



Liverpool Household COVID-19 Cohort Study (COVID-LIV)

Parent/Guardian Information Sheet for COVID-LIV

- You were contacted by telephone or you have contacted us and verbally agreed that your child will take part in a research study called COVID-LIV.
- Please now take time to read the following information carefully (note, you may have received this information via email following the telephone call). **Part 1** tells you the purpose of the study and what will happen to your child if you take part. **Part 2** gives you more detailed information about the conduct of the study.
- You can ask a member of the clinical team if there is anything that is not clear, or if you would like more information.
- Taking part is voluntary. If you don't want your child to take part then you don't need to give a reason.
- If you want your child to take part but other members of the household do not want to, we may not be able to include your child in the study.
- The COVID-LIV study team are studying how COVID-19 spreads in the community, inside households.
- This is being done using swab tests – the same tests that you would have if you came into hospital with COVID-19.
- We need all kinds of different households across Liverpool city region to take part.
- The study is currently funded for 12 months whilst additional funding is obtained to continue for a further three years.

How to contact the study team:

If you have any questions about this study please talk to a member of the study team who visits your friend/relative, or call: <telephone number>

Professor Neil French is the lead Investigator.

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If your child becomes ill or you suspect they have COVID-19, please follow government guidelines

PART 1: Purpose of the study and what will happen if your child takes part

Why are we doing the COVID-LIV study?

COVID-19 (or COVID for short) is the name of the disease that is caused by the new coronavirus. This coronavirus was first found in China in January 2020. The new coronavirus has since spread all round the world. COVID-19 is caused by a virus strain called SARS-CoV-2. We want to understand what factors determine transmission of the virus and how our bodies respond and become resistant to it.

Most people who get COVID-19 will be fine as it is not a serious disease in most people. Some people might not even know that they had it. But in a few people, COVID-19 makes them very sick. They may need a ventilator to help them breathe, or may even die. In order to prevent this, the government has asked everyone except essential workers to stay at home whenever possible. Whilst this will work, it has other effects, for example preventing people from working, so there is a great cost to the country, and to our personal freedoms. We need to understand how COVID-19 spreads, so we can help tell the government when to stop advising people to stay home, and what might happen as they do tell us we can go out again.

The results from this study will be used to provide valuable information for the government and local public health to plan the next stage of the COVID-19 response – that is how we step down from the lock down and back to more contacts and interactions.

Why has my child been chosen?

Your child, and your household, have either been selected because you were part of another study before, called CLAHRC NWC Household Health Survey or you have responded to one of our communications seeking volunteers. Those on the household study gave permission to be re-contacted again about other studies. Therefore, we are contacting you to ask if you would be happy for your child to take part in this study.

We are selecting different types of households (for example with different numbers of people, or those with and without children) to take part in COVID-LIV. We need all different kinds to take part so we have not

approached your child based on anything particular about them or your household, or family. We are looking for around 1000 people from 300 different households to take part, so that we can be sure the people in the study are just like those in the whole community.

Does my child have to take part?

No, taking part is voluntary. It is up to you to decide whether or not your child should take part.

We also want all the members of the household to take part. If you want your child to take part but other members of the household do not want to participate, we may not be able to include your child.

If you do decide that your child should take part, we will ask you to sign a consent form.

If you decide that your child should part, you can also change your mind at any time without giving a reason.

The decision you make on whether your child should take part or not will not affect the care they receive for COVID-19 now, or in the future.

What will happen to my child if they take part?

After you have signed the consent form, we will ask you to complete a questionnaire about your child (we will ask you about members of their household, diet, employment, and some other things). The researcher will take a very small blood sample from your child – they will do this by gently pricking their fingers and collected the spot of blood that surfaces. We will also collect a sample of saliva with a mini sponge and a sample of nasal fluid with a small piece of special filter paper. We will then explain how you can take nose swabs from them or other members of the household and ask you to do the first swab in the presence of a researcher to check you are able to do it correctly. These swabs are for COVID-19 testing, and are easy to use. If your child feels ill at the time of the first visit we will only take the nose swab to see if your child has COVID19 and arrange a further visit to collect blood and other

samples depending on the swab result. You will swab their nose once a week, for 12 weeks (or at any other time if they have fallen ill with fever, cough, sore throat, breathlessness or flu-like symptoms). We will phone you, or send a text message, to remind you to take the nose swabs once a week. If you struggle to take the nose swabs yourself, simply let us know and we can arrange for the researcher to visit and help take the swabs.

