

## INFORMED CONSENT FORM ( $\geq 18$ years old)

By signing below, I confirm the following:

- I have been given oral and written information about the proposed study; have read/been read and understood the information given
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily
- I know that participation in this project is voluntary, and I have understood the content and the objective of the study
- I am further aware that the information and specimen I will provide will only be utilized in the proposed study
- I recognize that all the information regarding myself will be kept completely confidential, and I know that I can quit any time from this study without providing any reason for doing so
- I know that sputum or culture (*M. tuberculosis*) will be transferred to Norway, veterinary institute for advanced laboratory analyses.

It is therefore with full understanding of the situation that I am giving my voluntary informed consent

Name \_\_\_\_\_ Signature \_\_\_\_\_ Place \_\_\_\_\_ Date \_\_\_\_\_

Witnesses name (for those who do not read and write)

1. Name \_\_\_\_\_ Signature \_\_\_\_\_

Name of the person who take consent \_\_\_\_\_

signature \_\_\_\_\_ Place \_\_\_\_\_ Date \_\_\_\_\_

## **INFORMED ASSENT FORM (15-17 Years of Age)**

By signing below, I confirm the following:

- I have been given oral and written information about the proposed study; have read/been read and understood the information given.
- I have had sufficient time to consider participation of my child/relative in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I know that participation in this project is voluntary, and I have understood the content and the objective of the study.
- I am further aware that the information and specimen my child /relative will provide will only be utilized in the proposed study
- I recognize that all the information regarding my child/relative will be kept completely confidential, and I know that I can quit any time from this study without providing any reason for doing so.
- I know that sputum or culture (*M. tuberculosis*) will be transferred to Norway, Veterinary institute for advanced laboratory analyses.

It is therefore with full understanding of the situation that I am giving my voluntary informed consent

Name \_\_\_\_\_ Signature \_\_\_\_\_ Place \_\_\_\_\_ Date \_\_\_\_\_

Name of family/next of kin \_\_\_\_\_ Signature \_\_\_\_\_ Place \_\_\_\_\_ Date \_\_\_\_\_

Witnesses name (for those who do not read and write)

1. Name \_\_\_\_\_ Signature \_\_\_\_\_

Name of the person who take consent \_\_\_\_\_

signature \_\_\_\_\_ Place \_\_\_\_\_ Date \_\_\_\_\_

**Questionnaire for Patients**

## Questionnaire for patients

Date of data collection: \_\_\_\_\_ E.C

Name of data collector and signature: \_\_\_\_\_ Mobile: \_\_\_\_\_

Name of Health institution (Health center /Hospital): \_\_\_\_\_ Zone: \_\_\_\_\_

Patient Card number: \_\_\_\_\_ sputum Code (assigned by data collector): \_\_\_\_\_

### **Gen X-pert Results**

**A. MTB Detected, Rif not detected or R susceptible** \_\_\_\_\_

**B. MTB Detected, RR** \_\_\_\_\_

### **TB enrolment**

TB register number: \_\_\_\_\_ MDR register number: \_\_\_\_\_

## Demographic and Socio-economic data

1. Patient's Full Name \_\_\_\_\_

2. Where do you live (**Residence**)?

A. Urban

B. Rural

2.1. Location: Block number : \_\_\_\_\_

Kushet/ketena \_\_\_\_\_ Tabia/Kebelle: \_\_\_\_\_

Wereda/district: \_\_\_\_\_ Zone: \_\_\_\_\_

mobile Number \_\_\_\_\_

3. Sex

A. Male

B. Female

4. **Age:** \_\_\_\_\_

5. Marital status?(**for patients ≥18**)

A. Single

B. Married

C. Widowed

D. Divorced

E. Not applicable

5.1.If married women **≥18**, number of births/child: \_\_\_\_\_

5.2.If married women **≥18**, current condition

A. Pregnant

B. Lactating

## Questionnaire for Patients

- C. None pregnant and none lactating
6. What is your family size? \_\_\_\_\_
  7. What is your monthly family income (in birr)?
    - A. <500
    - B. 500-2000
    - C. >2000
    - D. No means of income
  8. What is the highest level of education you have attained at present?
    - A. Illiterate
    - B. 1-8 grades
    - C. 9-12 grades
    - D. Diploma and above
  9. What is your current occupation?
    - A. House wife
    - B. Farmer
    - C. Self employed
    - D. Government employee
    - E. Student
    - F. No work

