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*

**From:** AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) [mailto:hra.amendments@nhs.net]
**Sent:** 31 January 2017 14:54
**To:** Paul Baker; Baker Paul (RTR) South Tees NHS Trust
**Cc:** Millar Joe (RTR) South Tees NHS Foundation Trust; Rowbotham Julie (RTR) South Tees NHS Trust; Kottam Lucksy (RTR) South Tees NHS Trust
**Subject:** RE: IRAS ID: 200852; REC ref no: 16/EM/0341; -OPAL -HRA Notification of Non Substantial Amendment - Category A amendment

Dear Mr Paul Baker,

| | |
|---|---|
| **IRAS Project ID:** | 200852 |
| **Short Study Title:** | OPAL |
| **Date complete amendment submission received:** | 31/01/2017 |
| **Amendment No./ Sponsor Ref:** | NSA #2 - minor changes to Protocol |
| **Amendment Date:** | 31/01/2017 |
| **Amendment Type:** | **Non-substantial** |

Thank you for submitting the above referenced amendment. In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category A** - An amendment that has implications for, or affects, ALL participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the three conditions below, you will be able to implement the amendment at your participating NHS organisations in England **35 days after you notify them of the amendment**. A template email to notify participating NHS organisations in England is provided here.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion where applicable, (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England, plus to local research teams at any participating NHS organisations in Northern Ireland, Scotland or Wales*.

- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.

**Note**: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below) after the 35 days have passed, you may then immediately implement this amendment at all participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study.

There is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

* Where the study involves NHS organisations in Northern Ireland, Scotland or Wales, the HRA will forward regulatory approvals to the relevant national coordinating function to distribute to their research management support offices.

**Participating NHS Organisations in England – Confirmation of Assessment Arrangements**

**Further to the details above, I can confirm that this amendment will be assessed by the HRA** to confirm that it meets the expected criteria and standards. An Assessor from the HRA will contact you and you will receive separate notification that the HRA Assessment is complete. You should not implement this amendment at participating NHS organisations in England until the outcome of the HRA assessment is confirmed and the conditions detailed in the categorisation section above have been met.

Please do not hesitate to contact me if you require further information.
Kind regards

Alka Bhayani
HRA Approvals - Amendments Coordinator

**Health Research Authority**
HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH
E: hra.amendments@nhs.net
www.hra.nhs.uk

**Would you like to receive the latest updates on HRA work? Sign up** here

**For more information on the HRA Approval process** Click here

The HRA is keen to know your views on the service you received – our short feedback form is available **here**

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 the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

29 May 2018

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** |
| **Amendment number:** | **3** |
| **Amendment date:** | **26 April 2018** |
| **IRAS project ID:** | **200852** |

The above amendment was reviewed 22 May 2018 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Discussion**

There were no ethical issues raised.

**Approved documents**

The documents reviewed and approved at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Covering letter on headed paper | | 25 April 2018 |
| Covering letter on headed paper [Feasibility patient screening cover letter] | 1 | 27 March 2018 |
| GP/consultant information sheets or letters [Feasibility GP letter] | 1 | 20 April 2018 |
| Interview schedules or topic guides for participants [Surgeon interview schedule] | 1 | 27 March 2018 |
| Interview schedules or topic guides for participants [GP interview schedule] | 1 | 27 March 2018 |
| Interview schedules or topic guides for participants [AHP-HOT interview schedule] | 1 | 27 March 2018 |
| Interview schedules or topic guides for participants [AHP-RTWC interview schedule] | 1 | 27 March 2018 |
| Interview schedules or topic guides for participants [Patients interview schedule] | 1 | 27 March 2018 |
| Letters of invitation to participant [Surgeon letter of invitation ] | 1 | 27 March 2018 |
| Letters of invitation to participant [GP letter of invitation] | 1 | 27 March 2018 |
| Letters of invitation to participant [AHP letter of invitation ] | 1 | 27 March 2018 |
| Non-validated questionnaire [Feasibility 8 week follow up hip questionnaire] | 1 | 20 April 2018 |
| Non-validated questionnaire [Feasibility 8 week follow up knee questionnaire] | 1 | 20 April 2018 |
| Non-validated questionnaire [Feasibility 16 week follow up hip questionnaire] | 1 | 20 April 2018 |
| Non-validated questionnaire [Feasibility 16 week follow up knee questionnaire] | 1 | 20 April 2018 |
| Non-validated questionnaire [Feasibility baseline hip questionnaire] | 1 | 20 April 2018 |
| Non-validated questionnaire [Feasibility baseline hip questionnaire] | 1 | 20 April 2018 |
| Notice of Substantial Amendment (non-CTIMP) | 3 | 26 April 2018 |
| Other [Schedule of events] | | 25 April 2018 |
| Other [Statement of activities] | 2 | 04 October 2016 |
| Other [Feasibility contact information form] | 1 | 20 April 2018 |
| Other [Feasibility Employer handbook] | 1 | 01 April 2018 |
| Other [Feasibility occupational checklist] | 1 | 27 February 2018 |
| Other [Feasibility patient workbook] | 1 | 01 April 2018 |
| Other [Consent form for patients] | 1 | 27 March 2018 |
| Other [Occupational advice intervention summary] | 1 | 20 April 2018 |
| Other [Screening log] | 1 | 27 March 2018 |
| Other [Consent log] | 1 | 27 March 2018 |
| Other [Employer or workplace representative verbal consent form] | 1 | 27 March 2018 |