We will ask you to let us know when the swabs have been taken and we will then arrange for a courier to collect the swabs – this will happen on a weekly basis. The swabs will be taken to a laboratory team who will do COVID-19 tests on them. This takes up to three days, and we will phone you, or send a text message, with the results.

After the first 12 weeks, we do not need swabs every week. However, we would still like you to collect nose swabs from your child at any point in the study if they have fallen ill with fever, cough, sore throat, or breathlessness. At this point, the processing of swabs may change depending on local NHS testing policy.

The researcher will visit and carry out finger prick and blood spot collections after your child has been in the study for 12 weeks (3 months), then again at 6 months, 1 year, 2 years and 3 years after they started the study. At these visits, you will also complete a questionnaire.

If your child's first or following weeks nose swab has positive test results: *We will provide support in terms of your child's healthcare (either via the phone, or face-to-face), and we will also visit them a few days after their positive result, and then 2 weeks after that. We will inform their GP of their positive result. Public Health England maybe informed in line with their current guidelines. When we visit, we will ask you more questions, and take some more samples. The samples we will take are: another nose swab, a swab for saliva, a stool sample, and another finger prick and blood spot collection. We may also provide a special device for rapid diagnosis to take a nose/throat swabs from your child, but this is only if it is approved for use and part of NHS guidelines.*

If, at any point, your child becomes ill or you suspect they have COVID-19, you can call the telephone number given on the first page of this information sheet. If you

suspect they have COVID-19 and need to talk to someone outside of usual office hours, you should call **NHS 111**.

The study is planned to last for three years. At the moment the study is going to be started for the first 12 weeks (3 months); continuing the study after that will depend on the study team obtaining more funding. However, our intention is to run the study for three years, so we are asking for permission for this up front from you, so that we do not need to keep coming back to you.

We will let you know when the study ends.

What will I and my child have to do if I decide they can take part?

If you agree your child can take part, you will be asked to sign a consent form. You will be given a copy of the consent form and the information sheet to keep.

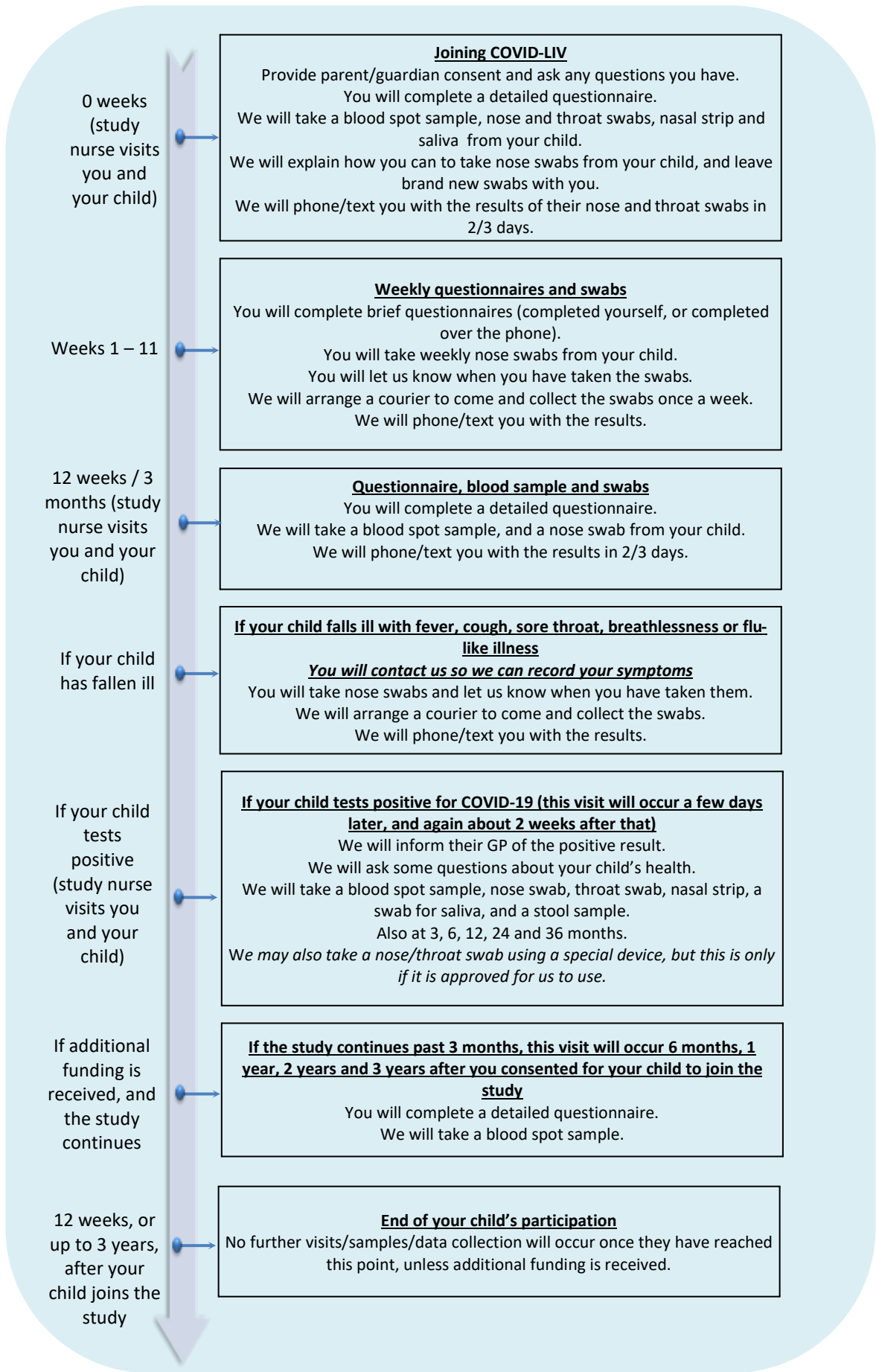
Once you have signed the consent form, you and your child will be asked to follow the study plan (see study timeline diagram below).

