



National Research Ethics Service

NRES Committee North West - Cheshire

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19 October 2011

Dr Yeng Ang
Consultant Gastroenterologist
Wrightington, Wigan and Leigh NHS Foundation Trust
Endoscopy Unit
Royal Albert Edward Infirmary
Wigan Lane
Wigan
WN1 2NN

Dear Dr Ang

Study title: A morphological study of adenocarcinoma of the gastro-oesophageal junction.
REC reference: 11/NW/0632

Thank you for your letter of 30 September 2011, responding to the Committee's request for further information on the above research.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

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, 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).

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		22 August 2011
Investigator CV	Yeng Ang	14 August 2011
Investigator CV	Stephen Hayes	
Investigator CV	Keng Ngee Hng	22 August 2011
Protocol	1	14 July 2011
REC application	3.3	22 August 2011
Referees or other scientific critique report		25 July 2011
Response to Request for Further Information		30 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/NW/0632

Please quote this number on all correspondence

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

Yours sincerely



Mr Jonathan Deans
Chair

Email: shehnaz.ishaq@northwest.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Sandra Latham - Wroughtington, Wigan & Leigh NHS Trust

NRES Committee North West - Cheshire

Attendance at Sub-Committee of the REC meeting on 18 October 2011

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Nick Bronnert	GP Member	Yes	
Rev'd Stephen Burmester	Vicar	Yes	
Mr Jonathan Deans	Consultant ENT Surgeon	Yes	