



Drug resistant (DR) TB contacts Registry

'Assent Information Sheet'

Part 1

1. Drug resistant TB contacts Registry.

You are being asked to take part in research. Please read this carefully then decide if you want to take part. Please ask us if you have any questions.

2. What is the purpose of the study?

Tuberculosis (TB) is an infection that affects people all over the world at all ages. It makes people sick for a long time but can be treated with drugs. TB spreads when someone with TB coughs or breathes the TB bacteria onto people close to them. Everyone who has TB is asked for a list of all the people they spend a lot of time with. These are the people who might get TB in the future. They are called TB contacts. In the NHS all contacts are tested for TB and for latent TB infection, this is where the TB is inside them but not making them sick. 1 in 10 people with latent TB infection will get sick with TB in the future. So this means we check all people in contact with TB for 2 years. Children under 5 years old often get sick with TB.

In drug resistant (DR) TB this is even more important, the drugs we use to treat TB don't work anymore. Treatment for DR TB takes much longer and doesn't work as well. We want to know when and who gets checked after becoming a TB contact. We are creating a list of everyone in contact with DR TB and checking they are well for 2 years. We are calling this a registry, it will help look after DR TB contacts. We want to know who stays well and who gets sick after 2 years.

3. Why have I been chosen?

Someone in your home or school has had drug resistant (DR) TB, and you have spent time with them. You need to be checked for TB over the next 2 years.

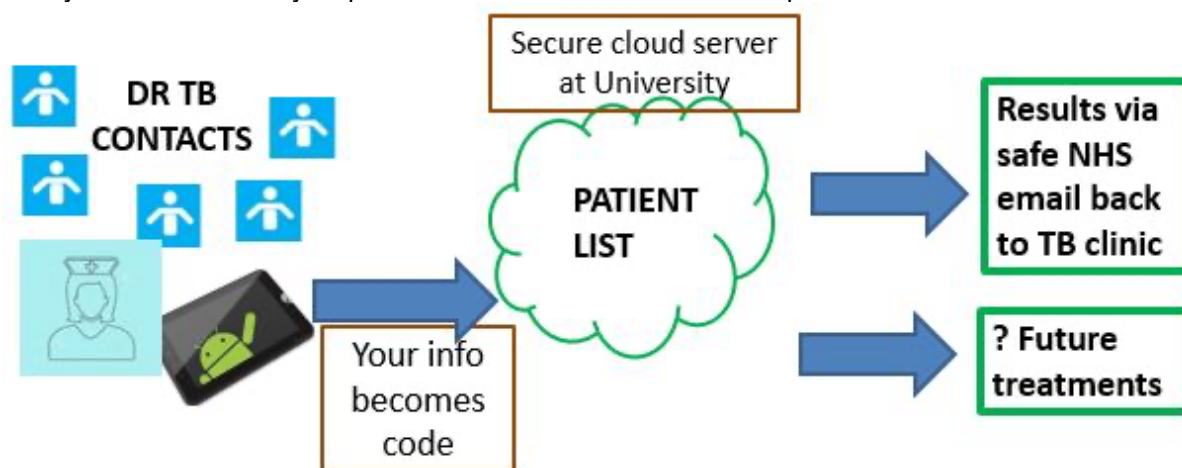
4. Do I have to take part? No.

You decide. It will not affect how the nurses and doctors treat you. If you take part, you will be given this information and asked to sign a consent form with your parent. You will get a copy of these. You can decide to stop taking part at any time and without a reason. You can access your data.

5. What will happen to me if I take part?

You don't need to do anything. How we store your information will change. Your care will be the same.

The nurse will keep your details and they will also be put onto a secure list. Your care will be the same by the same team. Your nurse will use a software tool to collect your data. Your details will be changed into code and sent to a secure list at a university called the London School of Hygiene & Tropical Medicine (LSHTM). No one will be able to see this or read about you. Only the research team will be able to decode your data. You will see a nurse at five visits over 2 years to check you have not developed TB, the mobile app will be used to enter your data onto the patient list. You will be on this list for 10 years after the study stops in case future treatments become possible.



6. What is the drug, device or procedure that is being tested?

This software tool was made to help health workers collect and share data. We want to use it across England to follow all the DR TB contacts in England.

7. What are the alternatives for diagnosis or treatment? Your care will be the same.

8. What are the other possible disadvantages and risks of taking part?

If someone else sees your details and you are recognised from this. We don't think this will happen. We have planned every step of storing your data safely. If anything happens you will be told, the problem will be fixed and we will stop it from happening again. **We have planned carefully so this will not happen.**

9. What are the possible benefits of taking part?

We cannot promise the study will help you but we might help the treatment of future DR TB contacts. Once on the registry we can contact you if new treatments become available.

10. What happens when the research study stops?

You will be followed up for two years in clinic by your TB nurse. After this the follow up stops.

11. Will my taking part in the study be kept confidential?

Yes. All the information about your taking part will be kept confidential. Your GP will know you are in a study.

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 kate.gaskell@lshtm.ac.uk.

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 team 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 stop at any time, without a reason and no new data will be collected.

15. What if something goes wrong?

If someone starts to be able to see your data we will fix the system and check why it happened.

Complaints If you have concerns or wish to complain please contact the TB nurses or the researcher so that we may fix the problem together. Contact kate.gaskell@lshtm.ac.uk. If you do not want 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 carelessness to individuals covered by their duty of care. This protection and insurance for careless harm is available to all participants.

The LSHTM holds insurance which applies to this study. If you become harmed or injured because of taking part in this study, you may be able 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 being careless, then you may be able to take legal action.

Part 2

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. Your GP will be informed you are taking part in a research study. Ethics teams may review your data to check that the study is being carried out correctly. We all will have a duty to keep all your details private – we can tell no one your details. The research team will not share any information about you with anyone else without your consent.

17. What will happen to the results of the research study?

The results of the study will be printed. If you are interested the researcher will provide you with a copy of the results. You will not be recognisable 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 (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.