## Clinical Presentation

10. Would you please tell me if you have one of the following symptoms currently?
  - A. Weight loss
  - B. Chest pain when breathing or coughing
  - C. Coughing up sputum > 2 weeks
  - D. Hemoptysis
  - E. Shortness of breath
  - F. Intermittent fever
  - G. Night sweats
  - H. Loss of appetite
  - I. Fatigue and malaise
  - J. Other \_\_\_\_\_
11. When do you start coughing? \_\_\_\_\_

## TB history and related disease

12. Type of TB case
  - A. New (never treated before for  $\geq 1$  month)
  - B. Relapse
  - C. Return after default

## Questionnaire for Patients

### D. Failure after treatment

13. Do you have any history of TB patient in your family?

- A. Yes
- B. No

14. Do you have any close contact with TB patient or chronically coughing patient?

- A. Yes
- B. No

15. If yes, for how long do you had a contact? \_\_\_\_\_

16. Have you any close contact with MDR patient?

- A. Yes
- B. No

17. If yes, for how long do you had a contact? \_\_\_\_\_

18. History of diabetes mellitus?

- A. Yes
- B. No

19. HIV status

- A. Positive
- B. Negative

20. Nutritional status/Anthropometric measurement

- A. Weight in Kg \_\_\_\_\_
- B. Height in cm \_\_\_\_\_

21. Are you currently taking treatment for chronic disease?

- A. Yes
- B. No

22. If yes, type of treatment/type of chronic disease: \_\_\_\_\_

## Behavior of the patient ( $\geq 18$ years)

23. Do you have the habit of **alcohol taking**?

- A. Yes
- B. No

24. If yes, how many time per week? \_\_\_\_\_

- A. 1-2/week
- B. 3-5/ week
- C. 6-7 /week
- D.  $\geq 2$  /day

25. What habit do you have?

- A. Khat chewing

**Questionnaire for Patients**

- B. Cigarette smoking
- C. Others \_\_\_\_\_
- D. No habit

26. History of prison?

- A. Yes
- B. No

27. If yes, for how long you have been in prison? \_\_\_\_\_

 **Date of release to regional laboratory** \_\_\_\_\_ **E.C**

**Laboratory data recording format for patients**

**Laboratory results:**

✓ Date of specimen received by THRL: \_\_\_/\_\_\_/\_\_\_ E.C

Name of investigator: \_\_\_\_\_ Mobile: \_\_\_\_\_

Laboratory sputum ID: \_\_\_\_\_, Culture Number: \_\_\_\_\_

1 <sup>0</sup> smear	Media Smear	Blood agar	Capila

**TB Culture results**

Neg	Pos	conta	NTM	Method

Date reported: \_\_\_/\_\_\_/\_\_\_ Name and Signature of expert \_\_\_\_\_

**Results of *M. tuberculosis* drug susceptibility test**

✓ **Molecular method used (LPA)**

Result	1 <sup>st</sup> line drugs					2 <sup>nd</sup> line drugs							Other	
	H	R	S	E	PZA	OFX	LFT	MFX	AMK	CAP	KAN	VIO		

**Legend:** H= Isoniazid, R= Rifampicin, PZA= Pyrazinamide, E=Ethambutol, S= Streptomycin, Ofx= Ofloxacin, Lft=levofloxacin, Mfx= Moxifloxacin, AMK= Amikacin, CAP= Capromycin, KAN=kanamycin, Vio=viomycin, S = Sensitive, R = Resistant, C = Contaminated, ND = Not done

Comment: \_\_\_\_\_

Date reported: \_\_\_/\_\_\_/\_\_\_ Name and Signature of expert \_\_\_\_\_