vaccines and treatments all require a better understanding of how the immune system responds to a COVID-19 infection and vaccination. This study aims to look in detail at the long-term immune response of people who have been infected and compare this to the symptoms they had during the infection. It will also compare long-term health outcomes in people who have and have not had COVID-19.

### Why have I been invited to take part?

You have been invited to take part because you are a participant in Children of the 90s and we know whether or not you are likely to have been infected by the virus. We have this information from:

- an answer you gave in earlier questionnaires about COVID-19 OR
- the result of a blood test you completed at home (serology test) for Children of the 90s OR
- information in your NHS medical records indicates you had COVID-19 (if you gave consent for us to look at this)

We are looking for participants in both groups; those who have had the infection and those who have not, so we are able to compare results.

### What will I have to do?

We would like you to attend up to 3 visits over a 12-month period.

#### Visit 1

A 65-minute session at our centre in Oakfield House, where you will;

1. **Provide a blood sample (5 tubes)**  
We will ask for a sample of blood from your arm, this will be taken in the usual way. You can eat and drink as normal before providing this sample. Although we will need to collect 4 blood tubes from you this will not be more than 50ml of blood which is about a quarter of a teacup.
2. **Provide a urine and saliva sample.**
3. **Complete the following physical measures:**  
**Height and weight** – We will measure your height and weight so that we can work out your current BMI (Body Mass Index)

**Respiratory function test** – We will ask you to complete a simple sit to stand test to assess how well you breathe during exercise. We will ask you to get up from a chair and then sit back down as many times as you can in one minute. During this test you will wear a monitor to measure your oxygen level and heart rate.

If you cannot complete a sit to stand test, then you will be asked to complete a 6-minute walk test instead.

4. **Computer based questionnaire.**

You will be asked to complete a short computer-based questionnaire about your quality of life and how you feel when you are doing different types of exercise.

**Visits 2 and 3**

After the first visit your blood and saliva samples will be tested for the SARS-CoV 2 virus and the number of antibodies to the virus will be measured. The results of this will be used to choose some people to continue with the study.

If you are chosen, we will invite you back to do the same tests 2 more times, 3 months and 8-12 months after your first visit.

If after your first visit you go on to have a positive test for COVID-19 or you have symptoms of COVID-19, please let us know.

If we do not invite you back for further visits, this does not mean you have or have not had COVID-19. It just means the level of the response you have at this time is not suitable for this research study and we will let you know that you do not need to do any more visits.

**Because we don't yet know if people can be reinfected, how long vaccinations provide immunity or when people who have COVID-19 are no longer infectious you should continue to follow all government guidance on social distancing to help prevent the transmission of the virus to others.**

**What will you do with my samples?**

- All samples will be stored with unique ID numbers so that we can link your test results to other data about you. Researchers cannot identify you from your samples.
- We will test your saliva for the virus. We will look for the presence of virus RNA (its genetic material) to do this.
- We will look in your saliva and blood to see if we can detect antibodies to the virus, if found, they show that you have been infected by the virus at some point and that your body has responded to this infection. After this, we can then look to see how this response changes at each visit.
- We would like to store some of your blood, saliva and urine for answering more detailed questions. For example, we will store some of your white blood cells, that we know are involved in the immune response. By looking in detail at these cells we will be able to describe how your body has responded to the infection and which parts of the immune system have been involved in this response.

**Will you use my blood sample for DNA and genetics?**

Some of the tests will involve looking at your DNA. With your consent we will extract DNA from your blood for genetic and epigenetic research. We will also use your samples for RNA analysis. RNA is the genetic material that carries out the instructions of DNA. You can find more information about DNA and genes [here](#).

You can choose separately whether to consent for genetic research without it affecting your involvement in the rest of this research study.

### **Future research**

Most of the research using your samples will take place in Bristol but some of your samples may be made available to researchers working in universities, hospitals or other organisations in the UK or abroad to answer other research questions. We may ask for a fee from researchers to help cover the costs of storing your samples as well as the costs associated with sending them to other places. We will not sell or make any profit from the samples you donate, and they will only be used in ethically approved research.

Your data will be used for research purposes only and will only be analysed by researchers who have been approved by the Children of the 90s Executive. None of these researchers will have access to your personal information.

### **How your health data will be used in this research**

If you have previously consented for Children of the 90s to link to your health data then we will be able to access information like if you have sought advice from your GP or 111 or have had a test completed by the NHS for COVID-19. If you had severe COVID-19 symptoms we will also be able to see if you have had care at a hospital. Understanding details about your care will help the researchers understand how COVID-19 has affected different people.

### **Am I eligible to take part?**

Please note that due to the nature of this study if you do not want to provide a blood sample you will not be able to take part.

