Participant Information Sheet and Consent Form

Study Title: **"A study on out of pocket expenditure among MDR Tuberculosis patients and its determinants"**
Locality: Bhopal District, Madhya Pradesh, India

Principle investigator:	**Co-Principle investigator**:	**Co-Principle investigator**:
Dr Shweta Sharma **Designation:** Resident, **Department:** Community and Family Medicine AIIMS,Bhopal Email: drshweta9740@gmail.com Phone: 9329558266	Dr Arun M Kokane **Designation:** Professor and Head **Department:** Community and Family Medicine AIIMS,Bhopal Email: arun_Kokane.cfm@aiimsbhopal.edu.in Phone:8989010831	Dr Ankur Joshi **Designation:** Assistant Professor **Department:** Community and Family Medicine AIIMS,Bhopal Email: ankur.cfm@aiimsbhopal.edu.in Phone: 8818899050

Name of the Participant :

TU code :

Participant unique Identification Number:

Contact Number :

WHAT IS THE PURPOSE OF THE STUDY?

Hidden TB-related costs remain understudied, and there is no international consensus defining catastrophic costs incurred by patients and households affected by TB. We sought to clarify and characterize TB- related costs and explore whether there is a relationship between the hidden costs associated with free TB treatment programs. Simultaneously we are measuring the QoL of TB patients using a scale named WHOQoL-Bref which consists of 26 questions . You need to answer each question on a scale of 1 to5 . These questions will determine the QoL in 4 different domains of Quality of Life in Multi Drug Resistant (MDR) Tuberculosis .

WHAT WILL BE YOUR PARTICIPATION IN THE STUDY?

Study subjects will be all the registered MDR TB patients in Bhopal District registered during the whole calendar year of 2017. The participants will be recruited from 5 Tuberculosis Units (TUs) from Bhopal district .

BENEFIT FROM THE STUDY:

You may not receive any direct benefits from this study. The study will provide the evidence related to TB related costs and the association of hidden costs with free TB treatment programs and the

quality of life of MDR TB patients in Bhopal district. It will provide the recommendations related to need for incorporating QoL measurement tools, specific domains in which QoL in relation to MDR to be addressed the appropriateness WHOQOL -Bref to measure the quality of life in MDR -TB patients

RIGHT TO WITHDRAW FROM THE STUDY

As already informed your participation in this study is voluntary. You are free to withdraw from this study at any time and that will not involve any penalty or loss of benefits to which you are otherwise entitled. However, during the withdrawal, you should notify the investigator and his/her staff for documentation and to make sure you are safe with no adverse events or a disease condition.

REMOVAL FROM THE STUDY

The investigator of the study will not normally withdraw you from the study but based on his/her assessment to improve your health care or due to your failure to follow the study timeline you may withdrawn.

CONFIDENTIALITY:

Data will be entered in a pre-designed format based on the information recorded in the registers. Names / TB registration number will be used to trace patients from one register to the next, but confidentiality will be maintained by keeping data collection forms securely in a lockable cabinet and the electronic data file will be kept in a password protected computer accessible only to the investigators. Both data sets will be maintained securely for five years after completion of study.

POTENTIAL HARM FROM THE STUDY:

There is no risk to the participants who are just undergoing clinical and laboratory evaluation. There is no invasive investigation to be done. Participants having MDR will be treated with standard medication in a supervised and controlled manner as per the Revised National Tuberculosis Control Program (RNTCP) guidelines . As such no risk is associated, however as precautionary measures you will be observed for any unwanted effects throughout the study.

WHO DO YOU CONTACT FOR MORE INFORMATION OR IF HAVE CONCERNS

If you have any questions, concerns or complaints about the study at any stage, you can contact:

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