Research participants' consent form

Title of the study: Assessment of the performance of three diagnostic tests for pulmonary Tuberculosis among HIV patients presenting to Kibra Community Health Centre, Nairobi County, Kenya.

Kichwa cha utafiti: *Tathmini ya utendaji wa vipimo vitatu vya uchunguzi wa Kifua kikuu cha mapafu kati ya wagonjwa wa VVU wanaowasilisha katika kituo cha afya ya Jumuia ya Kibra Nairobi, Kenya.*

Principle Investigator and institutional affiliation: Eunita Atieno Ochola, University of Nairobi, School of Public Health

Kanuni ya Kichunguzi na ushirika wa taasisi: Eunita Atieno Ochola, Chuo Kikuu cha Nairobi, Shule ya Afya ya Umma

Supervisor (*Msimamizi*):

Dr. Marshall Mweu,

University of Nairobi, School of Public Health (*Chuo kikuu cha University of Nairobi, shule wa afya ya umma)*

Introduction: My name is Eunita Atieno, a student pursuing a master's degree in Public Health. Among the requirements for the award of the degree is to conduct a research. This study aims to estimate the diagnostic accuracy of sputum smear microscopy, Xpert Ultra and LAM antigen tests in the diagnosis of TB among people living with HIV presenting to Kibra Community Health Centre, Nairobi County, Kenya. This form provides the necessary information to guide you in deciding whether or not you would like to participate in the study.

Utangulizi:*Jina langu ni Eunita Atieno, mwanafunzi anayefuata digrii ya uzamili katika Afya ya Umma. Miongoni mwa mahitaji ya tuzo ya shahada hiyo ni kufanya utafiti. Utafiti huu un akusudia kukadiria usahihi wa utambuzi wa microscopy ya sputum smear, Xpert Ultra na vipimo vya antijeni vya LAM katika utambuzi wa TB kati ya watu wanaoishi na VVU wanaowasilisha kituo cha afya ya jumuiya ya Kibra, Kaunti ya Nairobi, Kenya. habari ya kukuongoza katika kuamua ikiwa ungependa kushiriki katika utafiti au la.*

Procedure:

Once you have agreed to take part in the study, you will be asked to sign this consent form and questions relating to your demographic and clinical information will also be obtained. You shall then be requested to provide sputum and urine samples for analysis. Instructions on the collection of the following samples will be provided.

Utaratibu:

Mara tu utakapokubali kushiriki katika utafiti, utaulizwa kusaini fomu hii ya idhini na maswali yanayohusiana na habari yako ya idadi ya watu na kliniki pia yatapatikana. Kisha utaombwa kutoa sampuli za makohozi na mkojo kwa uchambuzi. Maagizo juu ya ukusanyaji wa sampuli zifuatazo yatatolewa.

Benefits:

There are no monetary benefits, but the laboratory tests will be done free of charge. The information obtained will also be relayed to your primary physician to facilitate your treatment.

Faida:

Hakuna faida ya kifedha, lakini vipimo vya maabara vitafanywa bila malipo. Habari iliyopatikana pia itapelekwa kwa daktari wako wa msingi kuwezesha matibabu yako.

Risks:

No risk is anticipated in the provision of a sputum sample except for mild chest discomfort from the coughing process while attempting to expectorate sputum for testing. You might also experience some slight discomfort at the sight of venipuncture when blood is being drawn.

Hatari:

Hakuna hatari inayotarajiwa katika utoaji wa sampuli ya makohozi isipokuwa usumbufu mdogo wa kifua kutoka kwa mchakato wa kukohoa wakati wa kujaribu kutazamia makohozi kwa upimaji. Unaweza pia kupata usumbufu kidogo machoni pa kupeana damu wakati damu inachorwa.

Confidentiality:

Strict confidentiality will be maintained and all data obtained will be securely stored with password protected computers and used for purposes of this study only.

