Less Invasive Autopsy: A study to evaluate and compare the use of Computerised Axial Tomography (CT) and Magnetic Resonance Imaging (MRI) with conventional autopsy.

You have being invited to allow your relative to take part in a research study. Although the study consenter has talked to you by telephone already 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 there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to continue to take part in this study.

Questions
It is important that you understand everything that is been asked of you to consider. We have tried to write this information sheet in non-medical terms but there may be terms used within it that you may still feel unsure about.

If there is anything at all, at any point as you read this sheet that you do not fully understand please ask us to explain it to you in more detail.

What is the purpose of the study?
In collaboration with Her Majesty’s Government Department of Health (DoH), the East Midlands Forensic Pathology Unit and Imaging Department, University of Leicester are undertaking a study to evaluate and compare the use of special types of x-ray examinations commonly known as CT scans against that of a conventional autopsy (post-mortem
examination) to consider whether an x-ray examination of the recently deceased could replace in part or whole the necessity to undertake an autopsy.

What is a CT scan?
A CT scan is a special form of x-ray examination undertaken in a hospital. It produces very detailed two and three-dimensional images of the body. It is used in day to day clinical practice to examine patients for the presence of disease in the organs and cavities of the body as well as the bones as it produces more information than traditional x-ray examinations. The images can be made better with the use of a special dye (known as contrast) which can be injected into blood vessels. In clinical practice this would be used for example to investigate someone who was thought to have had a heart attack or a problem with the blood vessels taking blood to the heart.

Why has my relative been chosen for this study?
The DoH and Ministry of Justice wish to investigate whether examinations such as CT scans can one day replace the need for a traditional autopsy. They wish that as many causes of death, be it natural or unnatural be included within the research programme to see which causes of death can and cannot be diagnosed purely with the use of CT. As the majority of autopsies undertaken in England and Wales are undertaken at the request of H.M.Corneer these deaths form the basis of this study.

As Her Majesty’s Coroner has requested that an autopsy is to be undertaken on your relative you have been approached to consider whether or not you will allow us to enter your relative into the research programme.

Why did you not come and see me in person?
The reason that we approached you by phone and not in person was because the time period between us being notified that an autopsy was requested by HM Coroner and the undertaking of the examination is very short. We are not allowed to do anything that slows down the process of HM Coroner. As there will be several such requests to different families on the same day, some of which we would also approach, although we would wish to, it is not possible for us to visit each and every person personally especially if relatives live outside the immediate City of Leicester boundaries. Thus we have had to take the option of using the telephone to speak to you.

Do I have to allow my relative to take part?
It is up to you to decide whether or not to allow your relative to take part. As you have already decided to allow them to take part we have sent you this information sheet as requested to keep and consider. If you decide not to allow them to continue to take part in this study, it will not affect the autopsy that is to be undertaken on your relative.

What will happen to my relative if I allow them to take part?
By consenting on the telephone for your relative to take part in this research programme they were first allocated a unique code by a coding officer to ensure that your relatives details are anonymised within the study. Your relative was taken from the mortuary at the Leicester Royal Infirmary where they presently lie to the Imaging Department at the Leicester Royal Infirmary. They underwent a full body CT scan.

If you consented for them to have additional angiography then they have undergone that procedure as well. A tube was inserted into the neck and a special dye was injected down the tube. This filled the vessels of the heart to allow us to see these vessels in more detail on the imaging. Another CT image of the heart was then taken. The tube was then removed and the incision closed.

After this they were taken back to the mortuary where they will lie at rest until it is time for the autopsy procedure.

An autopsy examination will be undertaken as instructed by HM Coroner. At this examination, if you consented to it, a number of tiny pieces of tissue were taken from the principle organs and any major pathology and taken to the east Midlands Forensic Pathology Unit. From this tissue glass slides will be cut and looked at under a microscope. The tissue will be stored to the end of the study and used or disposed off as you have indicated.

Due to the number of images present and the fact that the images arise from a deceased, not a living person, the CT scans will be stored on the national Department of Health cadaveric CT database known as the FiMag system. This is a secure storage system. No identifying details will be available on the images so these images cannot be identified as coming from your relative.

**What do I have to do?**
The only thing for you to do is to consider this document to ensure that your questions have been fully answered.

**What is the procedure that is being tested?**
The remit of the programme is to explore whether there are alternatives to a conventional autopsy. Thus it is to consider whether special types of x-rays with or without the use of contrast yield the same information that is required of an autopsy to answer the questions for which the autopsy is to be undertaken.

