# Informed Consent Forms

**NAME OF INSTITUTION**

**Study Title**: **Costing the delivery of tuberculosis services in Country name from a health systems’ perspective**

**Lay Title:** Examining how much it costs to deliver tuberculosis services in Country name

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| *Lead institutions* | *Investigator* |
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| *Other Institutions* |  |
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**Who is carrying out this study and what is this study about?**

This study is being carried out by name of lead institutionwith the Ministry of Health’s (MOH) National Tuberculosis Programme (NTP), in collaboration with collaborator name (PI name is the Principal Investigator).

(Briefly describe lead institution).

Our researchers are visiting health facilities providing services for Tuberculosis (TB), to estimate the costs of providing these services. The aim of this research is to provide a comprehensive set of unit costs for TB services in Country name. This cross-sectional survey involves (insert # facilities) healthcare facilities in Country name sampled from private (for-profit and non-profit) and public facilities of different service levels. Your facility is one of those selected through a two-stage stratified cluster sampling process. The study will involve interviews with key staff members (between 3 and 5 individuals) in your facility, document reviews, observations and timesheets filled in by some of these staff members.

**Why do you want to talk to me and what does it involve?**

As a key member of staff, we would like to ask you a number of questions about the running costs of providing TB services, the activities that are you are involved in, and how much of your time is taken up by each activity.

If you agree to participate in this research, trained research assistants will perform the following:

* We will ask some questions about your knowledge and experiences with managing patients with TB, the training and supervision that you have received, and the challenges that you encountered while managing TB.
* In order to value the type and quantities of inputs used in your daily clinical duties, we will review your facility’s project reports, financial and expenditure records, with your consent.
* We would also like to observe you as you carry out your daily clinical duties, in order to understand how much time in general it takes you to conduct these activities. The observations will involve being present at the facility and observing and making notes about the conduct of various TB services provided. We will not be present during patient consultations but record the length of time of the consultation by observing from a common area adjacent to the consultation area.
* We would also like to ask you to complete a timesheet that covers your activities during your working hours over the period of one week.

**Are there any risks or disadvantages to me of taking part?**

There are no major risks in participating in the study. The interview will take about 60 minutes, while the observations will be conducted over a working day. We will not record the interview or the observations, but we will take detailed notes. All responses and observations will be treated confidentially.

You may be uncertain whether you have the correct answers to some of the questions to be asked and this may make you feel uncomfortable. You are free to refuse to answer any questions. However, in order to have good results from the study, it is important that you try to answer all questions correctly.

**Are there any advantages to me of taking part?**

There are no individual benefits to taking part. In talking to us however, you will directly help the National Tuberculosis Programme (NTP) improve its services, and will help to plan its spending over the medium term. The overall data collected may also help National TB Programmes in other countries estimate the costs of their TB services, and plan better for their resources.

**Who will have access to the information I give?**

All of our documents are stored securely in locked cabinets and on password protected computers. Your questionnaire will not bear your names; this way your responses will be anonymous. Information on your workload and typical resources used in the process of providing TB services will be aggregated into a total estimate of the unit cost per TB episode.

The knowledge gained from this research will be shared in summary form, without revealing individuals’ identities, with all participating facilities, the TBL and collaborating institutions, and the wider scientific community, for instance through policy briefs and scientific publications.

In order to do this study, we will also share anonymized individual information we collect or generate with the Global Health Cost Consortium in ways that do not reveal individual participants’ identities. The cost data from this project will be incorporated in the web-based GHCC platform to improve extrapolations of cost across settings undertaken by the GHCC.

**Who has allowed this research to take place?**

All research at AHRI has to be approved before it begins by several institutional, national and international committees who look carefully at planned work. They must agree that the research is important, relevant to Ethiopia and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants’ safety and rights are respected.

**What will happen if I refuse to participate?**

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree to participate, you can change your mind at any time without any consequences and without the need to give a reason.

**What if I have any questions?**

You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Name, address, and contact information of lead at the research institute xxx, Telephone: +xxx, Email: [xxx@yyy.com](mailto:xxx@yyy.com)

**If you want to ask someone independent anything about this research, please contact:**

Name, address, and contact information of the ethics lead at the research institute xxx, Telephone: +xxx, Email: [xxx@yyy.com](mailto:xxx@yyy.com)

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**CONSENT FORM**

I have had the study explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. Please write your initials next to each of the following three statements to provide consent.

\_\_\_\_\_\_\_\_\_\_\_\_ **Yes, I agree for the interview/discussion to be conducted**

\_\_\_\_\_\_\_\_\_\_\_\_ **Yes, I agree to take part in the observational research**

\_\_\_\_\_\_\_\_\_\_\_\_ **Yes,** **I agree to fill in a working timesheet over one week**

I understand that I can change my mind at any stage and it will not affect me in any way.

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| --- | --- | --- | --- | --- |
| **Signature:** |  | **Date:** |  | |
|  |  | | | |
| **Participant/guardian name:** |  | **Time:** | |  |
|  | ***(please print name)*** |  | | |

***[Following section is recommended where verbal consent is obtained, and must be signed by person undertaking informed consent.]***

I have followed the study’s standard operating procedure to obtain consent from the participant. S/he appeared to understand the nature and purpose of the study and consents to participation in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

**Designee/investigator’s signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_\_

**Designee/investigator’s name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Time** \_\_\_\_\_\_\_\_\_\_\_\_ ***(please print name)***