Your child will have to:

- Provide swab of the nose and throat at the beginning and repeated weekly taken by you thereafter
- Provide blood samples via a finger prick and blood spot collection
- Provide saliva swabs and stool samples (only if they test positive for COVID-19)

You will have to:

- Take nose swabs from your child
- Inform us when you have taken their swabs so we can send a courier to collect them (once a week)
- Complete questionnaires (either by yourself or over the telephone)
- Provide information on your child's health and wellbeing



What are the benefits and risks of taking part?

The main benefit is that you and your child will know if they have had COVID-19 or not. If they have symptoms, and the test is negative, we will tell you this. This means that, once your child has **self-isolated for 7 days** (as per government advice at the beginning of June, if this changes we will let you know), they can continue with their current activities because we will know for sure that they have not got COVID-19. We will also be doing antibody tests on your child's blood, so they will be tested for immunity as well. However, at the moment we are not sure if these tests means that they will actually be protected from repeat infections in the future. Studying that is one of the aims of the study.

The risks to your child are minor bruising from the blood samples taken, and researchers entering your house. However, the researchers will be wearing Personal Protective Equipment (PPE) at all times, to prevent transfer of COVID-19.

What happens if I change my mind?

If at any point you decide that your child should stop taking part in the study, you can let a member of the research team know. In order for us to understand why participants withdraw from the study, we may ask you why you have decided to withdraw your child. However, you do not have to give a reason, if do not want to.

If you do decide that your child should stop taking part, this will not affect their current and future medical care, and legal rights will not be affected in any way.

Information on how we will handle your and your child's information in the event of them withdrawing is detailed in Part 2 of this Information Sheet.

What happens when the study stops?

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. Confidentiality will be ensured at all times and neither you nor your child will be identified in any publication.

Any information derived directly or indirectly from this research, as well as any patents, diagnostic tests, drugs,

or biological products developed directly or indirectly as a result of this research may be used for commercial purposes. Neither you nor your child have any right to this property or to any share of the profits that may be earned directly or indirectly as a result of this research. However, in signing this form and donating swabs and blood samples for this research, your child does not give up any rights that they would otherwise have as a participant in research.

What if there is a problem?

If, at any point, your child becomes ill or you suspect they have COVID-19, you can call the telephone number given on the first page of this information sheet. If you suspect they have COVID-19 and need to talk to someone outside of usual office hours, you should call **NHS 111**.

Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information is given in Part 2 of this information sheet.

Will taking part in the study be kept confidential?

Yes. All the confidential information about your child's participation in this study will be kept confidential. Detailed information on this is given in Part 2.

PART 2: Detailed Information about the conduct of the study

Who is running the study?

