Cambridgeshire 3 Research Ethics Committee
Victoria House
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17 August 2009

Dr Mark Reacher
Consultant Epidemiologist, Health Protection Agency, East of England
Health Protection Agency
Institute of Public Health
Robinson Way
Cambridge
CB2 0SR

Dear Dr Reacher

Study Title: **Survival analysis of a cohort of Clostridium difficile infected and non- infected patients admitted to Addenbrooke's Hospital between 2005 and 2007**
REC reference number: **09/H0306/62**

The Research Ethics Committee reviewed the above application at the meeting held on 06 August 2009. Thank you for attending to discuss the study. Please pass on the Committee's thanks to Dr Jones for attending as well.

After the Committee's initial deliberations, you were invited to join the meeting to clarify some issues. You kindly provided the Committee with the further information and clarifications set out below.

The Committee advised that they had no major ethical concerns and felt that the study could be given a favorable opinion if the Committee's queries were answered satisfactorily.

You thanked the Committee and explained that you would now be to seek approval from NIGB (National Information Governance Board for Health and Social Care) which had now replaced PIAG.

1 Members commented that they had noted that it was the intention to mask the notes but that they felt that it would be clear to the investigators if the patient had C difficile if the drug vancomycin had been prescribed. You advised that you had considered this and so this would be the last piece of information obtained.

2 Members asked for clarification regarding the false positives. You explained that this would just be a way of double checking that the cases/ non cases met the definition. For example if a patient had been viewed as a case but there was no laboratory confirmation of this then their notes would not be used in the study.

3. The Committee asked if the records would be robust enough. You confirmed that they did not think that this would be an issue. You had accessed the records for a previous study that had similar questionnaires without problems. The researchers

taking the information would be trained in the methodology of the study and it was expected that they would spend 1 –to 1½ hours looking at the case notes.

4. Members asked if you planned to contact the patient's GP. You advised that you had considered that but that you had discounted it as it would be too laborious and would place too much of a burden on the GP.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Statistician Comments: Letter from Andre Charlett		13 July 2009
Summary	1	09 July 2009
Protocol	1	09 July 2009
Investigator CV: Dr Mark Reacher		13 July 2009
REC application (Submission Code 13968/49763/1/59)		
Applicant's Checklist		

Membership of the Committee

The members of the Ethics Committee who were present 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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0306/62	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mr Stuart Kent
Vice-Chair

Email: lynda.mccormack@eoe.nhs.uk

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

"After ethical review – guidance for researchers"

Copy to: *Mr Stephen Kelleher*
R&D Office
Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
CB2 0QQ

Cambridgeshire 3 Research Ethics Committee

Attendance at Committee meeting on 06 August 2009

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Richard Griffiths (Chair)	Consultant Anaesthetist	No	Apologies given
Mr Stuart Kent (Vice-Chair)	Retired Consultant Surgeon	Yes	
Mr John Richardson (Alternate Vice-Chair)	Lay member	Yes	
Dr Sati Ariyanayagam	Consultant Physician	Yes	
Mrs Anna Eden	Lay Member	No	Apologies given
Mr David Lankester	Lay Member	Yes	
Mr David Lewin	Research Officer	Yes	
Miss Jennie Lowes	Critical Care Outreach Matron	No	Apologies given
Dr Stella Lowry	General Practitioner	No	Apologies given
Ms Sue McIntosh	Lead Nurse Theatres, Day Surgery & Procedural Areas	No	Apologies given
Mrs Veronica Orton-Johnson	Lay member	No	Apologies given
Rev David Parkes	Chaplain	No	Apologies given
Mrs Nikki Phillimore	Senior Pharmacist	Yes	
Mrs Ingrida Robinson	Clinical Governance Facilitator	No	Apologies given
Professor Michael Simmonds	Retired academic pharmacologist	Yes	Co-opted from the Cambridgeshire 1 REC

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Lynda McCormack	REC Co-ordinator
Mr Robin Scovil	REC Assistant Administrator