**Parent Information Leaflet**

*FAMILY MICRO Study:* ***F****amily Rese****A****rch of* ***MI****crobes* ***L****inked to Respirator****Y*** *Infections*

You and your family are being invited to choose to take part in a research study. We would like to collect some samples from all family members once every two weeks for six months to learn more about how healthy adults and children are protected or not against respiratory infections. Before you decide if you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

**What is the study about?**

We all have bacteria in our nose and mouth even when we are healthy. Some bacteria may protect against other infections. We constantly share these bacteria with people that we are frequently in contact with including our partner and children and hands are shown to be main vehicles of bacterial transmission. The type of bacteria and how many of them we have depends on our age and may change due to different factors like smoking, alcohol, antibiotic use, and other infections. Some people in the same household may be more likely to get a respiratory infection some get mild or severe infection, whilst others have no symptoms when infected with the same bacteria. We hope that by studying bacteria in the nose, mouth and hands of family members and how the different factors influence their change over time, we can use this information in future to develop better treatments that protect against respiratory infections.

We have developed an easy to use sampling technique to self-collect saliva and fluid close to the lining of the nose at home. We would like to find out if it is practical for families to collect these samples at home.

**Why has my family been chosen?**

Your family has been chosen because has four members and they are generally well. We are recruiting a small number of families (32)from different parts of Liverpool (including Merseyside and Wirral) seeking preliminary data to perform a larger study in the future. Thus, your participation and feedback are very important for us.

**What will happen if my family agrees to take part?**

* We will ask you to sign a consent form when you are sure you want to take part. If all members of the family attend the face to face appointment, then written consent will be sought from all members. If a family member is absent, then the written consent form can be brought to us by the parent who attends the appointment. Children over 11 years of age will be asked to sign an assent form.
* You will be asked to give some personal details about family members such as age and gender and answer a few questions about their general medical history and general habits (e.g. smoking, dietary preferences).This can be completed at home.
* You will be given training of how to collect samples at home from you and your children. We will ask you to spit a small amount of saliva in a tube, we will place a paper strip in the nose for 1-2 minutes to collect some nasal liquid and swab your hands for less than a minute (optional). In case of infants a sponge on a stick (swab) will be used to collect saliva. These tests will allow us to look at the bacteria commonly found in the nose and mouth of you and your family members.
* You will be given a sampling bag with cool packs to keep the samples cool and a thermometer to record the temperature of the samples. You will take the samples collected at this appointment (if collected) back home with you. Once at home, samples must be stored in your freezer with the thermometer.
* At home, all family members will be required to take saliva and nasal liquid once every two weeks for six months. Ideally this is the same day e.g. every other Saturday (time of day does not matter). When giving a saliva sample, we ask that you do not drink or eat for 30 minutes before. You will be given a sampling timetable explaining exactly when the samples are due to be taken. Samples will be stored in your freezer in a small plastic box with the thermometer. Samples will be transferred to the Liverpool School of Tropical Medicine (LSTM) laboratories by taxi (paid by LSTM), at 3 months and then at the end of the study.
* You will be asked to photograph the samples once taken on your phone and send via WhatsApp to the research team so that we have a record of when (time and date) samples are collected.
* We will ask you to complete a questionnaire every time you collect samples so that we can learn more about how practical this is for you.
* We will ask you to keep a monthly diary describing everyday life e.g. smoking, alcohol use, how you travel to work etc. to find out how different habits affect the type and number of bacteria in the nose and mouth of different family members.
* We would like your opinion on the study to help us optimise the design for a larger study in the future. At the end of the study, you will be invited to an interview via phone or face to face. Interviews are optional and will be recorded with your permission.

**What will happen to my family’s samples?**

We will process your samples in laboratories at LSTM, the Royal Liverpool University Hospital and the Centre of Genomic Research, University of Liverpool. We will identify and measure the bacteria and viruses in your nose and mouth. To make full use of your samples, we ask that you “gift” your samples to LSTM for future research including sending to collaborators involved in same research globally (universities, NHS organisations or companies involved in health and care research in this country or abroad). We would not send your personal details.

**Are there any disadvantages to my family taking part in this study?**

We do not expect any discomfort as sampling techniques are no invasive. Sometimes your eyes may water after placing the paper strip in your nose.

**Are there any benefits to my family taking part in this study?**

No. While this study will not benefit your family directly, it may help us to understand more about how healthy people are protected from respiratory infections to help us to prevent happening in the future.

**Will my family’s GP be informed of our participation in this study?**

As this is an observational study and does not involve a treatment, we do not plan to inform your GP.

**Do I have to take part?**

No. It is up to you and your family members (in case of children where possible) to decide whether to take part. You can withdraw from the research at any time and without giving a reason. To withdraw, please email 2volresearch@lstmed.ac.uk Your decisions about this will not affect the standard of care your family receives. If you would like to take part, you will be given this information sheet to keep and be asked to sign a consent/assent form.

