Health Research Authority
London - London Bridge Research Ethics Committee
Skipton House
80 London Road
London
SE1 6LH

Telephone: 02071048308
Fax:

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

03 January 2017

Dr Katherine Gaskell
SpR ACF Infectious Diseases and General Medicine
London School of Hygiene and Tropical Medicine
Room 369, Department of CRU, Third floor, LSHTM, Keppel Street
London
WC1E 7HT

Dear Dr Gaskell

Study title:	**Drug resistant TB contacts registry. A register of multi-drug resistant TB contacts. V4**
REC reference:	**16/LO/2032**
Protocol number:	**QA929**
IRAS project ID:	**214570**

Thank you for your letter 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 Vice-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, Mr Ryan Erfani-Ghettani, nrescommittee.london-londonbridge@nhs.net.

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 REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions 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).

Non-NHS sites

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]	1	27 October 2016
Covering letter on headed paper [response letter]	1	08 December 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	1	17 October 2016
GP/consultant information sheets or letters [GP letter]	1	20 October 2016
IRAS Application Form [IRAS_Form_31102016]		31 October 2016
IRAS Application Form [IRAS_Form_15122016]		15 December 2016
Letter from sponsor	1	17 October 2016
Letters of invitation to participant	1	19 October 2016
MHRA Notice of No Objection Letter (Medical Devices) and relevant correspondence	1	27 October 2016
Non-validated questionnaire [anon feedback]	1	20 October 2016
Non-validated questionnaire [nurse questionnaire]	1	20 October 2016
Non-validated questionnaire [app questions]	4	19 October 2016
Other [University ethics committee letter]	1	02 December 2016
Other [University ethics response letter]	1	08 December 2016
Other [Protocol_V5_tracked changes]	5	08 December 2016
Participant consent form [consent]	3	08 December 2016
Participant consent form [Assent form]	2	08 December 2016
Participant consent form [structured questionnaire consent]	1	08 December 2016
Participant consent form [consent_tracked changes]	3	08 December 2016
Participant information sheet (PIS) [Patient information sheet]	4	08 December 2016
Participant information sheet (PIS) [Assent information sheet]	2	08 December 2016
Participant information sheet (PIS) [structured questionnaire PIS]	1	08 December 2016

Participant information sheet (PIS) [PIS_V4_tracked changes]	4	08 December 2016
Participant information sheet (PIS) [Assent information sheet_tracked changes]	2	08 December 2016
Research protocol or project proposal [Drug resistant TB contacts registry protocol]	5	08 December 2016
Summary CV for Chief Investigator (CI)	1	27 October 2016
Validated questionnaire	1	

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/

16/LO/2032	**Please quote this number on all correspondence**

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

Yours sincerely

PP

Ms Jane Smith
Chair

Email:nrescommittee.london-londonbridge@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mrs Patricia Henley*
Mrs Kathryn Simpson, Research Portfolio Manager. Whittington Health NHS Trust