NRES Committee London - Harrow
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03 June 2013

Professor Fares Sami Haddad
Professor in Orthopaedics
University College London Hospital
235 Euston Road
London
NW1 2BU

Dear Professor Haddad

Study title:	**A randomised controlled trial of Polyglactin 910 Triclosan coated sutures versus standard Polyglactin 910 sutures in patients aged 18 or over undergoing primary unilateral hip and knee arthroplasties in the Department of Trauma and Orthopaedics at University College London Hospital**
REC reference:	**13/LO/0435**
IRAS project ID:	**67960**

Thank you for your letter of 07 May 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Libby Watson, nrescommittee.london-harrow@nhs.net.

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

NHS 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).

Non-NHS sites

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. We 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.

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study 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 a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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

It is the 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 final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		03 December 2012
GP/Consultant Information Sheets	3	10 January 2013
Investigator CV	F S Haddad	01 March 2013
Investigator CV	M Sukeik	10 January 2013
Investigator CV	R Kallala	11 October 2013
Investigator CV	David Wilson	15 January 2013
Letter from Statistician		17 November 2010
Letter from Statistician		01 May 2013
Other: Adverse Events Sheet	2	10 January 2013
Other: Data Collection Sheet	4	10 January 2013
Other: Previous REC Decision Letter		06 April 2011
Other: External Peer Review Letter		16 November 2011
Other: Letter from APR Wilson re: ASEPSIS Score		01 May 2013
Participant Consent Form	8.0	07 May 2013
Participant Information Sheet	8	07 May 2013
Protocol	8	07 May 2013
Questionnaire: Post Discharge Questionnaire	2	01 March 2013
REC application		15 February 2013
Response to Request for Further Information		07 May 2013

Statement of compliance

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

After ethical review

Reporting requirements

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

- Notification of serious breaches of the protocol
- 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.

Feedback

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.

Further information is available at National Research Ethics Service website > After Review

13/LO/0435	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

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

Yours sincerely

PP

Dr Jan Downer
Chair

Email:nrescommittee.london-harrow_nrescommittee.southcentral-hampshireb@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mr David Wilson*
Miss Shahina Begum-Meah, UCLH/UCL Joint Biomedical Research Unit