You will be unable to take part if you:

- are currently taking blood thinners (e.g. warfarin) or have a known clotting disorder

We may have to delay or stop you taking part if you:

- are required to self-isolate under the latest government guidelines:
  - You or someone in your household/bubble are swabbed positive for Coronavirus or are symptomatic of COVID-19 (new continuous cough, fever or change to or loss of sense of smell)
  - You have been asked to self-isolate by the contact test & trace program
  - You have recently returned from a country on the Government's high-risk list
- are in a 'high risk' category and required to 'shield' during this coronavirus pandemic, or you feel you are high risk of becoming unwell if you were to catch coronavirus (e.g. due to underlying health conditions etc)

**Please contact us immediately if you think this may apply to you so we can discuss this with you.**

### **Do I have to take part?**

No – it is up to you to decide whether or not to take part. If you decide to take part, you can withdraw from the research at any time by contacting us at Children of the 90s using the contact details enclosed. If you decide not to take part, it will not affect any other Children of the 90s activities that you or your family may be involved in.

### **Is this COVID-19 safe?**

Children of the 90s and the University of Bristol have implemented a wide range of measures to protect staff, students and visitors while they are in and around the University. This includes the use of face coverings, one-way systems and provision of hand sanitiser and hand washing facilities. In addition, staff and participants involved with this study will have a temperature check on arrival at Oakfield House and there will be limited numbers of participants and staff in the building to enable social distancing. Additional PPE will be worn by staff and participants for the blood sample to be taken as this is the only time we will not be able to maintain 2m social distance.

This study is open to participants across the UK, providing you are able to travel in accordance with current UK government guidance. We understand that this is constantly changing, and we will be happy to discuss how we can best support you taking part in this research.

**Where will it take place?**

Children of the 90s, University of Bristol, Oakfield House, 15-23 Oakfield Grove, Bristol, BS8 2BN

**How long will it take?**

Each visit should last about 65 minutes. Appointments will be available across the day, including some weekend and evening options.

**Will I receive anything for my time?**

As a thank you we will offer you £10, in electronic shopping vouchers (or paid by bank transfer on request), for each visit you complete. We will also reimburse your travel expenses and can provide a taxi or free parking at Children of the 90s, if required.

**Are there any benefits to me if I take part?**

There are no direct health benefits to you for taking part, and this is not a health check or a diagnostic test for COVID-19. We are asking you to help us with research that could help with future treatment and vaccine development for COVID-19.

**Are there any risks or disadvantages if I take part?**

There are no serious risks involved in taking part. You might find giving a blood sample slightly uncomfortable and you might have a temporary bruise on your arm.

**What do I have to do now?**

If you want to take part, call us or reply to this email now to let us know your decision and to book an appointment. If you do not want to take part, please let us know so we do not send you any more reminders about this study. You can find our contact details at the end of this information sheet.

**Confidentiality and data protection**

Any data we collect from you will be stored with an individual ID number but with no personal information (your name, address, or date of birth) attached. Files that link this ID number to your personal details will be securely stored. Data will be used for research purposes only and will only be analysed by researchers who have been approved by the Children of the 90s Executive. None of these researchers will have access to your personal information. Your personal details will not be shared with third parties except for certain service providers working on our behalf. For example, VCars if you ask us to book a taxi for your visit.

Children of the 90s is compliant with GDPR (General Data Protection Regulation) and with the Data Protection Act (2018) for the collection, processing, storage and disclosure of personal information. If you would like to find out more, please see our privacy notice here:

<http://www.bristol.ac.uk/alspac/participants/privacy/>

The results of the study will be published in scientific journals and participants can see a summary of the results. No individual information or names will be published.

**What if something goes wrong? What if I have questions or concerns?**

If you have questions or concerns about any area of this research, please contact Children of the 90s (telephone 0117 331 0010, or email [info@childrenofthe90s.ac.uk](mailto:info@childrenofthe90s.ac.uk)). If we are unable to answer your question or concern directly, we will refer this to the Children of the 90s Chief Operating Officer, or you can do this yourself,

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**Who is organising and funding the research?**

This research is organised by Children of the 90s, the principle investigator is Professor Nicholas Timpson. This study is part of the a larger study called 'A UK underpinning platform to study immunology and immunopathology of COVID-19:The UK Coronavirus Immunology Consortium' (or UK CIC), and the PI is Professor Paul Moss who is based at the University of Birmingham. The research is funded by The Medical Research Council

**Who has reviewed this research?**

- Children of the 90s Executive
- Children of the 90s Ethics and Law Committee (ALEC)
- Children of the 90s Original Cohort Advisory Panel (OCAP)
- An NHS Research Ethics Committee.

**Contact for further information**

Tel: 0117 331 0011 Email [visits@childrenofthe90s.ac.uk](mailto:visits@childrenofthe90s.ac.uk)

**Thank you for taking the time to read about our COVID-19 research  
and for your ongoing support of Children of the 90s.**