INFORMATION SHEET

Definition of Consent and Informed Consent

You and/ or your child are being asked to participate in a clinical research entitled “National Tuberculosis Prevalence Survey of 2016”. Clinical research is the study of human participants to improve diagnosis and treatment of certain conditions. In order to decide whether or not you agree for you or your child to be part of this research, you should understand enough about its risks and benefits. This process is called informed consent.

This consent gives information about the research study, which will be discussed with you. Take your time in understanding the information in this form. You do not have to decide today. You may take this form and discuss it with anyone you want. If you have any question, please discuss it with me or any of the members of the study team. Once you understand the study, you will be asked to sign this form as proof of your consent for you and / or your child to participate.

Purpose of the Study

Tuberculosis is an infection caused by bacteria that can affect the lungs and other parts of the body. Tuberculosis (TB) remains high in the Philippines. It still remains as an important cause of illness in our country. To understand how well we are combating this illness, it is important to know how many people may be sick with TB.

Dr. Mary Ann Lansang and her co-workers from the Foundation for the Advancement of Clinical Epidemiology (FACE Inc.) are doing a study on the National Prevalence of Tuberculosis. The objective of this study is to determine the number of Filipinos aged 15 years and above with pulmonary TB.

Participant selection

The study is being done in 108 barangays all over the country and involves 500 participants per barangay for a total of 54,000 participants. Your barangay has been selected to participate in this study. Because you (or your child) is above 15 years old and have lived in this barangay for at least 14 days, you are eligible to participate in this survey.

Voluntary participation

Your participation in this survey is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, you will continue to receive the care that you are entitled to from your health workers.

Description of the Research Procedure

If you consent to take part in this study, you will be interviewed, your data will be collected, and you will undergo a physical examination and may undergo a chest xray.

On Day 1 -- If your history is suggestive of or your chest x-ray is suspicious for TB, sputum will be collected for further examinations that will detect the TB organism. On Day 2 -- The following day, another specimen of your sputum will be collected. Your sputum will then be transported to a reference laboratory for further testing. No other tests will be done on your sputum except tests to detect the TB organism and, if present, whether it is susceptible to the TB organism to current medications.

Duration of participation

Your interview, physical examination, and chest x-ray should not take more than two hours. If your x-ray or symptoms you feel are suggestive of TB, sputum will be collected after the xray examination and the following day.

Possible Risks

The risks of participation include the risks of radiation during x-ray exposure which is very rare. If you are female and happen to be pregnant, there is a risk that the exposure to xrays can harm your baby.

There is also a risk that others may find out that you have TB, although we have instituted measures to ensure the confidentiality of your records.

Possible Benefits

The results of this study will be used to support programs for the diagnosis, treatment and prevention of TB; and may not benefit you directly. Rather, the data will benefit the National TB program, which aims to control TB. You will receive free tests for the diagnosis of TB and education to help you prevent it. If, in the course of your participation, you are diagnosed to have TB, you will be referred to the local TB Directly Observed Treatment Short course (DOTS) clinic for free treatment. Should it be discovered that you have an illness other than TB as a result of participation in the survey, you will likewise be referred to a health facility for proper treatment.

Compensation

You will not receive any compensation or payment for your participation in this research. You will receive a token of appreciation for participation.

Right to Refuse and Withdraw

You may refuse to participate in this survey or parts of this survey or withdraw your consent without any change in the care given to you. You may also choose not to undergo

X-ray examination for whatever reason, but especially if you are female and suspect you are pregnant.

Privacy and Confidentiality of Records

Your personal information obtained from this study will be kept confidential. Information about you that will be collected during the survey will be stored and no

one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number. Your study files will be kept in a locked cabinet that will only be accessible to the study personnel. Information obtained from this study may be published or given to other people doing research, but neither your name nor your child's name will be mentioned.

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Results of the Survey

The results of this study will be submitted to the Department of Health (DOH) through the Philippine Council for Health Research and Development (PCHRD). If you wish to obtain a copy of the summary of the results of the study, you are more than welcome to request this by writing to: ntps.face@gmail.com. There is also a possibility that the results will be used for publication in academic journals.

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Name of Chair of the National Ethics Committee: Dr. Marita V.T. Reyes
Contact information: Tel. No. +63 (2) 837-7537

Name of Project Leader: Dr. Mary Ann D. Lansang
Contact Information: Tel. No. +63 (2) 525-4098

Name of Field Team Leader: _____
Contact Information: CP No. _____

By signing this document, you are saying that you have read it, understood it, and that you agree that you or your child will participate in this study. Please indicate the specific components that you are consenting to.

☐ I agree to participate in this study including all screening procedures and chest x-ray.

_____ _____

Name of respondent Age / Sex

_____

Witness

☐ I agree to participate in this study including all screening procedures but I prefer not to undergo a chest x-ray.

_____ _____

Name of respondent Age / Sex

_____

Witness

☐ I agree for my child to participate in this study including all screening procedures and chest x-ray.

_____ _____

Name of respondent Age / Sex

_____

Witness

☐ I agree for my child to participate in this study including all screening procedures but I prefer not to have a chest x-ray done.

_____ _____

Name of respondent Age / Sex

_____

Witness

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential FGD participant, and to the best of my ability made sure that the participant understood the 1) objectives of the study, 2) details of their participation, 3) confidentiality and anonymity, and 4) risks and benefits of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Informed Consent obtained by:

_____

_____

Signature over printed name Date Signed