**What are the alternatives for diagnosis or treatment?**
There is at present no alternative to a limited or whole conventional autopsy.

**What are the side effects of any procedure to your relative when taking part?**
There are no side effects or complication to your relative to the additional x-ray procedures. There are no external or internal marks caused by the procedures and there will be no effect on the choice of cremation or burial of your relative. There will be no delay incurred prior to the autopsy examination that could delay the release of your relative from the mortuary.
What are the possible disadvantages and risks of taking part?
None

What are the possible benefits of taking part?
There is no direct benefit to your relative in taking part. The benefit may be to the relatives of those that die in the future who may or may not, depending upon the outcome of the research, have to undergo an autopsy.

What happens when the research study stops?
The data collected from the research programme will be analysed and presented to the Department of Health and interested bodies within the medical, scientific and lay people communities as to whether or not alternative less invasive procedures exist to replace the need for an invasive autopsy.

We wish also to be allowed for the x-rays and slides to be used for the teaching and training of doctors and technicians who in the future may use this procedure as part of their day to day medical job instead of having to perform autopsies.

If you do not permit the images and slides to be retained for teaching and training purposes they will be destroyed at the end of the study.

What if something goes wrong?
If your relative is harmed by taking part in this research project, there are no special compensation arrangements. If your relative is harmed due to someone’s negligence, then you may have grounds for a legal action but you may 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 your relative treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

Will my taking part in this study be kept confidential?
All information which is collected concerning your relative during the course of the research and teaching/training will be kept strictly confidential. Any information about your relative which leaves the hospital will have their name and address removed so that they cannot be recognised from it. The radiology images will have the unique code, gender and age present but no other details.

What will happen to the results of the research study?
The following will happen:

- The results will be made available to the Department of Health.
• The study report will be made available to the local Coroners department, Police forces and community organisations who are supporting this programme.
• The results will be used for higher degrees (Doctorates) which will be held within the University of Leicester Library
• The results will be presented at local, national or international scientific meetings
• The results will be published within medical peer reviewed journals
• The results will be used for training and teaching of future doctors and associated technicians

The CT scans, slides and any opinion related to the autopsy arising from the study will NOT be made available to HM Coroner or yourselves. At present the gold standard for the diagnosis is the autopsy and the opinion that arises from the pathologist undertaking the examination. As it has not been proven to date that a CT scan yields the same, worse or better information (hence the study) then it is considered appropriate that the outcome of the autopsy, not the study, forms the basis for HM Coroner’s inquiry.

**Who is organising and funding the research?**
The work is at present been funded by the East Midlands Forensic Pathology Unit and Imaging Department of the University of Leicester. Funding may become available from the Department of Health or Ministry of Justice.

**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**
Professor Guy N Rutty,
Professor of Forensic Pathology and Chief Forensic Pathologist
East Midlands Forensic Pathology Unit
University of Leicester

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‘Thank you for reading this.’
You will be given a copy of the information sheet and a signed consent form to keep.
Study Number: 04/Q2501/64
Patient Identification Number for this trial:

VERBAL CONSENT FORM

Title of Project:

Less Invasive Autopsy: A study to evaluate and compare the use of Computerised Axial Tomography (CT) and Magnetic Resonance Imaging (MRI) with conventional

Name of Researcher: Professor Guy N Rutty,
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University of Leicester
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To be completed by the Study Consenter during the time of the telephone consenting process. Please initial each box to confirm verbal consent procedure and consent was given.
I confirm that I spoke by phone to (insert relatives name)………………………………………… on (insert date)………………

I confirm that the relative of the deceased gave informed verbal consent for their relative’s participation in this study.

I confirm that the relative of the deceased gave informed verbal consent for a CT scan with or without angiography (delete as appropriate) for the purpose of this study.

I confirm that the relative of the deceased did or did not (delete as appropriate) give informed verbal consent for tissue to be retained at autopsy for the purpose of this study.

I confirm that the relative of the deceased did or did not (delete as appropriate) give informed verbal consent for their relative’s CT images to be used for teaching and training purposes.

I confirm that the relative of the deceased did or did not (delete as appropriate) give informed verbal consent for the histology slides to be used for teaching and training purposes.

I confirm (delete as appropriate) yes or no that the relative of the deceased wished to receive the information sheet

______________________________
Name of Person taking verbal consent

________________________
Date

______________________
Signature

Insert address for information sheet to be sent to if different from that on coroner’s officer’s death report: