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SCHOOL of
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MEDICINE



Observational / Interventions Research Ethics Committee

Dr Katherine Gaskell
LSHTM

13 October 2020

Dear Dr Katherine

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

LSHTM Ethics Ref: 11938 - 1

Thank you for your application for the above amendment to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Observational Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to 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 for the amendment 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
Other	DRTBcontactsRegistry_Protocol - v6_corrections	20/02/2020	6
Other	Nurse+structured+questionnaire_TBtoolkit_V2_20200220_tracked	20/02/2020	2
Other	preimplementation_nursequestionnaire_DRTBRegistry_V0.1_20200220	20/02/2020	0.1
Other	NURSING_PIS_DRTBcontactsRegistry_V2_20200220_tracked	20/02/2020	2
Other	Nursing_Consent_DRTBcontactsRegistry_V2_20200220_tracked	20/02/2020	2
Other	Paeds 0-10 parental Consent_DRTBcontactsRegistry_V2_20200220_tracked	20/02/2020	2
Other	Assent+Information+sheet_DRTB+contactsRegistry_V3_20200220_tracked	20/02/2020	3
Other	PIS_DRTBcontactsRegistry_V5_20200220_tracked	20/02/2020	5
Other	Consent_DRTBcontactsRegistry_V5_20200220_tracked	20/02/2020	5
Other	NHS commissioned Multidrug resistant Tuberculosis treatment centres	24/08/2020	1
Other	LEO amendment application letter_20200910	10/09/2020	0.1
Local Approval	DR TB contacts registry_HRA approval amendment V4	11/09/2020	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.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

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,

J Whitworth

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Chair

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