

Informed consent form for Index case

Study ID: INDIGO#2

Date: 2020 – 2025

Title of Research Project

Monitoring the effect of prophylactic interventions in contacts of leprosy patients including field-application of a novel immunodiagnostic test in Bangladesh

Investigator(s)

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Purpose of the Research

Read out to the participants:

We are from The Leprosy Mission. Today we came to your house because your relative / neighbor were recently treated for leprosy. As protective measure we would like to examine the household members and other near contacts for symptoms of leprosy. If you have any symptoms of the disease, we will send you to the clinic for confirmation and treatment.

If you do not have any signs of the disease we would like to ask you to participate in a research study to test the preventive effect of the medicine rifampicin. This is a widely used therapy that has shown protective effect against leprosy. We would like to ask permission from you to participate in the study. You will be given the medicine rifampicin, and afterwards we will return after 2 weeks, 4 weeks, and 6 months to take a very small blood sample by means of a finger prick.

We will first ask you some personal data, like name, date of birth and relation to the patient with leprosy. Then we will examine you. We will not ask any confidential or sensitive issues. Then we will give the medication and take a blood sample. We will come back after 2 weeks, 4 weeks and 6 months from now.

The medicine rifampicin does normally not cause any discomfort. Your urine may have a red color for a day after taking the medicine. This is harmless. You may also feel a little unwell, just like when having a mild cold. This will go away soon. In the rare occasion that you fall ill after taking the medicine, we will offer you free consultation and treatment. Our address: Rural Health Program, The Leprosy Mission International Bangladesh, Notkhana, Nilphamari Mobile: +8801713362781. Your participation is completely voluntary and you may choose not to participate, or stop at any point of time. Your decision not to volunteer, or to refuse to answer particular questions, will not affect your relationship with the researchers or other staff members of The Leprosy Mission. At the successfully completion of the study we will inform you about the result of the study.

All information you supply will be held in confidence and will only be available for the researchers and staff of The Leprosy Mission involved in the study. Your name will not appear in any report or publication of the research. The information of this study will be stored for 15 years according to regulation and afterwards destroyed.

If you have questions about the research in general or about your role in the study, please feel free to ask them now. You can also contact The Leprosy Mission in Nilphamari at any point in time with questions or concerns. On the vaccination card you will find how you can reach us.

We would like you and all of your selected contacts to sign this form if you agree to participate in the study.

Consent contact

Consent of selected household/ nearest neighbor contact and the patient/ guardian (if age below 18 years):

I consent voluntarily to participate as a participant in this research after my best understanding. The signed below indicates my consent of taking medicine/collecting blood sample.

ID no.	Date	Name	Age	Relation to index	I agree to take medicine	I agree to give my blood sample

I have witnessed the accurate reading of the consent form to the potential participant/ participant himself has read the consent form accurately, and where the individual has had the opportunity to ask questions independently. I confirm that the individual has given consent freely.

Name of researcher : _____

Signature of researcher : _____

Date : _____