University of Liverpool is the Sponsor of this study and is responsible for managing it. They are based in United Kingdom. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool), and the samples your child provides will be managed by members of a laboratory team at the University of Liverpool and Liverpool School of Tropical Medicine (LSTM).

The study has been reviewed by the National Research Ethics Service Committee to make sure that the study is scientifically and ethically acceptable.

This study is funded by the National Institute for Health Research (NIHR) Health Protection Research Unit in Emerging and Zoonotic Infections (HPRU-EZI), Centre of Excellence in Infectious Diseases Research (CEIDR) at University of Liverpool in partnership with Public Health England (PHE), Alder Hey Charity and in collaboration with Liverpool School of Tropical Medicine. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

We will not receive any payment for including your child in this study.

How will my and my child's information be collected and handled?

University of Liverpool is the Data Controller for this study and will need to use information from this research project.

This information will include your name and initials, and your child's name, initials, date of birth, contact details, postcode and their NHS number (we will request this from their GP). People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

Individuals from University of Liverpool, the LCTC, LSTM, and relevant regulatory organisations may look at your

child's research records to check the accuracy of the research study.

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

Data will be sent from the University of Liverpool researchers and LSTM to the LCTC. Data may also be sent from your child's GP to University of Liverpool researcher, who will then send this to LCTC.

We may notify your child's GP that they are taking part in the study, and if they test positive for COVID-19, for their information.

We will keep all information about you and your child safe and secure.

Once we have finished the study, we will keep the data for a minimum of 10 years, so we can check the results. We will write our reports in a way that no-one can work out that you and your child took part in the study.

What are my choices about how my information is used?

You can choose for your child to stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have.

We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you or your child see or change the data we hold about you, or them.

Information sharing for other research

When you agree for your child to take part in a research study, the information about their health and care may be beneficial to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your child's

information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards.

If you agree for your child to take part in this study, you will have the option for them to take part in future research using their data saved from this study.

Where can I find out more about how my and my child's information is used?

You can find out more about how we use your and your child's information:

- at the LCTC website: www.lctc.org.uk/privacy
- at LSTM website: <https://www.lstmed.ac.uk/lstm-privacy-statement>
- at www.hra.nhs.uk/information-about-patients
- in the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- by contacting the University of Liverpool Data Protection Officer on LegalServices@liverpool.ac.uk
- by asking one of the research team
- by sending an email to <email>, or
- by ringing us on <phone number>

What will happen to the nose and throat swabs, and the blood, saliva and stool samples my child gives?

Samples collected for use in COVID-LIV

We will use your child's samples to test for their body's response to the COVID-19 virus. This will be able to tell us whether they have had the infection with no symptoms, in some cases. We will test their blood to see if they have been exposed before to other coronaviruses.

Your child's samples will be sent to laboratories at the University of Liverpool and LSTM for analysis. These samples will be coded and the researchers carrying out tests on the samples will not be given information they do not need to carry out the tests and analyse the results. Coded is not the same as anonymous. The study team will need to know who the sample came from to inform you of the results. It will be possible to use the codes to identify that a result is from your child's sample. However, once we have given you your results, we do not

plan to do this unless there is a good reason to do so. We will maintain this information so that we can properly manage the samples. For instance, sometimes we may need to update our record of your child's clinical details to help us interpret the results of tests.

If your child tested positive for COVID-19: We may also test your child's blood with other viruses as controls, such as the glandular fever virus, flu, and some other common cold viruses. Then, on later samples, we will do much more detailed and complex tests. We will look in detail at the responses of specialised white blood cells in their blood called lymphocytes.

We may store some of your child's blood, or the cells from your child's blood for up to 25 years after this research has finished. We may also use some of their cells to make what are called "cell lines" – these are cells that can be kept alive in the lab for a long time (maybe forever) and are used to make it easier to detect and study the lymphocyte responses we are interested in.

We will extract DNA to look at your child's genes by sequencing the whole of your child's genome. This will help us understand whether certain genes are related to their ability to fight off the COVID-19 coronavirus. This will include some of the genes unique to their individual immune system, called HLA. These are the same tests that are done before organ transplants, and they are used to tailor our research to each person. There will be left over DNA after we have done this, which would be stored, like the cells from your child's blood, for up to 25 years after the research has finished.

Samples collected for Future Research

We would like your permission to do other research on these stored samples in the future. This would include looking at factors which are involved in fighting off coronaviruses, and other controls for our experiments such as herpes viruses (like glandular fever), flu, and enteroviruses (e.g. common cold viruses), and other common human viruses. We cannot say now all the experiments we might do because new things might be discovered in the future that we would like to investigate.