| | | |
|---|---|---|
| Other [Employer or workplace representative letter of invitation ] | 1 | 27 March 2018 |
| Participant consent form [Surgeon consent form ] | 1 | 27 April 2018 |
| Participant consent form [GP consent form] | 1 | 27 March 2018 |
| Participant consent form [AHP consent form] | 1 | 27 March 2018 |
| Participant consent form [Verbal consent form for patients] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [Surgeon PIS] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [GP PIS] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [AHP PIS] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [Employer or workplace representative PIS] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [PIS for patients] | 1 | 27 March 2018 |
| Participant information sheet (PIS) [Employer or workplace representative PIS] | 1 | 27 March 2018 |
| Research protocol or project proposal [Clean] | 4 | 16 April 2018 |
| Research protocol or project proposal [Tracked] | 4 | 16 April 2018 |

**Membership of the Committee**

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

**Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

**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.

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

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

Yours sincerely

pp Sulya Rybnik

**Dr John S Fenlon**
**Chair**

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

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

*Copy to:* *Mr Joe Millar, South Tees Hospitals NHS foundation Trust*

Health Research Authority

**East Midlands - Derby Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 24 May 2018**

## Committee Members:

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Dr John S Fenlon (Chair) | Statistical Consultant | Yes | |
| Mrs Janet Mallett | Retired Nurse | Yes | |

## Also in attendance:

| *Name* | *Position (or reason for attending)* |
|---|---|
| Silje Dybing | REC assistant (Minutes) |

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

Email: hra.approval@nhs.net

04 October 2016

Dear Mr Baker

**Letter of HRA Approval**

| | |
|---|---|
| **Study title:** | **Occupational advice for Patients undergoing Arthroplasty of the Lower limb (OPAL)** |
| **IRAS project ID:** | **200852** |
| **Protocol number:** | **R&D Number: 2016013** |
| **REC reference:** | **16/EM/0341** |
| **Sponsor** | **South Tees Hospitals NHS Foundation Trust** |

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

**Participation of NHS Organisations in England**

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

*Appendix B* provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

**Appendices**

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

**After HRA Approval**

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

**Scope**

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

**HRA Training**

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **200852**. Please quote this on all correspondence.

Yours sincerely

Alison Thorpe
Senior Assessor

Email: hra.approval@nhs.net

*Copy to:* *Mr Joe Millar, South Tees Hospitals NHS Foundation Trust, Lead NHS R&D and Sponsor Contact*

NIHR CRN Portfolio Applications Team

Participating NHS organisations in England

## Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

| *Document* | *Version* | *Date* |
|---|---|---|
| Covering letter on headed paper [OPAL Covering Letter to HRA and Ethics] | | 25 July 2016 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of York] | | 18 July 2016 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Nottingham Insurance] | | 20 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 |
| 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 |
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| 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 [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 |
| Other [Schedule of events] | 1 | 15 September 2016 |
| Other [Statement of activities] | 2 | 04 October 2016 |
| Other [Schedule of events - GPs] | 1 | 04 October 2016 |
| Other [Statement of Activities - GPs] | 1 | 04 October 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 |
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| Participant consent form [OPAL Study Phase 1 Verbal Informed Consent Form for Patients] | 1.0 | 08 August 2016 |
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| Validated questionnaire [OPAL STudy Baseline Hip Questionnaire clean] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study baseline Hip Questionnaire tracked] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study baseline Knee Questionnaire clean] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study Baseline Knee Questionnaire tracked] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study Post-operative Hip Questionnaire clean] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study Post-operative Hip Questionnaire tracked] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study Post-operative Knee Questionnaire clean] | 2 | 30 September 2016 |
| Validated questionnaire [OPAL Study Post-operative Knee Questionnaire tracked] | 2 | 30 September 2016 |

