



Covid19 Mapping and Mitigation in Schools (CoMMinS)

Household Study: Information Sheet for Adults (Index Case)

The University of Bristol is doing research on Covid-19 in schools, to understand how Covid-19 spreads and how to stop it (the Schools Study). We are asking the family members and regular contacts, of individuals who have had a positive Covid-19 test within the last 5 days, to give saliva samples twice a week for 1 week. If all of the saliva samples from participating members of your household test negative, you won't need to do anything else. If any of the saliva samples from your household test positive, we will invite you to continue to give twice weekly saliva samples for another 3 weeks. The test is easy to do, it does not involve needles, and it is not to do with vaccines.

PART 1: ABOUT THIS STUDY

1. Can you help with our research?

We want to know how Covid-19 spreads in schools and in the close contacts of school children and staff, and how to stop it spreading so that schools can stay open safely. We are inviting you to do saliva tests twice a week, at home. If the initial two samples from all participating members of your household (those collected in the first week) test negative in the lab, you won't need to do anything else. If either of these samples test positive in the lab, we will invite you to continue for another three weeks. Please read this leaflet to help you decide whether you want to take part. If anything is not clear or you have any questions, please email the study team: commins-household@bristol.ac.uk. If you would like to talk about it in another language, let us know and we will arrange a translator.

2. Why have you asked me?

You have recently had a positive test for Covid-19. We are inviting you to take part in the CoMMinS Household Study because of this. We would also like to invite all members of your household to take part, if they want to.

3. Do I have to take part?

No. It is up to you. Each person should make their own decision. If you agree to take part, we will ask you to sign a consent form online via a link sent by the study team. If you don't want to take part, you don't have to give a reason. If you do take part now but change your mind later, you can stop at any time without giving a reason. Your healthcare will not be affected whatever you decide.

4. What does taking part involve?

We will ask you to fill in a form online with your contact details. We will deliver testing kits to you at your home address (or another address of your choice), for you to take two times during the next week. You will know when to take each test as you will receive an email reminder from the study team. The kit will include a small tube for you to provide a saliva (spit) sample. We will give you a sheet of instructions and show you a study video about how to collect the saliva sample. Doing each test takes less than 5 minutes (please wait until 2 hours before it's due to be collected before providing the sample). We will deliver the test kits in advance, and arrange for the study team to collect them the morning your sample is due. We will pay to send and collect the kits.

Each saliva sample will receive at least two tests in a University of Bristol laboratory. Firstly, it will be tested for current Covid-19 infection using a very accurate PCR test. Secondly, we will check for antibodies to find out if you have had Covid-19 infection in the previous 3 months (this test is still in development). If you agree, we will send any positive samples for a third test, which involves looking at the genetic material of the virus (RNA). None of the tests involve looking at your personal genetic material (DNA).

If both initial samples from all participating members of your household test PCR negative, you won't need to do anything else and your involvement in the study will end. If either of your initial samples from participating members of your household test PCR positive, you will be invited to continue within the study for a further 3 weeks.

At the start of the study and every time you give a sample we will ask you to fill in a short questionnaire about your social contacts, to help us to understand how infection is passed on. This questionnaire will not ask about individual names or places, and your answers will not be shared with anyone else.

5. What other information will you need from me?

We will ask if we can contact you, if any important details are missing, and we will ask for your phone number and email so we can do this (we will delete your contact information when the study has finished).

When you agree to join the study we will ask you if we can share your Covid-19 saliva PCR test result, in a safe way, with your GP, and NHS Test and Trace. We will also ask if we can link your results with your NHS medical records. To enable this, we would need your NHS number. If you do not already know this, you can find out from the NHS online services here: <https://www.nhs.uk/nhs-services/online-services/find-nhs-number/>. Alternatively, with your permission, we can request this information from your GP surgery on your behalf. We will only share and link in this way Covid-19 saliva test results that have undergone PCR testing in the lab.

If you develop symptoms or have a Covid-19 test somewhere else, please let the study team know (by email to commins-household@bristol.ac.uk).

6. What happens if my saliva test shows I have current Covid-19 infection?

If your saliva PCR test shows you are positive for current Covid-19 infection, we will contact you as soon as we find out (within 72 hours of you giving the sample). We will ask you to follow government policy by staying at home. NHS Test and Trace may contact you as well. We will also tell your GP.

