

How to guide

Setting up your site

Things you need to be aware of:

We have a Data Protection Impact Assessment at LSHTM which you can access on this site.

The LSHTM privacy notice which you can access [here](#).

We have HRA approval for all MDR TB commissioned centres in England who have shown interest in participating. We are applying for approval for sites in Wales and Scotland.

The sites involved so far are listed at the end of this document.

To set up your site you will need

1. Local ethical approval

To do this you need to complete:

a) The organisation information document_V1 (OID) IRAS form. You can find this here.

To complete this you need signatures from

- a local PI (a lead TB clinician on site)
- a local point of contact for the LSHTM sponsor. If the NHS site has a Research and Development Office (R&D), Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) it should be a contact at the R&D/CRO/CTU. If these do not exist this can be a study sponsor, study manager, study coordinator or clinical research scientist.
- Amend the OID to reference your site only

b) Amend the IRAS schedule of events to ensure it is site specific. You can find this here.

c) Complete a delegation log (after training has been completed)

Submit all these forms to your local RDO and make sure you copy us in at

David.Moore@lshtm.ac.uk and kate.gaskell@lshtm.ac.uk

2. Ensure you have up to date Good Clinical Practice training. There are a few online refresher training courses, of which you can access one [here](#).

3. Once you have submitted these forms to your R&D and accessed the training documents, we will arrange training to access the contact registry at

<https://mdrtb-contacts.lshtm.ac.uk/>

Sites involved so far include:

Barts Health NHS Trust, Bradford Teaching Hospitals NHS FT, Cambridge University Hospitals NHS FT, Central Manchester University and North Manchester Hospitals NHS Trusts, Heart of England FT, East Lancashire Hospitals NHS FT, Guy's and St Thomas NHS FT, Hull and East

Yorkshire Hospitals NHS Trust, Imperial College Healthcare NHS Trust, Leeds Teaching Hospitals NHS Trust, Lewisham and Greenwich NHS Trust, London Northwest Healthcare, North Bristol NHS Trust, Nottingham University Hospitals NHS Trust, Oxford University Hospitals NHS Trust, Royal Free London NHS Foundation Trust, Royal Liverpool and Broadgreen University Hospitals NHS Trust, Sandwell and West Birmingham NHS Trust, Sheffield Teaching Hospitals NHS Foundation Trust, St George's Hospital London, The Newcastle upon Tyne Hospitals NHS FT, Whittington Health North Central London TB service London.