



Covid19 Mapping and Mitigation in Schools (CoMMinS)

Household Study: Information Sheet for Parents (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 school pupils 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 and your child 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 asking you if you agree to your child giving a saliva sample 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 your child 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 and my child?

Your child has been invited to take part in this Household Study because they have recently had a positive test for Covid-19. We are sorry about this test result and we know it is a worrying time for parents. We are inviting all members of your child's household to take part, if they want to.

3. Do I and my child have to take part?

No. It is up to you and your child. Each person should make their own decision. If you agree that your child can take part, we will ask you to sign a consent form online via a link sent by the study team, and we will ask your child to sign an assent form via the same link. If you or your child 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 and your child can stop at any time without giving a reason. Your child's education and 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 child's details, and with your contact details. We will deliver testing kits to you at your child's home address (or another address of your choice), for your child 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 your child 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 collecting 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 your child has 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 child's 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 on each day that your child provides a saliva 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 child's Covid-19 saliva PCR test result, in a safe way, with their Headteacher (or other responsible member of school staff), Bristol City Council's education team, your child's GP, and NHS Test and Trace. We will also ask if we can link your child's results with their NHS medical records. To enable this, we would need your child's 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 child's 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 your child develops symptoms or has a Covid-19 test somewhere else, please inform your child's school and let the study team know (by email to commins-household@bristol.ac.uk).

6. What happens if my child's saliva test shows they have current Covid-19 infection?

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

If your child becomes unwell and you are concerned about your child's health you need to seek help and advice as usual. Some useful information and advice can be found at these websites:

- **Children of all ages:** <https://www.rcpch.ac.uk/sites/default/files/2020-11/Coronavirus-poster-parents-2020-England.pdf>
- **Young people:** <https://www.rcpch.ac.uk/sites/default/files/2020-12/Coronavirus-poster-young-people-2020-England.pdf>

7. What happens if my child doesn'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. We only intend to contact participants if they have a positive test result showing current infection. If your child has 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 participants 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 parents know whether their child has had Covid-19 in the previous 3 months.

8. What are the possible benefits of taking part?

The spit tests are easy for your child to do. If your child has joined the study because of a positive rapid test result, the laboratory PCR tests of their saliva samples will confirm whether your child has Covid-19 or not. This will help you and your child not to spread it to other people. It will help to keep your child's school open. It will help the community. Your child's 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. Helping your child to do 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 child's saliva PCR test shows that they have Covid-19, you and your child will have to stay at home for 10 days from the date of your saliva PCR test. We know this can have a big impact on your life. Bristol City Council can provide help for families 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>

We are also aware that infection can sometimes make people treat children differently. We will try to prevent this by only telling your child's Headteacher or other responsible member of school staff, privately, if they have tested positive for Covid-19.

We cannot guarantee that there will be no false positive test results (when a test says that someone has Covid-19, but they 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.

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 your child to take part in this study, please complete the consent form via the link sent by the study team. Your child will be asked to fill in an online assent form at the same time, so please have them with you when you sign up. If you need these forms 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 about my child?

We will use the information you give, including your child's 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 child's 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 your child safe and secure, and only tell those people who need to know.

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

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

We will store your child's 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 child's 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 child's 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 child's 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 and your child withdraw from the study later, we will not be able to recall your child's 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 tell your child's school what we find out. We will put a summary of our results on the study website: <https://commins.org.uk>.

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

We will not tell anybody that your child is taking part in the research. We will keep all information about your child safe and secure. Nobody other than authorised researchers will be able to see your child's name or contact details. Your child's 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 your child 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.

17. Will other people know if my child has tested positive for Covid-19?

If your child's saliva test result is positive, we will tell their Headteacher or other responsible member of school staff. They will not tell anyone else. If you and your child have to self-isolate, other people might guess that you or your child has Covid-19.

18. Where can I find out more about how my child's 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!