Joint Research Management Office
Queen Mary Innovation Centre
5 Walden Street
London
E1 2EF

Tel: 020 7882 7260
Fax: 020 7882 7276
Email: Sponsorsrep@bartshealth.nhs.uk

FINAL R&D APPROVAL

26 March 2014

Professor Charles Knowles
Institute of Cellular & Molecular Science
Royal London Hospital
London E1 1BB

Dear Professor Knowles,

Protocol: **Studies in the aetiology and investigation of perianal fistula**

ReDA Ref: **009347 QM**
REC Ref: **14/LO/0071**

I am pleased to inform you that the Joint Research Management Office for Barts Health NHS Trust and Queen Mary University of London has approved the above referenced study and in so doing has ensured that there is appropriate indemnity cover against any negligence that may occur during the course of your project. Approved study documents are as follows:

Type	Version	Date
REC approval	Conditions met	14.03.2014 corrected 26.03.2014
REC approval	With conditions	24.01.2014
Protocol	v.2.1	03.12.2013
Participant Information Sheet	v.2.3	28.01.2014
Participant Consent Form	v.2.3	28.01.2014
Participant Consent Form: semi-structured interview	v.1.2	05.02.2014
Semi-structured interview	v.1.2	05.02.2014

Please note that all research within the NHS is subject to the Research Governance Framework for Health and Social Care, 2005. If you are unfamiliar with the standards contained in this document, or the BH and QMUL policies that reinforce them, you can obtain details from the Joint Research Management Office or go to:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

You must stay in touch with the Joint Research Management Office during the course of the research project, in particular:

- If there is a change of Principal Investigator
- When the project finishes
- If amendments are made, whether substantial or non-substantial

This is necessary to ensure that your R&D Approval and indemnity cover remain valid. Should any Serious Adverse Events (SAEs) or untoward events occur it is **essential** that you inform the Sponsor within 24 hours. If patients or staff are involved in an incident, you should also follow the Trust Adverse Incident reporting procedure or contact the Risk Management Unit on 020 7480 4718.

We wish you all the best with your research, and if you need any help or assistance during its course, please do not hesitate to contact the Office.

Yours sincerely

Gerry Leonard, Head of Research Resources

NRES Committee London - Queen Square
HRA Head Office
Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 797 22580

14 March 2014

Mr James B Haddow
National Centre for Bowel Research and Surgical Innovation
Blizard Institute, 1st Floor Abernathy Building
2 Newark St, London
E1 2AT

Dear Mr Haddow

Study title:	**Studies in the aetiology and investigation perianal fistula**
REC reference:	**14/LO/0071**
IRAS project ID:	**136873**

Thank you for your letter of 05 February 2014, 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 HRA 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 REC Assistant Hayley Fraser NRESCommittee.London-QueenSqaure@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

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

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 within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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		10 December 2013
Evidence of insurance or indemnity	REF: B1262F10152813	29 July 2013
Investigator CV	Prof Charles Knowles	21 October 2013

Letter from Sponsor		10 December 2013
Other: CV: Prof Robin Phillips		10 December 2013
Other: CV; Mr James B Haddow		
Other: Semi-Structured Interview	1.2	05 February 2014
Participant Consent Form	2.3	28 January 2014
Participant Consent Form: Semi-Structured Interview	1.2	05 February 2014
Participant Information Sheet: Participant Information Sheet	2.3	28 January 2014
Protocol	2.1	03 December 2013
REC application	136873/539195/1/12	11 December 2013
Referees or other scientific critique report	Project Ref No: B1/PR/13/169	17 October 2013
Response to Request for Further Information	Letter from Professor Charles Knowles	05 February 2014

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.

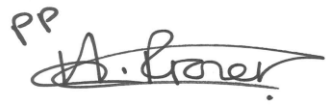
Further information is available at National Research Ethics Service website > After Review

14/LO/0071 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



Dr Yogi Amin
Chair

Email: NRESCommittee.London-Central@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Mr Gerry Leonard*
Prof Charles Knowles, Queen Mary and Westfield College, University of London
Mr Gerry Leonard, Queen Mary University of London