Usiri:

Usiri mkali utadumishwa na data zote zilizopatikana zitahifadhiwa salama na kompyuta zilizolindwa na nywila na kutumika kwa madhumuni ya utafiti huu tu.

Withdrawal from the study:

Should you want to opt out of the study at any point you are free to do so without compromise to your care as participation in this study is voluntary. You are free to ask any questions now or later, before and after signing the consent form. The principal investigator, Eunita Atieno on mobile number: 0719246186 or the KNH-UoN Ethics Review Committee (ERC), Kenya through email at uonknh_erc@uonbi.ac.ke.

Kujiondoa kwenye utafiti:

Ikiwa unataka kuchagua kutoka kwa utafiti wakati wowote uko huru kufanya hivyo bila kuathiri utunzaji wako kwani kushiriki katika utafiti huu ni kwa hiari. Uko huru kuuliza maswali yoyote sasa au baadaye, kabla na baada ya kusaini fomu ya idhini. Mchunguzi mkuu, Eunita Atieno kwa simu ya rununu: 0719246186 au Kamati ya Kupitia Maadili ya KNH-UoN (ERC), Kenya kupitia barua pepe kwauonknh_erc@uonbi.ac.ke.

Consent form

The study has been explained to me together with the answers to my questions. I have understood all what this study is about. I willingly accept to participate in this study

I give informed consent to participate in this study and for the collection of required samples

YES ☐ **NO** ☐

Participant's signature: _____ **Date** _____

Participant's name: _____ **Time** _____

Where subject is illiterate :(Witness to observe and sign below)

I verify the study has been explained to the participant together with the answers to the questions. The participant fully understands and freely agrees to participate in the study

Witness' signature: _____ **Date**_____

Investigator's statement

I have clearly communicated to the study participant and s/he understands and has freely accepted to give consent to participate in the study

Researcher's signature: _____**Date** _____

Researcher's name : _____ Time_____

Fomu ya idhini

Utafiti umeelezwa kwangu pamoja na majibu ya maswali yangu. Nimeelewa yote utafiti huu unahusu nini. Ninakubali kushiriki katika utafiti huu

Ninatoa idhini kamili ya kushiriki katika utafiti huu na ukusanyaji wa sampuli zinazohitajika

NDIO LA ☐ ☐

Saini ya mshiriki: _____ Tarehe _____

Jina la mshiriki: _____ Wakati _____

Pale ambapo somo halijui kusoma na kuandika: (Shahidi wa kuchunguza na kusaini hapa chini)

Ninathibitisha kuwa utafiti umeelezewa kwa mshiriki pamoja na majibu ya maswali. Mshiriki anaelewa kikamilifu na anakubali kwa uhuru kushiriki katika utafiti

Saini ya Shahidi: _____ **Tarehe**_____

Kauli ya mchunguzi

Nimewasiliana wazi na mshiriki wa utafiti na anaelewa na amekubali kwa hiari kutoa idhini ya kushiriki katika utafiti

Saini ya mtafiti: _____Tarehe _____

Mtafiti jina: _____ Wakati_____

Appendix 2: Questionnaire & Data collection tool

Interviewee code (*Kitambulisho cha mhojiwa*): _____

Interview date (DD/M/year) (*Tarehe la kuhojiwa*): _____

Point of recruitment (*Pahali pa ajira*): _____

Part 1: Background information

1. Date of birth (DD/M/Year) (*Tarehe ya kuzaliwa*) _____

2. Sex of the respondent (*Jinsia ya mhojiwa*)
    - ❑ Male (Mwanamme)
    - ❑ Female (Mwanammke)
3. Weight in Kg (*Uzito wa kilo*) _____
4. Highest level of education of respondent (*Je, mhojiwa amekamilisha kiwango gani cha juu kabisa cha elimu?*)
    - ❑ None (*Hajasoma*)
    - ❑ Primary (*Elimu ya msingi*)
    - ❑ Secondary (*Elimu ya sekondari*)
    - ❑ Tertiary/ University (*Elimu ya Juu*)
5. Occupation of the respondent (*Kazi ya mhojiwa*)
    - ❑ Unemployed (*Wasio na ajira*)
    - ❑ Employed (Kuajiriwa)
    - ❑ Business man/ woman (*Mfanyabiashara*)
6. Type of residence of the respondent (*Aina ya makao ya mhojiwa*)_____
    - ❑ Urban informal (*Mjini isiyo rasmi*)
    - ❑ Urban formal (*Rasmi ya mjini*)
    - ❑ Rural (*Vijijini*)

