Health Research Authority

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

18 August 2016

Mr Paul Baker
Consultant Orthopaedic surgeon
South Tees Hospitals NHS Foundation Trust
Orthopaedics Department,The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Marton Road, Middlesbrough
TS4 3BW

Dear Mr Baker

Study title:	**Occupational advice for Patients undergoing Arthroplasty of the Lower limb (OPAL)**
REC reference:	**16/EM/0341**
Protocol number:	**R&D Number: 2016013**
IRAS project ID:	**200852**

Thank you for your letter, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Vic Strutt, NRESCommittee.EastMidlands-Derby@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Conditions of the favourable opinion

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

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" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Contract/Study Agreement [HRA Statement of Activities]		
Covering letter on headed paper [OPAL Covering Letter to HRA and Ethics]		25 July 2016
Interview schedules or topic guides for participants [OPAL Study Patient Interview Schedule]	1.0	13 July 2016
Interview schedules or topic guides for participants [OPAL Study AHP Interview Schedule]	1.0	13 July 2016
Interview schedules or topic guides for participants [OPAL Study Surgeon Interview Schedule]	1.0	13 July 2016
Interview schedules or topic guides for participants [OPAL Study GP Interview Schedule]	1.0	13 July 2016
IRAS Application Form [IRAS_Form_26072016]		26 July 2016
IRAS Application Form XML file [IRAS_Form_26072016]		26 July 2016
IRAS Checklist XML [Checklist_26072016]		26 July 2016
IRAS Checklist XML [Checklist_11082016]		11 August 2016
Letter from funder [HTA Project Funding Letter]		15 April 2016
Letter from statistician [OPAL Letter From Statistician]		25 July 2016
Letters of invitation to participant [OPAL Study AHP Letter of Invitation]	1.0	13 July 2016
Letters of invitation to participant [OPAL Study Surgeon Letter of Invitation]	1.0	13 July 2016
Letters of invitation to participant [OPAL Study GP Letter of Invitation]	1.0	13 July 2016
Letters of invitation to participant [OPAL Study GP Letter of Invitation]	2.0	08 August 2016
Non-validated questionnaire [OPAL Study Screening Form]	1.0	13 July 2016
Non-validated questionnaire [OPAL Study Screening Log]	1.0	13 July 2016
Non-validated questionnaire [OPAL Study Consent Log]	1.0	13 July 2016
Non-validated questionnaire [OPAL Study local confidential patient tracking log]	1.0	13 July 2016
Non-validated questionnaire [OPAL Study Contact Details Form]	1.0	13 July 2016
Non-validated questionnaire [OPAL Study Consent Log]	2.0	08 August 2016
Non-validated questionnaire [OPAL Study Contact Details Form]	2.0	08 August 2016
Other [HRA Schedule of Events OPAL Study]		
Other [OPAL Study Project Management Plan]	1.0	13 July 2016
Other [OPAL Study Project Oversight Group Membership List]		
Other [OPAL response to REC provisional approval - 08.08.16]		08 August 2016
Participant consent form [OPAL Study Phase 1 Informed Consent Form for Patients]	1.0	13 July 2016
Participant consent form [OPAL Study AHP Informed Consent Form]	1.0	13 July 2016

Participant consent form [OPAL Study AHP Verbal Informed Consent Form]	1.0	13 July 2016
Participant consent form [OPAL Study Surgeon Informed Consent Form]	1.0	13 July 2016
Participant consent form [OPAL Study Surgeon Verbal Informed Consent Form]	1.0	13 July 2016
Participant consent form [OPAL Study GP Informed Consent Form]	1.0	13 July 2016
Participant consent form [OPAL Study GP Verbal Informed Consent Form]	1.0	13 July 2016
Participant consent form [OPAL Study Phase 1 Informed Consent Form for Patients]	2.0	08 August 2016
Participant consent form [OPAL Study Phase 1 Verbal Informed Consent Form for Patients]	1.0	08 August 2016
Participant information sheet (PIS) [OPAL Study Phase 1 Participant Information Sheet for Patients]	1.0	13 July 2016
Participant information sheet (PIS) [OPAL Study AHP Participant Information Sheet]	1.0	13 July 2016
Participant information sheet (PIS) [OPAL Study Surgeon Participant Information Sheet]	1.0	13 July 2016
Participant information sheet (PIS) [OPAL Study GP Participant Information Sheet]	1.0	13 July 2016
Participant information sheet (PIS) [OPAL Study Phase 1 Participant Information Sheet for Patients]	2.0	08 August 2016
Participant information sheet (PIS) [OPAL Study GP Participant Information Sheet]	2.0	08 August 2016
Referee's report or other scientific critique report [HTA Initial Review Outcome Letter]		23 December 2015
Research protocol or project proposal [OPAL Study Protocol]	1.0	13 July 2016
Research protocol or project proposal [OPAL Study Protocol]	2.0	08 August 2016
Summary CV for Chief Investigator (CI) [CV Mr Paul Baker]		06 April 2016
Validated questionnaire [OPAL Study Baseline Hip Questionnaire]	1.0	13 July 2016
Validated questionnaire [OPAL Study Baseline Knee Questionnaire]	1.0	13 July 2016
Validated questionnaire [OPAL Study Post-operative Hip Questionnaire]	1.0	13 July 2016
Validated questionnaire [OPAL Study Post-operative Knee Questionnaire]	1.0	13 July 2016

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 HRA 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 HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

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/

16/EM/0341	**Please quote this number on all correspondence**

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

Yours sincerely

pp. V. Swift

Mrs Janet Mallett
Chair

Email: NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Mr Joe Millar*