

NRES Committee London - Stanmore

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18 November 2011

Dr Stuart McDonald
Lecturer
Queen Mary, University of London
Centre for Digestive Diseases
Blizard Institute of Cell & Mol.Sci
4 Newark Street, London
E1 2AD

Dear Dr McDonald

Study title: Analysis of the spread of genetic abnormalities involved
in the progression of pre-malignant disease to cancer in
the human gastrointestinal tract.
REC reference: 11/LO/1613

Thank you for your letter of 25 October 2011, 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 me (Committee Chair).

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

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:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|--|----------------|-------------------|
| Covering Letter | 1.0 | 16 September 2011 |
| Evidence of insurance or indemnity | | 05 August 2011 |
| Investigator CV | 1.0 | 16 September 2011 |
| Letter from Sponsor | 1.0 | 15 August 2011 |
| Other: Summery CV for Student- Sebastian Zeki | 1.0 | 16 September 2011 |
| Other: Letter from funder | 1.0 | |
| Other: CV - Stuart Alistair Charles McDonald | 1.0 | 16 September 2011 |
| Other: CV - Tania Ventayol Garcia | | 15 September 2011 |
| Other: CV - Noor Jawad | | 15 September 2011 |
| Other: CV - Dr Laurence Lovat | | |
| Other: CV - Manuel Rodriguez-Justo | | |
| Other: CV - Marco Riccardo Novelli | | |
| Other: CV - Jo-anne Chin Aleong | | |
| Other: CV - Shabuddin Khan | | |
| Other: GP certificate of Completion - Sebastian Zeki | | 11 August 2010 |
| Other: GP certificate of Completion - Tania Ventayol-Garcia | | 11 September 2009 |
| Other: GP certificate of Completion - Stuart McDonald | | 04 December 2009 |
| Other: GP certificate of Completion - Noor Jawad | | 04 December 2009 |
| Other: Email from CI authorising response to provisional opinion | | 08 November 2011 |
| Participant Consent Form: BLT | 1.1 | 25 October 2011 |
| Participant Consent Form: UCL | 1.1 | 25 October 2011 |
| Participant Information Sheet: BLT | 1.1 | 25 October 2011 |
| Participant Information Sheet: UCL | 1.1 | 25 October 2011 |
| Protocol | 1.1 | 25 October 2011 |

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|--|---|-------------------|
| REC application | 1.0 | 16 September 2011 |
| Referees or other scientific critique report | 1.0 | 03 August 2011 |
| Response to Request for Further Information | Covering letter from Sebastian Zeki | 25 October 2011 |
| Summary/Synopsis | 1.0 | 12 September 2011 |

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

11/LO/1613

Please quote this number on all correspondence

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

Yours sincerely

Mrs Rosemary Hill
Chair

Email: uzma.chaudhry@nwlh.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to:

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