**Will the information on me and my children be kept confidential?**

Yes, all personal information will be kept confidential and secure on password protected computers. Only the clinical team involved in the study will have access to the information. We plan to keep the research results and interview recordings for a minimum of 10 years. Research results cannot be traced back to you or your children. This study has been approved by the National Research Ethics Service, which includes lay members representing the local community. LSTM will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from LSTM and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in LSTM who will have access to information that identifies you will be people who need to contact you to regarding your participation in the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

LSTM (research site) will keep identifiable information about you from this study for 10 years after the study has finished.

LSTM will collect information about you for this research study from you. We will use this information to confirm your eligibility

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care.

**What is patient data?**

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It’s important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

**What sort of patient data does health and care research use?**

There are lots of different types of health and care research.

If you take part in a clinical trial, researchers will be testing a medicine or other treatment. Or you may take part in a research study where you have some health tests or answer some questions. When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. During the study you may have blood tests or other health checks, and you may complete questionnaires. The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

In other types of research, you won’t need to do anything different, but the research team will be looking at some of your health records. This sort of research may use some data from your GP, hospital or central NHS records. Some research will combine these records with information from other places, like schools or social care. The information that the researcher collects from the health records is research data.

**Why does health and care research use information from patients?**

In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than other. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient’s health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

**How does research use patient data?**

If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you about your research appointments, or to send you questionnaires. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your blood test might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

In other research, only the doctor copying the data from your health records will know your name. They will replace your name with a code number. They will also make sure that any other information that could show who you are is removed. For example, instead of using your date of birth they will give the research team your age. When there is no information that could show who you are, this is called anonymous data.

**Where will my data go?**

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. This may involve other hospitals, or universities or companies developing new treatments. Sometimes parts of the research team will be in other countries. You can ask about where your data will go. You can also check whether the data they get will include information that could show who you are. Research teams in other countries must stick to the rules that the UK uses.

All the computers storing patient data must meet special security arrangements.

If you want to find out more about how companies develop and sell new medicines, the Association of the British Pharmaceutical Industry has [information on its website.](https://www.abpi.org.uk/)

**What are my choices about my patient data?**

* You can stop being part of a research study at any time, without giving a reason, but the research team will keep the research data about you that they already have. You can find out what would happen with your data before you agree to take part in a study.
* In some studies, once you have finished treatment the research team will continue to collect some information from your doctor or from central NHS records over a few months or years so the research team can track your health. If you do not want this to happen, you can say you want to stop any more information being collected.
* Researchers need to manage your records in specific ways for the research to be reliable. This means that they won’t be able to let you see or change the data they hold about you. Research could go wrong if data is removed or changed.

**What happens to my research data after the study?**

Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it.

Usually your hospital or GP where you are taking part in the study will keep a copy of the research data along with your name. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked.

If you agree to take part in a research study, you may get the choice to give your research data from this study for future research. Sometimes this future research may use research data that has had your name and NHS number removed. Or it may use research data that could show who you are. You will be told what options there are. You will get details if your research data will be joined up with other information about you or your health, such as from your GP or social services.

Once your details like your name or NHS number have been removed, other researchers won’t be able to contact you to ask you about future research.

Any information that could show who you are will be held safely with strict limits on who can access it.

You may also have the choice for the hospital or researchers to keep your contact details and some of your health information, so they can invite you to take part in future clinical trials or other studies. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

**Will the use of my data meet GDPR rules?**

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a ‘legitimate interest’ in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of ‘a task in the public interest’.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

**What if I don't want my patient data used for research?**

You will have a choice about taking part in a clinical trial testing a treatment. If you choose not to take part, that is fine.

In most cases you will also have a choice about your patient data being used for other types of research. There are two cases where this might not happen:

1. When the research is using anonymous information. Because it’s anonymous, the research team don’t know whose data it is and can’t ask you.
2. When it would not be possible for the research team to ask everyone. This would usually be because of the number of people who would have to be contacted. Sometimes it will be because the research could be biased if some people chose not to agree. In this case a special NHS group will check that the reasons are valid. You can opt-out of your data being used for this sort of research. You can ask your GP about opting-out, or you can [find out more](https://www.hra.nhs.uk/information-about-patients/).

**Who can I contact if I have a complaint?**

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer

**What will happen to the results of the research study?**

The results will be published in medical journals and will contribute to the information needed when we plan future studies to develop new treatments against respiratory infections. We will also put a summary of the results in time onto the web site of the Liverpool School of Tropical Medicine (<https://www.lstmed.ac.uk/ehpc>).

**What if you have a concern or complaint to make about the study?**

You can contact: The Patient Advisory Liaison Service (PALS) Alder Hey Children’s Hospital , East Prescot Rd, Liverpool L14 5AB, Telephone: 0151 252 5374 Email: pals@alderhey.nhs.uk

**If would like further information about the study?**

Research Team: \*\*\*\*, EMAIL: \*\*\*\*, PHONE: \*\*\*\*