Drug resistant TB contacts Registry
'Participant Information Sheet'

Part 1

1. Drug resistant contacts Registry. A registry of resistant Tuberculosis contacts
You are being invited to take part in a research study. Before you decide if you would like to take part it is important for you to understand the research being done. Please take time to read the following information carefully and to decide whether or not you wish to take part. Ask us if there is anything that is not clear or if you would like more information.

2. What is the purpose of the study?
In the NHS all patients diagnosed with tuberculosis (TB) are asked for the details of all the people around them who have been exposed and are at risk of developing TB (TB contacts). All contacts are screened for active TB and for a condition called latent TB infection. 1 in 10 people with latent TB infection will go on to have TB disease in the future. It is important to know who has been screened for TB. All contacts are followed up for 2 years.
In multi-drug resistant (MDR) TB this process is even more important. In MDR TB the drugs we usually use to prevent TB don't work and we cannot use them. We need to control the spread of MDR TB as treatment for this takes 2 years and is less often successful. Currently we don't know who has been screened nor what happens to these people. We are following up people exposed to MDR TB for 2 years after their TB exposure by entering them into a registry. As part of routine care this registry will help in looking after patients and study contacts of MDR TB. Patient outcomes will be studied for 2 years. We are testing a software tool and a patient registry, we want to know how acceptable these are. The registry will be used to research who is most vulnerable to developing MDR TB.

3. Why have I been chosen?
You have been exposed to MDR TB. You need to be screened for TB and followed up for 2 years.

4. Do I have to take part? No.
It is up to you to decide if you want to take part. It will not affect the care you receive. If you do, you will be given this information sheet and asked to sign a consent form. A copy of these will be sent to you. You *can* withdraw at any time, without a reason and no new data will be collected.

5. What will happen to me if I take part?
You don't need to do anything. How we store your data will change. Your care will be the same.
Your details will be kept by the TB nursing staff as usual **and** entered into a secure registry. Your care will be the same by the same NHS staff. Your nurse will use a software tool called DHIS2 to collect your data. Your data will be encrypted on entering and saving on a computer before sending the data to the secure server at the London School of Hygiene & Tropical Medicine (LSHTM). No one will be able to access or interpret your data. Only the research team will be able to decrypt your data. Personal data will only be seen by the clinic looking after you and the research team.
The mobile app will be used to follow you up at five visits in total over 2 years, to check you have not developed TB or latent TB. The registry will hold your data for 10 years after study completion. There are no restrictions to your lifestyle, medications or diet required. Summary data for all the participants will be shared with the TB service but none of your personal details will be shared, the data will be anonymous.

6. What is the drug, device or procedure that is being tested?
This software tool was developed to help health providers standardise and share data. We aim to use it across England to follow all the MDR TB contacts in England. The LSHTM is a research university with a secure server that allows us to hold personal information in a safe way.

7. What are the alternatives for diagnosis or treatment? Your care will be the same. The medical communication about your care will improve.

8. What are the other possible disadvantages and risks of taking part?
The only risks are around your being identified from the data – these are very unlikely. We have reviewed personal data security incredibly carefully and have planned every step of storing your data. If anything should happen you will be informed immediately, your data will be returned, the security breach identified and prevented it from happening again. **We have planned carefully so this will not happen.** Taking part will not affect insurance policies.

9. What are the possible benefits of taking part?
We cannot promise the study will help you but we might improve the treatment of future MDR TB contacts. Once on the registry we can contact you if new treatments for latent MDR TB emerge.

10. What happens when the research study stops?
You will be followed up for two years. After this you will receive no further clinical follow up.

11. Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential.

12. Contact Details
If you have concerns about the study please ask your TB nurse. If you have concerns they cannot address please contact the main investigator Dr Kate Gaskell on DRTB.ContactsRegistry@nhs.net.
If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

13. What if relevant new information becomes available?
Your research doctor will discuss it with you. If the study is stopped for any other reason, you will be told why and your care will not be affected.

14. What will happen if I don't want to carry on with the study?
You can withdraw at any time, without a reason. No new data will be collected but old data will remain.

15. What if something goes wrong?
If your data is no longer secure we will recover it and perform a risk analysis into why it occurred.
Complaints If you have concerns or wish to make a complaint please contact the TB nurses or the researcher so that we may solve the problem together. Contact DRTB.ContactsRegistry@nhs.net.If you do not wish to contact her you can make a formal complaint to the Patient advisory Liaison service (PALS) or the LSHTM Research Governance and Integrity Office (RGIO), contact them on RGIO@lshtm.ac.uk.
NHS based research NHS bodies are liable for clinical negligence to individuals covered by their duty of care. This protection and indemnity for negligent harm is available to all participants.
The LSHTM holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that the School is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. You can ask for details about the data we hold on you and ask to see the data at any time.

16. Will my taking part in this study be kept confidential?
If you join the study, some parts of your medical records and the data collected for the study will be looked at by the research team at LSHTM. Representatives of regulatory authorities may review your data to check that the study is being carried out correctly. All will have a duty of confidentiality to you. All information which is collected about you during the course of the research will be kept strictly confidential. The research team will not disclose any information about you with any other professionals without your consent. Your GP will be informed you are taking part in a research study.

Part 2

17. What will happen to the results of the research study?
The results of the study will be published. If you are interested the researcher will provide you with a copy of the publication. You will not be identifiable in any of the reports.

18. Who is organising and funding the research?
The research is organised by LSHTM and funded by the Hospital for Tropical Diseases special trustees. The staff caring for you will not be paid to include you as part of the study.

19. Who has reviewed the study?
This study was given a favourable ethical opinion by the LSHTM Research Ethics Committee and the NHS Research Ethics Committee (the Health Research Authority).
You will be given a copy of the information sheet and a signed consent form to keep.
Thank you for considering taking the time to read this sheet.