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Observational / Interventions Research Ethics Committee

Dr Katherine Gaskell
Academic Clinical Fellow + Infectious Diseases SpR
Department of Clinical Research (CRD)
Infectious and Tropical Diseases (ITD)
LSHTM

13 December 2016

Dear Katherine

Study Title: Drug resistant (DR) TB contacts registry. A registry of multi-drug resistant TB contacts

LSHTM Ethics Ref: 11938

Thank you for responding to the Observational 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.

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

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

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

Document Type	File Name	Date	Version
Investigator CV	Kate Gaskell_CV	12/10/2016	1
Protocol / Proposal	Mobile app questions_DRcontactsRegistry_V4	19/10/2016	4
Protocol / Proposal	Nurse strucutred questionnaire_DRcontactsRegistry_V1	20/10/2016	1
Protocol / Proposal	Anonymous feedback_DRcontactsRegistry_V1	20/10/2016	1
Protocol / Proposal	Letter to GP_DRcontactsRegistry	20/10/2016	1
Local Approval	07.12.2016SL07_Provisional_opinion,_request_for_further_information 16.LO.2032	07/12/2016	1
Covering Letter	Response Letter LSHTM. 08.12.16	08/12/2016	1
Protocol / Proposal	DRTBcontactsRegistry_Protocol - v5	08/12/2016	5
Information Sheet	NURSING_PIS_DRTBcontactsRegistry_V1_08.12.16	08/12/2016	1
Information Sheet	Nursing_Consent_DRTB contactsRegistry_V1 08.12.16	08/12/2016	1
Information Sheet	Consent_DRTB contactsRegistry_V3 08.12.16	08/12/2016	3
Information Sheet	Assent Information sheet_DRTB contactsRegistry_V2_08.12.16	08/12/2016	2
Information Sheet	Assent Form_DRTBcontactsRegistry_08.12.16_2	08/12/2016	2
Information Sheet	PIS_DRTBcontactsRegistry_V4_08.12.16	08/12/2016	4
Local Approval	Response Letter REC. 08.12.16	08/12/2016	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor John DH Porter
Chair

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