

Ethical approval

Office for Research Ethics Committees Northern Ireland (ORECNI)

15 August 2005

Dr Kar Wai Lau
Achalasia Study
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Dear Dr Lau

Full title of study: **A case control study of aetiological factors in achalasia**
REC reference number: **05/NIR02/132**

The Research Ethics Committee reviewed the above application at the meeting held on 11 August 2005

Ethical opinion

- During the meeting, Dr Lau clarified that the GP will be contacted initially and then the patient will be contacted via the GP. In light of this clarification, the Committee advises Dr Lau to modify the letters to the GPs accordingly, as it appears Dr Lau is contacting the patients directly.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

The Committee has designated this study as having "no local investigators". There is no requirement for other Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

| Item | Notes | Version | Dated |
|---------------------|-----------------------|---------|------------|
| Application | | | 07/07/2005 |
| Investigator CV | Kar Wai Lau | | 07/07/2005 |
| Investigator CV | Brian Thomas Johnston | | 07/07/2005 |
| Protocol | | 1.5 | 30/09/2004 |
| Covering Letter | | | 07/07/2005 |
| Letter from Sponsor | | | 07/07/2005 |
| Peer Review | Letter from RVH | | 19/11/2004 |
| Peer Review | | | 01/04/2005 |

| Item | Notes | Version | Dated |
|---------------------------------------|------------------------|---------|------------|
| Compensation Arrangements | | | 06/07/2005 |
| Copy of Questionnaire | Case | 1.3 | 04/07/2005 |
| Copy of Questionnaire | Control | 1.3 | 04/07/2005 |
| Letters of Invitation to Participants | Patient | 1.4 | 04/07/2005 |
| Letters of Invitation to Participants | Control | 1.4 | 04/07/2005 |
| GP/Consultant Information Sheets | Patient Letter to GP | 1.4 | 04/07/2005 |
| GP/Consultant Information Sheets | Control Letter to GP | 1.4 | 04/07/2005 |
| Participant Information Sheet | Achilles Patients | 1.4 | 04/07/2005 |
| Participant Information Sheet | Healthy Volunteers | 1.4 | 04/07/2005 |
| Participant Consent Form | | 1.4 | 04/07/2005 |
| Other | R&D Office Assumptions | | 01/04/2005 |

Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

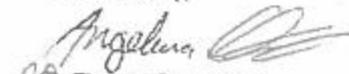
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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| 05/NIR02/132 | Please quote this number on all correspondence |
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With the Committee's best wishes for the success of this project.

Yours sincerely,


Dr Theresa Donaldson
Chair

Enclosures

Attendance at Committee meeting on 11 August 2005
Standard approval conditions

Signed: Helen Coleman