7. What happens if I don't have a current Covid-19 infection?

If all of the saliva samples from participating members of your household test PCR negative within the first week of the study, your involvement in the study will end and there is no need to do anything further. You will receive an email to confirm this. If you have had an earlier confirmed positive test result within the last 10 days, please continue to follow government guidance relating to the earlier positive test result, regardless of whether any more recent Household Study saliva test is negative.

At the moment, we are not planning to tell people if their saliva contains Covid-19 antibodies (due to previous infection), because the antibody test is still being developed. In the future, if and when we are sure that our antibody tests are as accurate as our PCR test for current infection, we will be able to let people know whether they have had Covid-19 in the previous 3 months.

8. What are the possible benefits of taking part?

The spit tests are easy to do. If you have joined the study because of a positive rapid test result, the laboratory PCR tests of your saliva samples will confirm whether you have Covid-19 or not. Your samples and data will help scientists and doctors to understand how to prevent Covid-19 from spreading.

9. Are there any disadvantages to taking part?

We do not expect any practical disadvantages to taking part except needing a small amount of your time, at home, twice a week for up to four weeks. Doing a spit test will take about 5 minutes per test. Answering the online questions takes 10-15 minutes each time. If you need help answering the questions you can ask us.

If your saliva PCR test shows that you have Covid-19, you will have to stay at home for 10 days from the date of your saliva PCR test. 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 your family or household is affected by the need to self-isolate, please see Bristol City Council's website for information about what help and support is available for people who have to stay at home due to Covid-19:

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

10. What are the risks of false positive test results in this study?

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

11. How can I agree to take part?

If you want to take part in this study, please complete the consent form via the link sent by the study team. If you need this form in print, or have any questions about the research, please get in touch (details below).

12. Contact us

If you have any questions, please contact us by email: commins-household@bristol.ac.uk.

If you urgently need to speak to us, please send us an email with your contact number, and we will phone you back.

PART 2: ADDITIONAL INFORMATION

13. What happens to the information I give?

We will use the information you give, including your name, date of birth and address, to do the research and to check that the research is being done properly.

We will also use information from your medical records including NHS number, any health conditions, medication, and visits to hospital or GP. This will help us to find out which health problems put people at risk from Covid-19.

We will keep all information about you safe and secure, and only tell those people who need to know.

14. What will happen to my information, saliva samples and research data after the study ends?

We will delete all of your personal data within a year of the end of the study.

We will store your saliva samples, test results and research data for a year, until the study analysis is complete. We will ask for your permission to store them for longer, as they could be valuable for other researchers to use in the future to study how Covid-19 infection spreads.

We will also ask for your permission to allow us to share your anonymised samples and/or research data with other researchers in the future. This means that other researchers may be able (with the right approvals) to use your samples and data after this study is over. These researchers could be from overseas or could be working in collaboration with commercial companies. None of them would be able to find out your name or address, as the samples or data will only be identified by a code number and any personal or identifiable details will have been removed. If you withdraw from the study later, we will not be able to recall your anonymised samples or data. The University of Bristol also needs to store some anonymised samples and data so that the relevant authorities can check that the research has been done properly.

15. Will you tell us what you find out?

We will put a summary of our results on the study website: <https://commins.org.uk>.

16. Will my taking part in the study be kept confidential?

We will not tell anybody that you are taking part in the research. We will keep all information about you safe and secure. Nobody other than authorised researchers will 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.

17. Will other people know if I have tested positive for Covid-19?

If you have to self-isolate, other people might guess that you have Covid-19.

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

- By asking one of the research team (send an email to commins-household@bristol.ac.uk)
- By asking the University of Bristol data protection team (send an email to data-protection@bristol.ac.uk).
- Details of how information about patients is used in research can be found at these websites: www.hra.nhs.uk/information-about-patients, and www.hra.nhs.uk/patientdataandresearch
- More information about data protection can be found on the University of Bristol's data protection web page: <http://www.bristol.ac.uk/secretary/data-protection/>.

19. Who is organising and funding the research?

Professor Caroline Relton, from the University of Bristol, is leading the research. Her team includes medical doctors, infectious disease experts, mathematicians, data scientists, engineers and psychologists. The UK government is paying for the research.

20. Who has checked the study will be run properly?

An NHS Research Ethics committee has made sure the research is being done safely. (approval ref: 20/HRA/4876, City and East Research Ethics Committee, 01 October 2020).

21. What if there is a problem or something goes wrong?

If you have any questions about any part of the study, please contact the study team (commins-household@bristol.ac.uk). If anything is wrong, or you would like to complain about the research, you can contact research-governance@bristol.ac.uk.

Thank you for reading this leaflet!