Adult Information Sheet

Study title **Virus shedding and environmental deposition of novel A(H1N1) pandemic influenza virus**

You are being invited to take part in this University of Nottingham sponsored medical research. Before you decide 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 or your child would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the research project?
An influenza pandemic has recently been declared, involving the novel A(H1N1) 'swine flu' virus. This has spread to almost 100 countries worldwide in less than two months, causing widespread disease so far in Mexico, USA and Canada. It is highly likely that over the next 12 months, many countries including the UK will be affected by widespread illness. In the UK this wave of intense flu activity is most likely to occur in late autumn 2009.

Very little is known about the new H1N1 pandemic virus. For example we do not know how long the virus is excreted by infected humans and how much virus is spread to surfaces and carried in the air. This is very important to know as soon as possible because it affects the advice that will be given to healthcare workers about controlling the spread of infection to themselves and other patients. Similarly we need this information so we can give good quality advice to families who will have to look after each other in their own homes.

The best way to obtain this information is to ask patients who get pandemic flu soon (in August, September and October) to help us by agreeing to give a daily nose swab sample for just over one week so we can see how much virus is in the nose day by day and how quickly this disappears. At the same time we will take samples from hard surfaces in a patient's room or home and sample the air using a special filter device. We can then work out how much virus is being excreted, how long the 'danger period' is, whether surfaces are more or less important than the air that we breathe (in terms of catching the virus) and if we can advise on a 'safe distance' from the patient, beyond which there is relatively little chance of catching the illness. We need to do these studies in children as well as adults.

The study involves a simple daily nasal swab and subjects who agree to take part will be inconvenienced to some extent. However, the technique of sampling from the nose is quick and not painful and should not present any problems. Normal medical care will not be affected in any way.

The team has been performing this kind of work for some time and is well qualified and experienced to carry out the study. Several members of the study team are leading international experts on influenza.

Why have I been chosen?
You have been chosen as you have had a diagnosis of swine flu made.
This trial will include about 100 adults and children from Nottingham, Leicester and Sheffield. We are recruiting patients both from the community and in hospital.

Do I have to take part?
No. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you do withdraw, we will ask why, as it might be important for other people, but you don't have to give a reason if you don't want to.

What will happen to me if we agree to take part?
If you choose to take part, the care you receive will not be different from that should you choose not to take part. You will be asked to sign a consent form. You will be given a copy of the information sheet and signed consent form to keep for your records.

We will confirm your entry into the study following a few questions. We will ask about your symptoms and their duration and if anyone else in your household has been ill. If your answers fit our criteria we might also then do a test for influenza by taking a nose swab. The test will be done whilst we are with you. If the test is positive you are eligible, if the test is negative you won't be able to take any further part. This test is only being done for our research purposes, the result will not change the way you are being managed by your GP or anyone else.

If eligible, you will be involved in the trial for a maximum of 10 days and a minimum of 7. The number of days will depend on how long you have had symptoms before we meet you. If we meet on the day your symptoms begin we would like to visit every day for 10 days. If we meet 2 days after symptoms begin we will visit every day for 8 days. A member of the research team will carry out the visit, the person will usually be a nurse but maybe another healthcare professional. All staff will have undergone the necessary checks and training needed to conduct such work. We will arrange appointment times with you.

We would like to visit you every day during the study and perform the following procedures (in addition to what has been mentioned above already);

- Symptom assessment – At the first visit you will be asked to complete a number of assessment forms that cover your medical history and current symptoms. Subsequently we will ask you to complete a diary of your symptoms. You will complete a simple chart which asks whether you are feeling certain symptoms and how severe they are. In addition to this we will take an oral temperature reading.

- Nose swab – A large cotton bud will be used to take a swab from the inside of the nose, it does not need to go very far back! This will be collected once every day (except on the first day when it might be done twice).

- Surface sampling – We have already chosen a number of common household and hospital room surfaces that we would like to swab, e.g. dining table, taps, door handles, remote control. We want to see if we can find influenza virus on these surfaces. After swabbing we will clean these surfaces. We will take swabs every other day when we visit. You will be randomly split into 2 groups for this; Group 1 will have swabs done on Days 1, 3, 5, 7 and 9. Group 2 will be done on Days 2, 4, 6, 8 and 10.

- Air sampling – For a few patients we would like to conduct some air sampling in the room in which they spend most time. This involves running 2 small machines that suck in air and collect air particles. We want to see if we can find influenza virus in these particles. The machines will stand in a room and run for a maximum of 3 hours. They do make a small amount of noise. This will be done every other day during the study. A member of the research team will be present to set the machine up and collect it afterwards.

Each of the visits will last for up to one hour except when air sampling is performed (see above) which will take longer. The researcher may set up the air sampling equipment, leave it running and then return before if finishes.

If you have been recruited in hospital and are later sent home, we would wish to follow you up at home for the remainder of the study period. Similarly, if you have been recruited in the community and need to be admitted to hospital we would follow you up in hospital.

This study will not interfere with the normal medical care you may receive. This includes the use of any medicines, e.g. antivirals

If for any reason you lose the capacity to consent during the study (e.g. the remote possibility that they are admitted to hospital and need to be sedated to help with breathing) we have included a box in the consent form to tick if you are happy for us to continue with our sampling during this period.

Initially your diagnosis of swine flu is likely to have been made on clinical grounds, i.e. the symptoms that you have. Some people may have a test to confirm this diagnosis (this will be different from the test we might have done initially on the nose

swab). If swine flu is confirmed you will remain in the study but should this test come back as negative, we will not perform any further sampling on or around you and you will be excluded from the study.

What are the possible benefits of taking part?
There is no specific treatment benefit as we will not influence your normal care. The work as a whole is seeking to provide information on swine flu infection that could improve the way we deal with it, particularly from an infection control point of view and the public will benefit from this.

You may gain some reassurance from the fact that a member of the research team will be visiting each day. However, as stated above they would not interfere directly with normal medical care. Of course, should there be any concerns they will raise them with you or your family so that you can contact your GP or other responsible medical professional.

Contact details
If you have any problems, concerns or other questions about this trial, you should contact the research member of staff who visits each day. If you have any complaints about the way the research staff are carrying out the study you can make a complaint to the study Chief Investigator, Professor Jonathan Van-Tam, Clinical Sciences Building, City Hopstial, Hucknall Road, Nottingham, NG5 1PB. Tel 0115 823 0276.

What will happen if I don't want to carry on with the trial?
You can withdraw from the study at any time but it would be best to stay in contact with us and keep to the study assessments if possible. We will ask for your reasons for withdrawing, as they might be important for other people. You don't have to give any reasons if you don't want to.

What if there is a problem?
In the event that something goes wrong and you are harmed during the trial the University of Nottingham carries insurance to make sure that if any participant incurs any unexpected adverse event that leads to their being harmed and that the event occurred as a consequence of the protocol (i.e. non-negligent harm), then the participant will be compensated. In addition, all research staff have their own professional indemnity insurance which will cover any unexpected adverse event that leads to participant harm caused by negligence.

This study will be conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines (directive CPMP/ICH/135/95), local regulatory requirements and the declaration of Helsinki, and all relevant local laws and regulations.

Will my participation in this trial be kept confidential?
When you enter the trial the researcher will record information about your illness, medical history and the subsequent course of the illness. Some of this information may be taken from your medical notes (if you are in hospital). Collection and analysis of this information is an important part of the research. Your contact details will also be recorded but will be kept separate from the study data on a secure database.

The results of the trial will be published in medical journals and sent to regulatory authorities. However, all identifying personal details will be kept strictly confidential and no information will be published or given out through which you could be identified.

What will happen to the results of the trial?
Any results will be presented to the Department of Health in the first instance. Subsequently, results may be presented at scientific medical meetings and published in a leading medical journal and possibly in national and local media too. You will not be individually identified in any report or publication.

Who is organising and funding the research?
The University of Nottingham is organising this study. The NHS Health Technology Assessment (HTA) Programme has provided the research grant and no member of the research team are being directly paid for including you in this study.

Who has reviewed the study?
The trial was peer reviewed before funding by the HTA. This study was given a favourable ethical opinion for conduct in the public-health sector by the Leicester 1Research Ethics Committee, and was approved by the local NHS Trust Research & Development departments.

You will be given a copy of this Adult Information Sheet and a copy of the signed Consent Form to keep.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION SHEET