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25 June 2015 (reissued 22 October 2015)

Professor Gary H Mills
Consultant in Anaesthesia and Intensive Care Medicine
Sheffield Teaching Hospital NHS Foundation Trust
General Intensive Care Unit,
Northern General Hospital, Herries Road,
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S5 7AU]

Dear Professor Mills

Study title:	**PRotective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in OBESE Patients – The PROBESE Randomized Controlled Trial**
REC reference:	**15/WA/0106**
IRAS project ID:	**167739**

Thank you for your letter of 30 May 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a Sub-Committee of the REC at a meeting held on 25 June 2015. A list of the Sub-Committee members is attached.

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 opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Tracy Biggs, Tracy.Biggs@Wales.nhs.uk.

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.

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).

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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters [GP Letter]	1	30 January 2015
IRAS Checklist XML [Checklist_06032015]		06 March 2015
IRAS Checklist XML [Checklist_11062015]		11 June 2015
Letters of invitation to participant	1	01 May 2015
Other [Probese study protocol]	v 3	30 May 2015
Other [Probese study protocol]	v 3	30 May 2015
Other [Probese post REC changes covering letter]	v 1	30 May 2015
Participant consent form [Consent Form]	1	30 January 2015
Participant consent form [Consultee Declaration]	1	30 January 2015
Participant consent form [Nominated Consultee Declaration Form]	1	30 January 2015
Participant consent form [Regaining Capacity Consent Form]	1	30 January 2015
Participant consent form [Telephone Checklist]	1	30 January 2015
Participant information sheet (PIS) [Consultee PIS]	1	30 January 2015

Participant information sheet (PIS) [Probese Patient Information Sheet UK V 1.1 (changes in red)]	v1.1	30 May 2015
Participant information sheet (PIS) [Probese Patient Information Sheet UK V 1.1 (clean)]	v1.1	30 May 2015
REC Application Form [REC_Form_06032015]		06 March 2015
Summary CV for Chief Investigator (CI) [CI CV]	CI CV	05 March 2013

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.

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 use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

15/WA/0106 **Please quote this number on all correspondence**

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

Yours sincerely

T.A. Biggs.

Dr Kath Clarke
Chair

Email:Tracy.Biggs@Wales.nhs.uk

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

Copy to: *Dr Erica Wallis,Research Coordinator, Research Department, Sheffield Teaching Hospitals NHS Foundation Trust*

Wales REC 4

Attendance at Sub-Committee of the REC meeting on 25 June 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Kath Clarke - Chair	Senior Investigations Manager	Yes	
Mr John Gittins	Coroner	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Tracy Biggs	Research Ethics Committee Manager