



National Research Ethics Service

East Yorkshire & North Lincolnshire REC

Yorkshire and the Humber Research Ethics Office

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Facsimile:

31 August 2010

Mr Zeiad I Hussain
Research Fellow in General Surgery
York Hospitals NHS Trust
York Hospital
Wigginton Road
York
YO31 8HE

Dear Mr Hussain

Study Title: Improving the quality of care in patients with faecal incontinence
REC reference number: 10/H1304/27

Thank you for your letter of 8th August 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a sub-committee of the REC at a meeting held on 25th August 2010. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, 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).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

NRES Committee Yorkshire & The Humber - Humber Bridge

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02 December 2011

Mr Zeiad I Hussain
Research Fellow in General Surgery
York Hospitals NHS Trust
Wigginton Road
York
YO31 8HE

Dear Mr Hussain

Study title: Improving the quality of care in patients with faecal incontinence
REC reference: 10/H1304/27

Thank you for sending the progress report for the above study dated 13 October 2011. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research.

10/H1304/27:

Please quote this number on all correspondence

Yours sincerely



Mrs Nicola Mallender-Ward
Committee Co-ordinator

E-mail: nicola.mallender-ward@nhs.net

Copy to: Ms Susan Final, University of York
Mrs Caroline, Mozley, North and East Yorkshire R&D Alliance Unit

R&D Unit reference: YOR-A01729

North and East Yorkshire Alliance R&D Unit
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York Hospital

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7th September 2010

www.northyorksresearch.nhs.uk

Dear Mr Hussain

NHS Permission to undertake a research study

Trust: York Teaching Hospital NHS Foundation Trust
Study Title: Improving the quality of care in patients with faecal incontinence
Ethics Committee Favourable Opinion dated: 31 August 2010

Thank you for submitting details of this study for NHS Permission from the above-named Trust, which is a member of the North and East Yorkshire R&D Alliance.

I confirm that the study has NHS Permission and can now begin in the Trust.

Please note that the study must be conducted in accordance with the approved protocol, the Department of Health *Research Governance Framework for Health and Social Care* and any applicable legislation.

Please check that you are aware of the sponsor's Standard Operating Procedures that are applicable to this study. If your study is sponsored by the Trust, please refer to the Standard Operating Procedures published on the Unit's website www.northyorksresearch.nhs.uk. These should also be used as a default for externally sponsored studies where the sponsor does not have its own procedure or where there are gaps in the sponsor's procedure due to local circumstances.

Please note that this NHS Permission applies only to those documents granted a favourable ethical opinion on the above date. Please ensure that you notify the R&D Unit if there are any amendments to the study or when the study has ended and send me details of any publications that result from it.

May I wish you every success with the study.

Yours sincerely



Caroline Mozley
On behalf of York Teaching Hospital NHS Foundation Trust

cc: Liz Cook