MDRTB contact registry

Standard Operating Procedure for obtaining informed consent

There are two categories of participant – the index case and the household contact (HHC).

- 1. Approach the eligible index case participant
 - a. in person during a clinic or household visit
- 2. Approach the eligible HHC participant either
 - a. in person during a clinic or household visit (with index case), or
 - b. by telephone (with the prior permission of the index patient)
- 3. Provide information about the registry project by
 - a. verbal explanation, and
 - b. supplying the participant information sheet (PIS) in hard and/or soft copy, and
 - c. consider sharing the github site link https://github.com/kmgas/MDRTB-contacts-UK with participants who wish to see all project-related documents

It is important to ensure that the participant is able to understand the information given.

- 4. Invite participation and obtain written informed consent through signing of two copies of the project consent form. One copy should be given to the participant (with a PIS) and the other should be filed in the site project folder.
- 5. Complete the DHIS2 record for the participant only once consent has been obtained

Definitions

<u>Index case patients</u> may have pulmonary or extra-pulmonary TB and may have multidrugresistant TB (resistant to rifampicin and isoniazid) or rifampicin mono-resistant or isoniazid mono-resistant TB.

Eligible participants

Index case patients and their household contacts (HHCs) are eligible to participate

HHC

The registry captures detail on time and duration of exposure to the index case for HHCs, so the sole criteria for eligibility for inclusion in the Registry as a HHC is:

the person (adult or child) should have lived in the same household as the index patient at the time of MDR-TB diagnosis or at any time in the preceding two months.