**Appendix B - Summary of HRA Assessment**

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

**For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.**

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Dr Lucksy Kottam (Study Manager), Lucksy.Kottam@stees.nhs.uk, 01642854814

Mr Joe Millar (Assistant R&D Manager), Joe.Millar@stees.nhs.uk, 01642854089

## HRA assessment criteria

| Section | HRA Assessment Criteria | Compliant with Standards | Comments |
|---|---|---|---|
| 1.1 | IRAS application completed correctly | Yes | The study lists three secondary care sites in Part C of the IRAS form.<br><br>The applicant has confirmed that primary care sites will also be identified for the purpose of recruiting GP participants. The CRN regions from which these GPs are currently proposed to be recruited have been identified as CRN North East and North Cumbria, CRN Eastern and CRN East Midlands.<br><br>There is no expectation from the HRA to be notified of each participating GP practice, but, should additional CRN regions be identified, these should be submitted as a non-substantial amendment. |
| | | | |
| 2.1 | Participant information/consent documents and consent process | Yes | Subsequent to REC opinion a non-substantial amendment was submitted to revise the questionnaires to add dd/mm/yy formats on the fields on all |

| Section | HRA Assessment Criteria | Compliant with Standards | Comments |
|---|---|---|---|
| | | | their cover pages and to add an extra EQ5D scale on Hip and Knee Baseline questionnaires. |
| | | | |
| 3.1 | Protocol assessment | Yes | No comments |
| | | | |
| 4.1 | Allocation of responsibilities and rights are agreed and documented | Yes | The sponsor intends that the statement of activities acts as the agreement between the sponsor and secondary care sites.<br><br>The sponsor does not intend to use any formal agreement between the sponsor and the primary care sites for the participation of GPs. |
| 4.2 | Insurance/indemnity arrangements assessed | Yes | Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study |
| 4.3 | Financial arrangements assessed | Yes | Funding provided to secondary care sites to support research nurse activity is detailed in the statement of activities.<br><br>There is no funding provided to primary care sites. |
| | | | |
| 5.1 | Compliance with the Data Protection Act and data security issues assessed | Yes | No comments |
| 5.2 | CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed | Not Applicable | No comments |
| 5.3 | Compliance with any applicable laws or regulations | Yes | No comments |

| Section | HRA Assessment Criteria | Compliant with Standards | Comments |
|---|---|---|---|
| | | | |
| | | | |
| 6.1 | NHS Research Ethics Committee favourable opinion received for applicable studies | Yes | No comments |
| 6.2 | CTIMPS – Clinical Trials Authorisation (CTA) letter received | Not Applicable | No comments |
| 6.3 | Devices – MHRA notice of no objection received | Not Applicable | No comments |
| 6.4 | Other regulatory approvals and authorisations received | Not Applicable | No comments |

## Participating NHS Organisations in England

| *This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.* |
|---|
| There are two types of participating NHS organisation: primary and secondary care sites. Secondary care sites will be involved in identifying and recruiting patients and staff participants to participate in focus groups, interviews and questionnaires. Staff participants only will be recruited from primary care sites to participate in interviews and focus groups.<br><br>The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.<br><br>If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision. |

## Confirmation of Capacity and Capability

*This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.*

Participating NHS organisations in England that are secondary care sites **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

The HRA has determined that participating NHS organisations in England that are primary care sites **are not expected to formally confirm their capacity and capability to host this research,** because the study involves staff participants taking part in short interviews or focus groups.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- Following issue of the HRA Approval letter, and subject to the two conditions below, it is expected that these organisations will become participating NHS organisations 35 days after issue of this Letter of HRA Approval (no later than **08 November 2016**):
    - You may not include the NHS organisation if they provide justification to the sponsor and the HRA as to why the organisation cannot participate
    - You may not include the NHS organisation if they request additional time to confirm, until they notify you that the considerations have been satisfactorily completed..
- You may include NHS organisations in this study in advance of the deadline above where the organisation confirms by email to the CI and sponsor that the research may proceed.
- The document "Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expectations, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

## Principal Investigator Suitability

*This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).*

A Principal Investigator is expected to be identified at the secondary care sites. Neither a PI nor local

collaborator is expected at the primary care sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

## HR Good Practice Resource Pack Expectations

*This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken*

Where external researchers are visiting sites to conduct focus groups or interviews with patient participants it is expected that a letter of access is obtained, with evidence of DBS and occupational health checks.

Where external researchers are conducting focus groups or interviews with staff participants in non-patient care areas there are no HR Good Practice Expectations.

## Other Information to Aid Study Set-up

*This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.*

- The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.