

Genetics of Influenza Susceptibility in Scotland (GenISIS)

INFORMATION SHEET FOR LEGAL REPRESENTATIVE, GUARDIAN, WELFARE ATTORNEY OR NEAREST RELATIVE [Version 2 (26/10/09)]

Your friend/relative is currently being treated in the intensive care unit with suspected or confirmed swine flu. We are undertaking a research study involving people with severe swine flu, which is why we have approached you.

Before you decide it is important for you to understand why the research is being done and what it would involve for your relative/friend. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information and take time to decide.

What is the study about?

Influenza ('flu') affects millions of people around the world every year. Most cases are mild, but some people with flu become very unwell. We do not understand why this happens. We want to investigate how our body fights the flu infection. Our "genes" (or DNA) determine how vulnerable we are to infections. For instance, swine flu causes some people to become desperately sick, whilst others get no symptoms at all. If we could find the genes that cause some people to be more vulnerable to swine flu, we may be able to develop better treatments for patients in the future. This study will compare the DNA of people who get very sick with swine flu to the DNA from other people among the healthy general public. This will help us to find "vulnerability genes" that make certain people more likely to get a severe infection.

Why has my friend/relative been approached?

We would like to include your friend/relative in this research study because he/she has severe swine flu. He/she is currently unable to decide for him/herself, so we would like to ask for your permission on his/her behalf. Please take into account what you know of his/her wishes and of any advance decisions he/she has made about taking part in research. Your decision is completely voluntary. The decision you make will not affect his/her care or treatment in any way.

What will happen if my friend/relative takes part in this study?

A single blood sample will be taken (9mls; roughly 2 teaspoons). This can be taken at the same time as other routine blood samples.

What will happen to the samples?

We will use the blood sample to extract and analyse the DNA of your friend/relative. We will compare it to the DNA of other people in Scotland, specifically people who did not have severe swine flu. In order to ensure that we find the best people to compare your friend/relative's DNA with, we will keep limited information about him/her on a secure file, including, for example, general information about his/her current and past illnesses.

With your permission, we would also like to store the sample and use it for future ethically approved research. We will also access your friend/relative's electronic medical record in order to confirm the diagnosis of swine flu and ensure that he/she is eligible to participate in the study.

Are there any benefits or disadvantages to taking part in this study?

No, there are none. While this study will not benefit your friend/relative directly, it may help us to understand more about flu and hopefully help us to find new treatments in the future.

Does my friend/relative have to take part?

No. The decision whether or not to take part will not affect his/her care in any way.

What if something goes wrong?

If you are unhappy about any aspect of this study, please ask to speak to the researchers, who will answer any questions you may have. You will also have access to the normal NHS complaints procedures.

Can I request that my friend/relative is withdrawn from the study at any point?

Yes. The blood sample would be destroyed. You may also ask for any existing information to be withdrawn.

What if I have any problems or would like further information about the study?

If you would like more information about the study you can contact the Principal Investigator in the ICU or telephone the trial coordinator (see below)

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