Part 2: Signs and symptoms (*Dalili*):

- ❑ Fever (*Homa*)
- ❑ Chills (*Baridi*)
- ❑ Chest pain (*Maumivu ya kifua*)
- ❑ Dyspnea (*Kupumua kwa pumzi*)
- ❑ Night sweats (*Jasho la usiku*)
- ❑ Weight loss (*Kupungua uzito*)
- ❑ Fatigue (*Uchovu*)
- ❑ Malaise (*Unyonge*)
- ❑ Productive cough (*Kikohozi cha uzalishaji*)
- ❑ Haemoptysis (*Kikohozi cha damu*)

- ❑ Lack of appetite (*Ukosefu wa hamu ya kula*)

Part 3: Chest x-ray results suggestive of PTB (*X-ray ya kifua inayopendekeza PTB*)

- ❑ Positive (*Chanya*)
- ❑ Negative (*Hasi*)
- ❑ Unknown (*Haijulikani*)
- ❑ Not done (*Haijafanywa*)

Part 4: Patient clinical information *(Sehemu ya 4: Habari ya kliniki ya mgonjwa)*

1. Known CD 4 count (*Hesabu ya CD4 inayojulikana*) _____
2. Known viral load (*Kiwango cha virusi kinachojulikana*) _____
3. ART status (Hali ya SANAA):
   - ❑ Naïve (*Naïve*)
   - ❑ Experienced (*Uzoefu*)
4. ART regimen(*Regimen ya SANAA*):
   - ❑ 1st line (*Mstari wa 1*)
   - ❑ 2nd line (*Mstari wa 2)*
5. Pre- existing lung disease (*Ugonjwa wa mapafu uliopo*)
   - ❑ COPD
   - ❑ Asthma (*Pumu)*
   - ❑ Bronchitis (*Mkamba)*
   - ❑ Others (*Wengine*)
6. Cigarette smoking (*Uvutaji sigara)*
   - ❑ Yes (*Ndio*)
   - ❑ No (*Hapana*)
7. Co- morbidities (*Magonjwa*)
   - ❑ Hypertension (*Shinikizo la damu*)
   - ❑ Diabetes(*Ugonjwa wa kisukari)*
   - ❑ Viral hepatitis (*Hepatitis ya virusi)*
   - ❑ Kidney disease (*Ugonjwa wa figo)*

Part 5: TB diagnostic Laboratory test results *(Sehemu ya 5: Matokeo ya uchunguzi wa Maabara ya uchunguzi wa TB)*

1. Sputum analysis results (*Matokeo ya uchambuzi wa makohozi*)
    - ❑ None (Hakuna)
    - ❑ +
    - ❑ ++
    - ❑ +++
2. TB LAM results (*Matokeo ya TB LAM*)
    - ❑ Grade 1 (*Daraja la 1*)
    - ❑ Grade 2 (*Daraja la 2*)
    - ❑ Grade 3 (*Daraja la 3*)
    - ❑ Grade 4 (*Daraja la 4*)
3. Xpert results and RIF resistance (*Matokeo ya Xpert na upinzani wa RIF)*
    - ❑ Negative (*Hasi*)
    - ❑ Positive (*Chanya*)
    - ❑ Invalid (*Si sahihi)*
    - ❑ RIF resistance detected (*Upinzani wa RIF umegunduliwa)*
    - ❑ RIF resistance **not** detected (*Upinzani wa RIF haujagunduliwa)*