

11 MAY 2009



National Research Ethics Service

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1

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07 May 2009

Professor Guy N Rutty
Professor of Forensic Pathology, Consultant Pathologist to the Home Office
University of Leicester
Forensic Pathology Unit,
Robert Kilpatrick Building,
Leicester Royal Infirmary, PO Box 65, Leicester
LE2 7LX

Dear Professor Rutty

Study title: Less Invasive Autopsy: A study to evaluate and compare the use of Computerized Axial Tomography and Magnetic Resonance Imaging with conventional autopsy.

REC reference: 04/Q2501/64

Amendment number: 1

Amendment date: 12 April 2009

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 01 May 2009.

Ethical opinion

The Sub-Committee requested further information regarding the approach and consent of relatives by Coroner officers. Professor Rutty clarified the following points:

1. The approach and consent is being done by phone because the coroner's officers never actually meet the people involved.
2. The project has actually changed a little since the submission and all the coroner's officers are to attend a half-day training course run by Professor Rutty and the coroner about the project.
3. The Sub-Committee had discussed using a tear off reply slip to allow relatives time to consider before making a decision. However, there is no written correspondence about the coroners autopsy with the relatives so the 'tear off strip' to return would not be practical, given the autopsy will have been done by the time the relative actually receive the PIS if it is posted.

As the officers are going to have some training in the project and how to approach relatives over the study it seems a pragmatic way of doing things and the Sub-Committee decided that they would be happy for this amendment to go ahead.

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	1	12 April 2009
Participant Information Sheet: Coroner's Case's CT Verbal Consent	1	13 April 2009
Participant Information Sheet: CT Angiography	1	13 April 2009
Participant Consent Form: Coroner's Case's CT Verbal Consent	1	13 April 2009
Participant Consent Form: CT Angiography	1	13 April 2009
Notice of Substantial Amendment (non-CTIMPs)	1	12 April 2009

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

04/Q2501/64:	Please quote this number on all correspondence
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Yours sincerely



Miss Jeannie D McKie
Committee Co-ordinator

E-mail: jeannie.mckie@nottspct.nhs.uk

Enclosures

List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:

University of Leicester
R&D office for NHS care organisation at lead site - UHL

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Attendance at Sub-Committee of the REC meeting on 01 May 2009

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Jonathan Barratt	Senior Lecturer and Honorary Consultant Nephrologist	Expert
Dr Carl Edwards	Director	Lay

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Jeannie McKie	Committee Coordinator