



# Participant Information Sheet: Year 12-13 Pupils

**Covid19 Mapping and Mitigation in** 

Schools (CoMMins)

### Invitation to participate

You are invited to take part in a research study to find out more about COVID-19 within schools. The study is being run by the University of Bristol in partnership with Bristol City Council and Public Health England.

Before you decide whether to take part, 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 want, talk about it with others (e.g. colleagues, family members or friends). If anything is not clear or if you would like more information before you decide, please contact us (details at the end of this information sheet).

#### What is the purpose of the study?

The study will test whether 1,000 staff and 4,000 pupils from ~20 primary and secondary schools in the Bristol area have active or past COVID-19 infection. This will help us to track transmission of COVID-19 where people do not have symptoms, as well as where they do. We aim to develop systems to help schools prevent and cope with an outbreak and find out which strategies best support the mental wellbeing of the school community now and in the future.

The study involves several parts, including:

- Every month, for six months, we will test staff and students for COVID-19.
- We will make a map showing where people have had COVID-19 in Bristol. This will help to show how COVID-19 spreads.
- We will use our data to improve models of how COVID-19 spreads in young people.
- We will use data to answer questions like *What makes some people more likely to catch COVID-19?* and *At home, are children more likely to infect adults, or are adults more likely to infect children?*
- We will advise on how to stop COVID-19 spreading. We will help schools to improve their contact tracing.

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

The school you work in has volunteered to take part. We are inviting pupils from your class to take part in the School Study.

#### Do I have to take part?

No. Just because your school has volunteered to be part of the study, it does not mean that you have to take part. It is up to you to decide whether to take part or not. If you decide to take part, you can change your mind and say that you don't want to continue at any time.

If you have any queries, please contact us using the details at the end of this document.

# What will taking part involve?

Your school will be visited by members of our CoMMinS study team. We will show you how to provide a saliva sample. Providing the sample will take less than 5 minutes. We will also ask you to complete a short questionnaire which will ask about your medical history, household contacts and about COVID-19 symptoms experienced previously. This will take around 10-15 minutes.

We will work with schools to make sure arrangements for collecting samples are best suited to participants and school facilities. Project staff will be fully trained and DBS-checked. We will use physical distancing and other infection precaution measures. We will request saliva samples and a repeat questionnaire every month for 6 months.

### What other information will you need from me?

We will ask for your permission to contact you, if any important details are missing which are needed to report your Covid-19 test results, and we will ask for your phone number and email address in case we need to get in touch.

We will ask for your consent to share your study test result data securely with your Headteacher *or other responsible member of school staff*, Bristol City Council's education team, your GP, Public Health England (PHE) and the NHS Test and Trace team (more details below in "**What happens if my test shows a current infection?**"). We will also ask for your consent to link the information you provide as part of this study with your NHS records for up to 10 years in the future.

Your NHS number is very important for this research. We will ask you for this if you agree to join the study. If you don't know your NHS number, we will ask for your permission to contact your registered GP practice to find it out.

We would like to hear from you (by email to <u>commins-school@bristol.ac.uk</u>) if you develop symptoms or seek a COVID-19 test via other routes in between our study visits.

### What will you do with my samples?

We will use two different tests to test your saliva for current and past COVID-19 infection. The test for current infection is called a PCR (polymerase chain reaction) test. The test for past infection will look for COVID-19 antibodies in your saliva.

We will carry out the tests in labs at the University of Bristol.

Samples will be labelled with a unique barcode, and only limited study personnel will have access your personal information (such as your name or address).

We will also ask for your consent to analyse the coronavirus genome, if we find it in your sample. This will look at the genetic material (RNA) of the coronavirus to see if there are between individuals (this tells us whether the source of infection was likely to be the same or different). We will not look at your genetic material (DNA or RNA).

Unused saliva will be stored securely at the University for the 12-month duration of the study.

We will ask for your consent to keep the remainder of your sample for future ethically approved infection and immunity research to benefit public health. These researchers could be in the UK, overseas or could be working in collaboration with commercial companies. We may ask for a fee from future users of study samples to cover costs of moving samples but will not make a profit. If you withdraw from the study later, we will not be able to recall your samples or remove your test result data from our analyses.

## What happens if my test shows a current infection?

If you test positive, we will contact you using text and/or phone, or your preferred method). We will aim to do this within 72 hours of the test being done. The most likely time of day to receive a result will be late afternoon (after the end of the school day). We will ask you to confirm that you have received the message and call you if you do not respond. The message will also ask you to follow your school's current policy and Public Health England (PHE) guidance. This will involve asking you to self-isolate at home with your household. We will need to inform Public Health England and the NHS Test and Trace programme so that appropriate actions can be taken by contacts you may have had. NHS Test and Trace will contact you directly too (possibly even before we do).

PHE or local health officials will trace your contacts and ask them to self-isolate too.

If you have provided us with your GP details in the questionnaire, we will inform them your GP. Your medical records will also be updated.

We will inform the Headteacher of your school using secure email.

We will also inform the Bristol City Council education team, using the same secure reporting procedure (a dedicated email inbox) used currently by local schools for any case identified using standard NHS coronavirus tests. This will allow the local authority education team to manage positive cases identified in this study, alongside cases identified through other routes.

If your study test result is positive, you and members of your household and your close contacts may also be invited to take part in a further Household Study. You will all receive information and consent forms electronically. You can request paper copies if you prefer. If you agree to take part, the Household Study will test individuals every week, using a saliva sample, for the following 4 weeks. A member of the project team will visit your home and leave saliva sampling kits for collection on the doorstep. Individuals who have consented will provide samples at their convenience and call to arrange collection. More information about the Household Study will be provided if you test positive. You can decide at that point if you would like to take part.

# What happens if I do not have a current infection?

If you do not have a current infection, you will not receive any communication from us about your test result. We only intend to contact participants if they have a positive test result showing current infection.

We will share the pooled results of the antibody tests for the whole school with your Headteacher. This information will not identify you personally.

At the moment, we are not planning to tell individuals if their saliva contains COVID-19 antibodies (due to previous infection), because we are still developing our antibody testing processes. In the future, if and when we are confident that our antibody tests are as accurate as our tests for current infection, we will be able to let people know whether they have had COVID-19 infection in the previous 3 months. We hope to do this within the 6 months of monthly testing.

# What are the possible risks or disadvantages of taking part?

We do not expect any practical disadvantages to taking part other than needing a small amount of your time. We appreciate that being informed of a positive test result can have a big impact on family and work life, because of needing to self-isolate. If you are affected by the need to self-isolate, please see Bristol City Council's website for information about what help and support is available:

### https://www.bristol.gov.uk/crime-emergencies/coronavirus-covid-19-what-you-need-to-know

We are also aware that infection, in some settings can be associated with stigma. We will try to prevent this by only informing selected people, as described above, of a positive test result.

We cannot guarantee that there will be no false positive test results (when a test says that you have COVID-19, but you don't really have it). However, the chance of this happening is low: we expect fewer than 1 in 100 tests that we do in people who do not have COVID-19 to be positive.

### What are the possible benefits of taking part?

You will benefit from knowing whether you have a current COVID-19 infection. You will be able to act to reduce the risk of transmission to others.

We cannot guarantee that participating in the project will detect <u>all</u> cases of COVID-19 nor prevent an outbreak. However, identifying any cases each month, including cases where people have no symptoms, will reduce the risk of an outbreak. Schools will also have access to our Germ Defence app, which will give practical advice to help reduce the infection rate at school, at home and in the community.

Because our test is very accurate, if you receive a positive test result, your actions will play an important role in reducing the spread of the virus within your community.

### What should I do if I feel unwell between monthly tests?

If you think you could have COVID-19 at any point, you should follow government guidance and get a <u>free NHS test</u> in addition to taking part in the study.

### What happens to the information I give?

We will need to use information from you in this research project.

The information will include your

- NHS number
- name
- contact details

We will use this information to do the research or to check your records to make sure that the research is being done properly.