If you agree that we can store your child's samples for future research, coded samples will be stored at the University of Liverpool and LSTM. These researchers

work closely with other scientists in the UK and elsewhere. We would like to allow other researchers, including those who also have ideas about coronaviruses, to apply to use your child's samples for similar work in the future too.

We would like your permission to allow your child's samples to be transferred outside of the University of Liverpool and LSTM for purposes including those of coronavirus immunity testing. We are asking this now so we don't have to ask you again in the future.

Any future experiments not related to coronaviruses would be approved by a research ethics committee. If you don't want your child's samples stored, that's fine, they can still take part in the rest of the study, we just won't keep their samples at the end. Or if you are happy with having their samples stored, but not sent to another lab, you can choose this as well.

The samples will be kept in a secure place until we need them; nobody outside of the study will have access to any confidential information that you or your child give to us.

Confidential details (such as your name, your child's name, their address and their GP details) will be kept locally and not made available to collaborators.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with one of the research team who will do their best to answer your questions.

Every care will be taken in the course of this research study. However, in the unlikely event that you or your child are harmed by taking part in this research project of the study Sponsor (University of Liverpool), the Sponsor holds Insurance for the conduct of clinical research. Compensation may be available and you may have to pay the related legal costs.

Thank you for taking the time to read and consider this information sheet. Should you decide that your child can take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.



Liverpool Household COVID-19 Cohort Study (COVID-LIV)

FOR SITE USE ONLY:

Site Name:	
Household ID:	
Participant ID:	
Participant Initials:	
Participant DOB:	/ /
Participant Postcode:	-

Parent/Guardian Consent Form

To be completed by the Parent/Guardian:

Once you have read and understood each statement please enter your initials in each box. Initial

- I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily.
- I understand that participation is voluntary and that I am free to withdraw my child from the study at any time, without giving a reason, and without their care or legal rights being affected. However, the study team may need to collect some limited information for safety reasons.
- I give permission for a copy of this fully completed consent form to be sent to the LCTC (where it will be kept in a secure location) to allow confirmation that my consent was given.
- I understand that relevant sections of my child's medical notes and any data collected during the study may be looked at by authorised individuals from the central study team and representatives of the Sponsor, and relevant regulatory authorities. I give permission for these individuals to have access to my child's records and data.
- I understand that a copy of this consent form which includes my name and initials, and my child's data will be kept by the University of Liverpool and all others archiving data in a confidential manner for up to a maximum of 25 years from the end of the study.
- I consent to samples of my child's blood, saliva and stool, and for nose and throat swabs to be taken and used for this study.
- I agree for my child to take part in the above study.

The statements below are optional (your child can still take part in the study even if you do not wish to agree to these):

- I agree for my child's data previously collected for other research to be looked at by the research team.
- I consent to my child's blood samples being stored by the University of Liverpool for testing for SARS-CoV-2 immunity, and immunity to other coronaviruses.
- I agree for my child's samples collected for future research to be stored at The University of Liverpool and LSTM.
- I agree for my child's samples collected for future research to be transferred outside of the University of Liverpool and LSTM, along with a copy of this Consent Form, for different tests for coronavirus immunity
- I agree to allow information or results arising from this study to be used in future healthcare and/or medical research providing my and my child's confidentiality is maintained.
- I agree to my child's GP being informed of their participation in the study, and if they test positive for COVID-19.
- I agree for my child's GP to be contacted for information relating to their health records, including the provision of their NHS number.



Liverpool Household COVID-19 Cohort Study (COVID-LIV)

FOR SITE USE ONLY:

Site Name:																						
Household ID:												Participant ID:										
Participant Initials:												Participant DOB:			/			/				
Participant Postcode:												-										

15. I agree that I or my child may be contacted in the future in relation to this or other related studies.

If you agree to statement 15 provide your details below:

Telephone number:																						
Email address:																						

To be completed by the Parent/Guardian:

Your child's full name (please print)																						
Your full name (please print):																						
Your signature:																Date:						

To be completed by the Researcher (after Parent/Guardian has completed the form):

Researcher full name (please print):																						
Researcher signature:																Date:						

Please file the original wet-ink copy in the COVID-LIV Investigator Site File, and make two copies: one for the participant and one to be sent to the LCTC.