South East Scotland REC 01
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Telephone: 0131 465 5473

08 October 2018

Prof Fang Gao Smith
Professor of Anaesthesia, Critical Care and Pain
University of Birmingham
Birmingham Clinical Trials Unit
Institute of Applied Health Research
University of Birmingham
B15 2TT

Dear Prof Gao Smith

Study Title:	**A Randomised Controlled Trial to investigate the effectiveness of ThOracic Epidural and Paravertebral Blockade In reducing Chronic Post- Thoracotomy Pain: 2**
REC reference:	**18/SS/0131**
Protocol number:	**RG 17_255**
IRAS project ID:	**248427**

The Research Ethics Committee reviewed the above application at the meeting held on 03 October 2018. Thank you to Dr Benjamin Shelley for attending to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

General:-

1. The Committee requested that a separate brief information sheet and consent form be developed for the audio recording part of the study (for the patients). The main PIS should be amended to remove the audio recording part of the study.

2. Ensure that the time that the audio recordings are held is detailed in the documentation. Also mention what happens to the audio recording once completed and that they are anonymised and encrypted to ensure confidentiality.

The Participant Information Sheet – (and protocol as applicable) should be revised as follows:-

1. Detail contact details for an independent contact that the patients can approach.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact the REC Manager, Mrs Sandra Wyllie, by email at Sandra.Wyllie@nhslothian.scot.nhs.uk

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: https://www.myresearchproject.org.uk/help/hlpethicalreview.aspx#After-submit-to-REC

Please submit a covering letter detailing the changes and revised documentation where appropriate, underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

If the Committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in the covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 07 November 2018.

Extract of the meeting minutes

Social or scientific value; scientific design and conduct of the study

The Committee queried what the audio recording of the consent process has to do with the main study and why it is being undertaken.

The researcher explained to the Committee that the group in Bristol are looking at about 20 surgical trials to try and determine how recruitment rates can be improved. It was further clarified that these audio recordings will only be of the consent part of the study when the study is discussed with the patients.

The Committee requested if the PIS/Consent Form for the audio recording part of the study could be separated out.

The researcher agreed that this could be done.

Recruitment arrangements and access to health information, and fair participant selection

The Committee requested more information regarding the patient pathway and when the study was going to be first introduced to the patient.

It was explained to the Committee that this would take place at around a week before the surgery at the pre-assessment appointment. Consent would be taken when the patients return for the surgery after they have had time to consider the PIS.

The Committee asked if the patients would be aware of their likely diagnosis and of the chronic pain they can expect to experience post surgery.

The Committee was advised that although the likelihood of a cancer diagnosis will be known the issue of chronic pain after surgery is sometimes not as well explained as it should be.

The Committee asked how many sites so far have expressed an interest in participating in this study.

The researcher explained that there would probably be a maximum of 20 sites involved.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked about the randomisation process and whether all the anaesthetists would be able to carry out either procedure.

It was clarified that all the anaesthetists at the different sites should be proficient to carry out either procedure.

The Committee queried whether or not the participants will know which of the two procedures they have had.

The Committee was advised that it is almost impossible to blind the patients and in the feasibility trial about half of the patients had worked out what procedure they had received.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee noted that the time that the audio recordings are held is not detailed in the PIS documentation and requested that this was amended as appropriate.

It was agreed to amend the documentation.

The Committee additionally noted that the PIS does not mention what happens to the audio recording once done or that they are anonymised and encrypted to ensure confidentiality.

The Committee queried if identifiable data was going to be retained for up to 25 years.

The researcher confirmed that this is the case and is to allow for any possible research in the future.

The Committee asked if there were processes in place to ensure that a patient had not deceased, before the follow up phone call for the optional post surgery interview was made.

The Committee was reassured to be advised that the Bristol site has robust processes in place to ensure that this will not occur.

Informed consent process and the adequacy and completeness of participant information

The Committee noted that there is no independent contact listed in the PIS and requested that this was detailed.

It was agreed to add this information.

Suitability of supporting information

The Committee enquired as to how study results would be made available.

The Committee was advised that there is a trial website where a lay summary of the results will be made available. No contact details of the patients will therefore be required to be held.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
GP/consultant information sheets or letters [TOPIC2 GP Letter]	1.0	12 September 2018
IRAS Application Form [IRAS Form 13092018]	248427/1248998/37/484	13 September 2018
Other [TOPIC2 ICF Participant Audio-Recording]	1.0	12 September 2018
Other [TOPIC2 Staff Information and Consent- Audio-Recording]	1.0	12 September 2018
Other [Acute Phase Patient Booklet]	0.4	08 May 2018
Other [TOPIC 2 QRI - Interview Schedule for Recruiters]	1.0	16 July 2018
Other [TOPIC2 QRI - Interview Schedule for Patients]	1.0	16 July 2018
Participant consent form [TOPIC2 ICF]	1.0	12 September 2018
Participant information sheet (PIS) [TOPIC2 PIS]	1.0	12 September 2018
Research protocol or project proposal [TOPIC2 Protocol]	1.0	12 September 2018
Summary CV for Chief Investigator (CI) [Prof F Gao Smith CV]		01 November 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [TOPIC2 Trial Summary]	1.0	04 September 2018
Validated questionnaire [Booklet: Patient Satisfaction Questionnaire; Visual Analogue Score; Brief Pain Inventory; Short Form McGill Pain Score; EQ-5D-5L; Hospital Anxiety and Depression Scale]	0.3	08 May 2018

Membership of the Committee

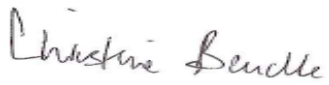
The members of the Committee who were present at the meeting are listed on the attached sheet

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.

18/SS/0131	**Please quote this number on all correspondence**

Yours sincerely



Mrs Christine Beadle
Vice Chair

Email: sandra.wyllie@nhslothian.scot.nhs.uk

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

Copy to: *Mr Hugh Jarrett, University of Birmingham*
Ms Elizabeth Adey, Heart of England NHS Foundation Trust

South East Scotland REC 01

Attendance at Committee meeting on 03 October 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Lynne Arnot	Medical Writing Coordinator	Yes	
Mrs Christine Beadle	Research Nurse	Yes	(In the Chair)
Mr Ben Bullen	Acute Diabetes Specialist Podiatrist	Yes	
Ms Sarah Clark	Senior Research Nurse - Critical Care Research Team	Yes	
Dr Kyle Gibson	ST6 Doctor (Anaesthetics and Intensive Care Medicine)	No	
Dr Lucy Kershaw	Senior Research Fellow	Yes	
Dr Eve Miller-Hodges	Specialty Registrar in Renal Medicine	Yes	
Mrs Linda Morrow	Independent Living Advisor	No	
Dr Derek Santos	Senior Lecturer - Faculty Of Health Sciences	No	
Dr Lillian Schweizer	Retired Molecular Geneticist	No	
Mrs Amy Shepherd	Senior Research Nurse - Regional Infectious Diseases Unit	Yes	
Mr Paul Van Rietvelde	Policy Online Project Manager	No	
Dr Isla Wallace	Senior Policy Advisor, Mental Health	Yes	
Mr Miles Welstead	Assistant Psychologist	No	

Also in attendance:

Name	*Position (or reason for attending)*
Dr Benjamin Shelley	Consultant in Cardiothoracic Anaesthesia
Mrs Sandra Wyllie	REC Manager