If you consent, we will also use information from your NHS medical records including:

- health conditions
- routinely prescribed medication
- hospital/GP visits
- date of birth

This information will also help us to understand which health issues influence the risk of getting COVID-19 or are related to health issues after having COVID-19.

If you withdraw from the study later, we will not be able to recall your data. It is also necessary for us to retain some data for audit purposes.

### Will my taking part in the research be kept confidential?

We will keep all information about you safe and secure.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

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. We would like to recognise the role all schools play in the study and will credit them in published outputs from the study.

The study team will visit your school to collect samples on agreed dates. We will try to collect samples as privately as possible. However, key school staff who are involved in co-ordinating study visits will know who at your school is taking part in the study, and others in the school may be aware of your involvement in the study as everyone will be providing samples on the same day.

We will share your test results with you, the Headteacher in your school (or other responsible member of school staff), the Local Authority Education team (who your Headteacher would have to inform anyway), your GP, Public Health England and the NHS Test and Trace programme. We will not share test results with others in school and we will ask the school to keep test results confidential. However, if your test is positive and you are asked to self-isolate, members of the school community may be able to work out that you are part of the study.

# What will happen to the information I give in the future?

The data we collect from you could be valuable for other researchers to use in the future to study the transmission patterns, causes and consequences of COVID-19 infection. We will ask your permission on the consent form to allow us to share anonymised data with other researchers in the future. This would mean that other researchers will be able (with appropriate ethical approval for their study) to apply to access your test results and health data once CoMMinS is complete. These researchers could be from overseas or could be working in collaboration with commercial companies. They will not be able to find out your name or contact details from this data, which will only be identified by a code number.

If you withdraw from the study later, we will not be able to recall your data. It is also necessary for us to retain some data for audit purposes.

# Where can I find out more about how my information is used?

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- The University of Bristol data protection page: <u>http://www.bristol.ac.uk/secretary/data-protection/</u>
- by asking one of the research team
- by sending an email to <u>data-protection@bristol.ac.uk</u> or
- by ringing the University of Bristol data protection team on 0117 39 41824.

### What will happen to the findings from the study?

We will provide research progress bulletins to the school CoMMinS contact person every month. When results are published, we will provide summaries for research participants. The study will provide important information for the region's Health Protection Team. We expect the research findings to be published in academic journals with international readers. We will also share study findings with the NHS, education specialists, the government and the media.

We will publish regular updates on our project website, which anyone can access: <a href="https://commins.org.uk/">https://commins.org.uk/</a>

We will make an online password protected dashboard for Headteachers. This will display past and present levels of infection to help school leaders to manage their school. It will display infections per year group (not at an individual level) and how they are changing over time.

As part of the study we plan to identify *Research Leaders* from our participating students in each school. They will play a role in promoting the study within their school and could meet with other school *Research Leaders* during the course of the research. They will also be invited to join a CoMMinS symposium towards the end of the study to discuss and share their views on the research process and study findings.

# Who is organising and funding the research?

The project is led by Professor Caroline Relton from the University of Bristol. The researcher team is large and include epidemiologists, virologists, data scientists, engineers and health psychologists. The project partners include Bristol City Council, Public Health England and two Bristol schools. The UK government are providing £2.7million funding for the 12-month study through the NIHR-UKRI COVID-19 rapid response initiative.

# Who has reviewed this study?

The study was reviewed and approved by City & East NHS Research Ethics Committee on 1 October 2020 (approval ref: 20/HRA/4876).

# What if there is a problem or something goes wrong?

If you have concerns about any part of the study, please contact the study team (details below). If you wish to make a complaint, you can contact <u>research-governance@bristol.ac.uk</u>.

# How can I agree to take part?

Thank you for taking time to read this information leaflet, and for considering taking part in the research. If you would like to take part, please complete the consent form via the link sent by your school. If you need a paper version of the consent form, or have any questions about the research, please get in touch with us using the details below.

# Contact us:

If you have any questions about the research, you can contact the study team by sending an email to: <u>commins-school@bristol.ac.uk</u>.

If you urgently need to speak to a member of the study team, many of whom are working from home, please send us an email with your contact number, and we will phone you back.