



National Research Ethics Service

North West 5 Research Ethics Committee - Haydock Park

North West Centre for Research Ethics Committees
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7819
Fax: 0161 237 9427

26 February 2010

Professor Steve Goodacre
Health Services Research
SchARR
University of Sheffield
Regent Court
30 Regent Street
Sheffield S1 4DA

Dear Professor Goodacre

Study title:	Evaluation and development of triage methods used to select patients with suspected pandemic influenza for hospital admission
REC reference:	09/H1010/60
Amendment number:	2, 29th January 2010
Amendment date:	29 January 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review decided that they could not give a favourable ethical opinion of the amendment, for the following reasons:

The swine flu pandemic has failed to manifest itself on the scale that had been expected. The predicted numbers of swine flu cases were used to inform the design and methodology of the study. To compensate for the greatly reduced number of cases presenting at hospital emergency departments' the amendment (Amendment 2; 29th January 2010) sought approval for a three month extension to the study and to undertake a retrospective examination of emergency departments' attendances in order to reconfigure the study along the lines of a case-control model. It is intended to retrospectively identify additional positive cases and add new positive cases to those accrued prospectively. Negative cases in the dataset will then act as the 'controls'. It is not proposed to inform patients who have been retrospectively identified as positive cases that the research team intends to use their data.

A revised protocol (version 5 dated 29 January 2010) had been submitted in support of the amendment.

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

The Sub-Committee expressed the following concern with the proposed amendment as follows:-

- A. It was noted that the study had received approval from the National Information Governance Board for Health and Social Care (NIGB) to process identifiable patient data without consent (under section 251 of the NHS Act 2006). It was further noted that the proposed amendment had also been submitted to the NIGB for approval. Thus the REC sought written confirmation that the NIGB approval to process identifiable patient data without consent had been extended to include patients who have been retrospectively identified as positive cases. Ethical approval for the amendment will not be issued until such time as notification of NIGB approval is received.
- B. Leading on from the above, the Sub-Committee questioned the rationale underpinning the proposal not to inform patients that their data would be used in research without consent, i.e. because it was not possible to reliably identify those who had fully recovered or those who had died. Specifically, if in the first instance it was possible to identify (presumably via NHS numbers?) retrospective cases from the examination of emergency department attendances, why was it not also possible to use NHS numbers to identify patients who had died? This would presumably enable reliable identification of patients who had subsequently recovered in order to seek informed consent to use their data.

In conclusion should Amendment 2 dated 29th January 2010 fail to obtain NIGB approval then the REC would expect the research team to fully address the issues which have been raised in point B above.

In light of the request for NIGB approval as outlined above, the REC had no option but to reject the proposed amendment.

We regret to inform you that the amendment is therefore not approved. The study should continue in accordance with the documentation previously approved by the Committee.

Modifying the amendment

You may modify or adapt the amendment, taking into account the Committee's concerns. Modified amendments should be submitted on the standard Notice of Amendment form. The form should indicate that it is a modification of the above amendment. Please ensure that you submit all of the documents again that need to be reviewed, that is any of those listed below which are still relevant, as well as any revised or new documents.

A revised Notice of Amendment form must be submitted at least 14 days before you plan to implement the amendment. The Committee will then have 14 days from the date of receiving the notice in which to notify you that the amendment is rejected, otherwise the amendment may be implemented.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
Covering Letter: From Richard Wilson, Project Manager		02 February 2010
Notice of Substantial Amendment (non-CTIMPs): 2, 29th January 2010		29 January 2010
Protocol	5	29 January 2010

Membership of the Committee

The members of the Committee who took part in the review at the meeting are listed on the attached sheet.

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.

09/H1010/60:

Please quote this number on all correspondence

Yours sincerely



Noel Graham
Committee Co-ordinator

E-mail: noel.graham@northwest.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copies to: Mr R Hudson
Research Office
The University of Sheffield
SHEFFIELD
S10 2TN

Mr R Wilson
Project Manager
The PainTED Study
Health Services Research Section
SchARR University of Sheffield
Regent Court
Regent Street
SHEFFIELD S1 4DA

R&D office for NHS care organisation at lead site: -

Ms G McVey
Sheffield Teaching Hospitals NHS Foundation Trust
Research Department
1st Floor
11 Broomfield Road
SHEFFIELD
S10 2SE

North West 5 Research Ethics Committee - Haydock Park

List of names and professions of members who took part in the review

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Donal Manning (Chair)	Consultant Paediatrician	Expert
Dr Tim Sprosen (Vice-Chair)	Chief Scientific Officer – UK Biobank and Medical Researcher/Epidemiologist	Expert
Professor Elizabeth Perkins	Director of The Health and Community Care Research Unit – The University of Liverpool	Lay