Ref:
Date:

Dear Sir or Madam,

We would like to invite you to take part in a research study entitled:

Title: *Causes of brain injury associated with cardiac interventions*

Principal Investigator: *Dr. Emma Chung (British Heart Foundation Fellow)*
Tel: *0116 2585610* **Email**: *emlc1@le.ac.uk*

You are about to undergo a cardiac procedure, which carries a small risk of brain injury due to particles and bubbles (emboli) entering the bloodstream during surgery. To better understand the causes of brain injury following cardiac surgery we are asking for volunteers to undergo a number of additional non-invasive investigations. These involve using ultrasound to monitor blood flow and detect emboli during surgery, and using Magnetic Resonance Imaging (MRI) of the brain and neuropsychological tests to assess brain function before and after surgery.

Before deciding if you wish to take part, it is important for you to understand why the research is being done and what it will involve. To help you to make an informed choice we have written a detailed information sheet to accompany this letter (dated 23/08/11 version 3a).

Once you have had time to consider taking part, there will be an opportunity for you to ask questions. If you agree to take part we will also ask you to sign a written consent form. Even if you have signed the consent form, participation is entirely voluntary and you can withdraw from the study at any time without giving a reason.

Please do not hesitate to contact Dr Emma Chung or myself if there is anything that is not clear to you or if you would like more information. Independent advice on becoming involved in a research study can also be obtained from 'Involve'. See http://invo.org.uk/ or call 02380 651088 for more information.

Thank you for your time and consideration.

Yours faithfully,

[*Name of consultant*]

RESEARCH PARTICIPANT INFORMATION SHEET (23/08/11, version 3a)

Causes of brain injury associated with cardiac surgery

Investigators: Dr E. Chung[1], Dr C. Banahan[2], Dr M Horsfield[1], Prof. T. Spyt[1,3], Mr N. Masala[3], Mr H. Abunsara[3], Mr J. Szostek[3], Mr M. Hickey[3], Prof V Egan[4], Prof. G. Cherryman[5], Prof. D.H. Evans[1,2], Mrs J. Janus[1] , Mr D. Spiers[1], Mr N. Patel[1]

1 Department of Cardiovascular Sciences, University of Leicester

2 Medical Physics Department, University Hospitals of Leicester NHS Trust

3 Department of Cardiothoracic Surgery, University Hospitals of Leicester NHS Trust

4 Department of Psychology, University of Leicester

5 Department of Neuroradiology, University Hospitals of Leicester NHS Trust

Invitation
You have been invited to take part in a research study. Before deciding 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 and discuss it with others if you wish. Ask us if anything is not clear to you, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
The aim of this study is to improve our understanding of the adverse effects of particles and gas bubbles (emboli) that enter arteries supplying the brain during cardiac surgery. During your operation we would like to use ultrasound to detect emboli moving through the arteries. Ultrasound signals recorded during this study will be use to predict the risk of brain injury for comparison with the results of neurological tests and Magnetic Resonance Imaging (MRI) scans performed before and after surgery.

How long will it take?
The study involves a number of additional investigations which will be completed alongside your routine care so that no extra hospital visits other than those associated with your normal care will be required.

<u>Before surgery:</u>
As a preliminary examination we will use ultrasound to measure blood-flow through the arteries in the head and neck. These checks will take approximately 30 mins. We will then

ask you to complete a series of neuropsychological tests (questionnaires and puzzles) to assess brain function, reaction times, memory and IQ. These tests will take approximately 1 hour. We will then ask you to undergo an MRI scan of the brain. This will take approximately 30 mins.

During surgery:
Ultrasound monitoring for emboli will be performed for the duration of your surgery. Ultrasound signals will be recorded to computer for later analysis.

After surgery:
During your routine outpatients' appointment (approximately 6 weeks following surgery) we will ask you to repeat the neuropsychological tests (1 hour) and MRI scan (30 mins).

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. Even if you have given your consent, 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.

What will be involved if I take part in the study?
Ultrasound equipment emitting inaudible sound waves will be placed gently on the head or neck and adjusted to monitor the flow of blood and particles through the arteries. The probe is covered in a small amount of gel and held by hand or fixed in place using an adjustable headset. Ultrasound monitoring is completely painless, and over 20 years of diagnostic measurements has not been shown to be harmful.

As with all patients who have an MRI scan, you will be asked to complete a questionnaire beforehand to make sure that it is safe for you to have a scan. You will be asked to remove any metal objects, including jewellery. The scanners are quite noisy, making a hammering noise during the scan. You will be provided with ear plugs to protect your ears. You will be asked to lie very still during the scans, which can be uncomfortable. However, you will be able to get comfortable again during the rest periods between scans. The MRI scanner is quite narrow, and some people feel claustrophobic within the scanner, but there is a 'panic button' which will enable staff to get you out of the scanner straight away if necessary. Many thousands of MRI scans are performed every day, and it is not thought that there are any long-term risks.

The neuropsychological tests involve you doing about an hour's worth of puzzles and tasks of the kind you might see on game shows on television. However, the tasks measure different aspects of your memory, attention and problem-solving. All have been used in studies like this one many times before and help us to understand what kinds of practical problems any brain injury might cause.

What are the possible disadvantages and risks of taking part?
As you are aware, there is a small risk of stroke associated with your surgery. Involvement in this study has no effect on this risk.

MRI does not use X-rays and is safe for the majority of people. However, the strong magnet at the centre of the procedure can affect medical devices, such as heart pacemakers and inner ear implants. If you have metal close to an important organ then you will be advised not to have an MRI.

As with all additional medical tests, there is a risk that the brain MRI will reveal abnormalities that you may have been unaware of. MRI images will be examined by a Radiologist and any abnormalities will be reported to your GP.

What are the benefits of taking part?
There are no direct clinical benefits for participants but the information we get from the study may improve the safety of cardiac surgery in the future.

Will the information obtained in the study be confidential?
If you wish to take part in this study your participation will be noted in your medical records. All information that is collected about you during the course of the research will be kept strictly confidential. Researchers may have future access to the study data, but all information that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What if I am harmed by the study?
It is highly unlikely that you will be harmed during this study and there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action against University Hospitals of Leicester NHS trust but you could have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated, the normal National Health Service complaints mechanisms would still be available to you

What if I have a complaint?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. (Please contact Dr Emma Chung, **Tel:** 0116 2585610). If you remain unhappy and wish to complain formally, please contact the University Hospitals of Leicester NHS Trust Patient Information and Liaison Service (PILS): Freephone: 0808 178 8337.

What will happen to the results of the research study?
The results of the study will be presented at medical conferences and will be published in specialised medical journals. The data will be completely anonymous and your identity will not be revealed in any publication or presentation of these results.

There will be an open lecture on research generated by the study to which all participants will be invited.

Who has reviewed the study?
All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by an NHS Research Ethics Committee before it goes ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision.

Contact for further information
If you have any questions or queries about this research project please do not hesitate to contact Dr Emma Chung. (**Tel:** 0116 2585610 **Email:** emlc1@le.ac.uk)

Thank you for reading this. This information leaflet is for you to keep.