Health Research Authority

National Research Ethics Service

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31 October 2014

Professor Ruth Gilbert
Professor of Clinical Epidemiology
UCL Institute of Child Health
Institute of Child Health
30 Guilford Street
London
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Dear Professor Gilbert

Study title:	**PREVenting infection using Antimicrobial Impregnated Long lines. An unblinded, 2-arm randomised controlled trial to determine the effectiveness of antimicrobial impregnated (with rifampicin and miconazole) long lines (termed peripherally inserted central catheters, or AM-PICC (AM-PICC)) compared with standard PICC (S-PICC) for reducing blood stream infection (BSI).**
REC reference:	**14/YH/1202**
Protocol number:	**12EB13**
IRAS project ID:	**160376**

Thank you for your letter of 21 October 2014, 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 the Chair.

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, Miss Helen Penistone, nrescommittee.yorkandhumber-sheffield@nhs.net.

Confirmation of ethical opinion

The Chair advised that he was happy with the revisions made to the Participant Information Sheet and GP letter. Furthermore, he advised that it is a principle of distributive justice that benefits and burdens of research should be shared amongst all sections of society but the inability to speak and/or read English could create a vulnerability that needs to be addressed, hence the previous request. The solution suggested by you in your response letter was helpful in ensuring that there was an inclusive strategy of recruitment whilst adequate steps are taken to

protect vulnerable participants.

Therefore, 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:

1. That when the trial starts babies whose parent/s can speak English can be recruited.
2. That, as per your suggestion, a Participant Information Sheet transliterated into Urdu is developed for use in the study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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*
Covering letter on headed paper		
Covering letter on headed paper [Cover letter]		21 October 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters [GP Letter]	1.0	16 October 2014
Instructions for use of medical device [Vygon GmbH & Co.KG Percutaneously Inserted Central venous Catheters (1261 & 6261) Instructions for Use]		01 September 2013
Letter from sponsor [UCL Sponsor in Principle Letter]		19 September 2014
Other [Sponsor Insurance Confirmation Letter]		19 September 2014
Other [HRA 2013 08 Paper - Language and Exclusion]		01 August 2013
Other [Summary CV for Co-Chief Investigator Dr Sam Oddie]		16 September 2014
Participant information sheet (PIS) [Parent Information Sheet and Consent Form]	2.0	21 October 2014
REC Application Form [REC_Form_19092014]		19 September 2014
Research protocol or project proposal [PREVAIL Protocol]	1.0	18 September 2014
Summary CV for Chief Investigator (CI)		17 September 2014

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/

14/YH/1202	**Please quote this number on all correspondence**

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

Yours sincerely

On behalf of
Professor Basil Sharrack
Chair

Email: nrescommittee.yorkandhumber-sheffield@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Emma Pendleton

Dr Thomas Lewis,
UCL Institute of Child Health