**Information sheet for families** REC: 16/ES/0084

Lead investigator: Dr David Dorward, NHS Lothian & University of Edinburgh

Before you decide whether you wish your relative to participate in this study it is important for you to understand why the research is being done and what it would involve. Please take time to read this information carefully. One of our team will go through the information with you. Please ask us if there is anything that is unclear or if you would like more information and time to decide. Your decision is completely voluntary, you are not obliged to help, and it will not affect the way your relative is cared for.

**What is this study about?**

COVID-19 is a new disease. The way in which the lungs and other organs are damaged by coronavirus (SARS-CoV-2) is not fully understood. This limits the types of drug treatments that may be useful in treating this disease. Knowing whether the damage is caused mainly by the virus itself or the body’s response to viral infection will help doctors treat other patients with COVID-19 and also possibly identify new medicines.

We are looking to conduct post-mortem examinations on patients who have recently died due to COVID-19 to find out what exactly caused them to die and to obtain tissue samples to learn more about what is causing lung and other organ injury.

**What will happen if I agree to this study?**

The details of the post-mortem examination are described in detail in the information leaflet that you have been given (NHS Scotland; Information about an Adult’s Post-Mortem Examination). The post-mortem examination will be conducted by an NHS consultant pathologist, assisted by a skilled mortuary technician. A full report will be sent to your relative’s hospital consultant within 6 weeks of the post-mortem. A lay summary can also be requested.

**Will any other information be gathered?**

With your authorisation, we will record information from your relative’s medical records in order to understand more about their background health and COVID-19. This will include information about the severity of their illness and the results of blood tests, scans and x-rays. We will record their Community Health Index number to anonymously link results from the study to information held in electronic medical records at a population-wide level. If they were enrolled in another research study about COVID-19, we will link information generated by this study with the results of any other studies they were enrolled in. Information will be held securely in NHS Lothian and the University of Edinburgh.

**What other questions will I be asked?**

You will be asked if anybody in your family or anyone close to the person who has died would object to a post-mortem examination and retrieval of tissue samples for research. If you know that they do, we would not ask you to agree. You will be asked if the research team can find out more about your relative’s state of health by checking records of their medical history.

**What will happen to the tissue samples?**

We will use the samples to learn more about where in the body the virus is multiplying and how the human body is responding to it. As part of this, we will analyse genetic information (DNA) to discover why people respond differently to infections.

Conducting post-mortem examinations on a large number of patients with COVID-19 allows researchers to increase their understanding of COVID-19. Often it is only through the study of large numbers of cases that significant observations can be made. We will therefore also store the samples collected at post-mortem examination as well as the digital data and images generated from them for further future research. The research team in Edinburgh works closely with specialist medical groups elsewhere in the UK and abroad and small tissue samples or the digital tissue images may be sent to these other groups to help in their ethically approved research.

**What are the benefits to taking part in this study?**

There is no direct benefit to participants, but the research may help others with COVID-19 or other severe lung disorders.

**Will the funeral be delayed?**

No. The funeral arrangements will not be affected by agreeing to participate in this study.

**What about genetic research?**

Samples of tissue are sometimes used for medical genetic research, which aims to discover the links between genes and disease by looking at DNA. Our genes can affect health in various ways; a gene abnormality may directly cause illness or more commonly variation in genes may predispose to illnesses such as high blood pressure. It is important to emphasise that these gene variations do not directly cause illness but in combination with other factors such as diet and smoking they may make a disease more likely. The genetic research undertaken on tissue from this bank will look at genes in the second group and will not directly impact on you or your family’s health. Should you wish further information regarding ongoing research please contact us at the numbers below.

**What about commercial research?**

Research groups are sometimes asked by commercial groups if they may obtain samples for ethically approved commercial research. This research is usually for the purpose of developing new drug treatments, which could eventually be marketed. Neither relatives nor the research groups profit financially from any developments of this kind.

**What about confidentiality?**

You can be assured that the identity of your relative, and of your family, is totally confidential and no identifying details will ever be made public. All information obtained in this study will be stored securely in the University of Edinburgh and retained indefinitely. The information may be shared in an anonymised form with other researchers, including commercial organisations, who are carrying out ethically approved research.

We request permission to contact your deceased relative’s GP to let them know, as a professional courtesy, that you agreed to your relative taking part in this study, and to request access to medical notes. In addition, we will seek authorisation to access hospital records.

Researchers from other centres can request tissue to support their research programmes. Tissue will only be released to research groups with peer reviewed funding. All tissue released will be completely anonymised to the research group with patient identifying data being known only to senior core staff within the ICECAP study team.

Regular update training is required for all staff, and local courses are available through both NHS Lothian and University of Edinburgh. The University has an ongoing policy for good practice in data protection. A senior member of the team will monitor compliance with data protection.

**What happens when the research is finished?**

The small tissue samples, which are embedded in paraffin blocks, and the slides, will be kept for at least 10 years and possibly up to 30 years (this is standard practice). Retained tissues may be kept for future medical research and disposed of lawfully when they are no longer useful.

**Who has reviewed this study?**

The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your relative’s records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Lothian, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

**If I agree now, can I change my mind later?**

Yes. You can make contact at any time and be assured that the tissue samples will no longer be used for research and education and that any retained tissues will be disposed of lawfully. Any stored data will be destroyed. Any samples that have not already been analysed can be destroyed if you request this, and we will ask for samples shared with other researchers to be returned to us for lawful disposal. We would, however, keep a small amount of data about your wishes to withdraw research authorisation. This would be a copy of your authorisation form with “authorisation withdrawn” written on it and a copy of any letters we may send you confirming withdrawal.

**Who do I complain to if I am unhappy about any part of this research study?**

If there is a belief that any harm has been suffered by taking part in this study, there is a right to pursue a complaint and to seek any resulting compensation through NHS Lothian who is acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Experience Team, Waverley Gate, 2nd Floor, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Telephone 0131 536 3370 or email [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone’s negligence, you may have grounds for a legal action against NHS Lothian, but you may have to pay your legal costs.

**Thank you for taking the time to read this Information Sheet and for considering to**

**take part in this study.**

**If you require further information or have any queries, please contact:**

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