THE UNIVERSITY OF SYDNEY

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PARTICIPANT CONSENT FORM FOR SCREENING HOUSEHOLD CONTACTS [Form C2]

I, ...[PRINT NAME], give consent to my participation in the research project

TITLE: THE V-QUIN TRIAL

In giving my consent I acknowledge that:

1. The procedures required for the project and the time involved have been explained to me, including any inconvenience, risk, discomfort or side effect, and their implications. Participation in the study will include a clinical assessment, chest X-ray and a tuberculin skin test for TB infection. It may also include giving a sputum sample for culture and blood for testing for markers of tuberculosis. Any questions I have about the project have been answered to my satisfaction.

2. I understand that if I am offered treatment for tuberculosis infection, I agree to be randomly assigned to either levofloxacin, or a placebo. I agree to take this therapy for 6 months. I agree to attend regular monitoring appointments during this time. I recognise that levofloxacin can cause side effects including liver toxicity, in less than 1% of cases.

3. I have read the Participant Information Statement about levofloxacin therapy and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.

4. I understand that being in this study is completely voluntary – I am not under any obligation to consent.

5. I understand that my involvement is strictly confidential. I understand that any research data gathered from the results of the study may be published however no information about me will be used in any way that is identifiable.

6. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or the National Tuberculosis Plan and its affiliated hospitals and clinics, or the University of Sydney, now or in the future.

7. I understand that if blood is collected, it will be used for the testing of biological markers of tuberculosis. Blood, and bacteria grown from sputum, will also be stored for further testing.

8. I agree to the following aspects of the study (tick each box if you agree):

Chest Xray	☐
Tuberculin skin test	☐
Taking levofloxacin or placebo therapy for 6 months, if indicated	☐
Giving blood to test for biomarkers of tuberculosis	☐
Having a sputum induction test to collect sputum, if required	☐

9. I consent to receiving feedback at the end of this study:

YES ☐ NO ☐

If you answered YES to the "Receiving Feedback" question, please provide your details i.e. mailing address, email address.

Feedback Option

Address: _____

_____

Email: _____

....
Signature of participant

.....
Please PRINT name

.....
Date (DD/MM/YYYY)

.....
Participant identification number (PID)

....
Signature of research staff

.....
PRINT name of research staff