**Request for Proposals (RFP)**

**For**

**Sub-award**

**in support of**

**Challenge TB Core Project:**

***Quantifying effect of interventions on transmission of Mycobacterium tuberculosis in Tanzania***

**USAID Cooperative Agreement No. AID-OAA-A-14-00029**

**Issuance Date: 11 March, 2016**

**Submit Questions to: coretransmission@kncvtbc.org**

**Submit Requests for proposals to: coretransmission@kncvtbc.org**

**Closing Date for Submission of requests for proposals: 2nd April, 2016**

**Managed by:**

**KNCV Tuberculosis Foundation**

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# Abbreviations

ARTI Annual Risk of Tuberculosis Infection

ATS American Thoracic Society

CAR Central Asia Region

CBO Community Based Organization

CI Confidence interval

CRF Case report form

CTB Challenge TB

CXR Chest X-Ray

DRS Drug-Resistance Survey

DST Drug sensitivity testing

EQA External Quality Assurance

HCW Health Care Worker

IRB Institutional Review Board

KNCV KNCV tuberculosis Foundation

LTBI Latent TB infection

MDR TB Multi-drug resistant TB

MoH Ministry of Health

*M.tb. Mycobacterium tuberculosis*

NTLP National TB and leprosy control Program

PI Principal Investigator

PLHIV People living with HIV

RFP Request for proposals

SOP Standard Operating Procedure

SOW Scope of Work

TB Tuberculosis

TB IC TB infection control

ToR Terms of reference

TST Tuberculin Skin Test

UCSF University College of San Francisco

USD US dollars

WGS Whole Genome Sequencing

WHO World Health Organization

# Introduction

**KNCV Tuberculosis Foundation**

KNCV Tuberculosis Foundation (KNCV) is an international non-profit organization dedicated to the fight against tuberculosis (TB), still the second most deadly infectious disease in the world. KNCV is an international center of expertise for TB control that promotes effective, efficient, innovative and sustainable TB control strategies in a national and international context. We are an organization of passionate TB professionals, including doctors, researchers, training experts, nurses and epidemiologists. We aim to stop the spread of the worldwide epidemic of TB and to prevent the further spread of drug-resistant TB.

Over the past century we have built up a wealth of knowledge and expertise, initially by successfully controlling TB in the Netherlands. Since the 1970s, we have also shared our knowledge and expertise with the rest of the world. We operate from a central office in The Hague in the Netherlands, a regional office in Central Asia and country offices worldwide. KNCV raises funds from private, institutional, corporate, and government donors.

**Challenge TB**

KNCV is the lead partner in Challenge TB (CTB), the current United States Agency for International Development (USAID)-funded 5-year global project to decrease TB mortality and morbidity in high burdened countries. We lead an international consortium with eight partner organizations: American Thoracic Society (ATS), Family Health International (FHI 360), Interactive Research & Development (IRD), Japanese Anti Tuberculosis Foundation (JATA), Management Sciences for Health (MSH), Program for Appropriate Technology in Health (PATH), The International Union Against Tuberculosis and Lung Disease (The Union), and the World Health Organization (WHO).

The overarching strategic objectives of CTB are to improve access to quality patient centered care for TB, TB/HIV, and MDR-TB services; to prevent transmission and disease progression; and to strengthen TB platforms.

CTB project includes TB control activities in 23 countries and several overarching core projects in multiple countries. For more information see [www.challengetb.org](http://www.challengetb.org).

**Core research project on transmission**

As one of several core projects USAID is funding a project called ‘Quantifying effect of interventions on transmission of Mycobacterium tuberculosis in Tanzania’. The core project is led by KNCV and ATS. This core project aims to do an impact evaluation of USAID-supported TB control interventions in several countries. Among the proposed countries is Tanzania. The evaluation will focus on the impact of interventions on transmission of TB. The project will be multiyear and community-based.

**Interventions to be evaluated**

A package of interventions is being determined and implemented by the CTB country office in collaboration with the National TB and Leprosy Control Program (NTLP) and other stakeholders, and may include community involvement in referral of presumptive TB patients, improved diagnostics and sample transport, activities related to active case finding among risk groups and TB infection control in facilities, early diagnosis and treatment, contact tracing and provision of preventive therapy.

**Sub-studies**

This project includes two research studies to determine the impact of TB control interventions on transmission of *Mycobacterium tuberculosis*. The first study will use Whole Genome Sequencing (WGS) in a community based examination of transmission patterns in a defined population. The second study will employ Tuberculin Skin Testing (TST) surveys of school children in the intervention and control communities. For both studies a summary of the proposed protocols is attached (annex 1).

# Purpose of Request for Proposals

This request for proposals is intended to identify a local research organization registered and based in Tanzania (further called ‘the organization’) with the capacity to conduct the research described.

# Scope of work

Scope of work of the organization will include all of the below (in collaboration with KNCV and ATS):

1. For both sub-studies:
	1. Ensuring ethics and administrative approvals of the 2 sub-studies.
	2. Implementing the research as per protocol and following international ethical standards for studies involving human participants utilizing good research practice, including obtaining written informed consent of participants.
	3. Documenting and recording results in a mutually agreed upon, quality-assured and accessible database.
	4. Data analysis and reporting
	5. Data collection should take place over at least 3 full years, starting in 2016. Reporting should be final by August 2019, since the CTB project ends in September 2019.
	6. Documenting implementation and fidelity of any TB control activities in the intervention and control areas and intermediate indicators (annex 2).
	7. Dissemination of research results.
	8. Efficiently managing resources allocated for the project
	9. In all of the above collaborate closely with KNCV, ATS, national, provincial and district TB control program, USAID and other stakeholders, such as local community based organizations.
2. For the first sub-study, the WGS study:
	1. Long-term community-wide data collection for all patients diagnosed with newly diagnosed pulmonary TB in the intervention community, including those in the private sector, during 3 years including demographic, clinical and detailed TB exposure and contact investigation data (“epidemiological data”)
	2. Ensuring high quality availability of an in-country quality-assured mycobacteriology laboratory with capacity to process 1500 specimens per year, providing smear microscopy, *mycobacterial* culture on liquid and solid media, extraction of DNA from cultured organisms, preparation and shipping of extracted DNA, and storing positive cultures, and storage of samples, all using appropriate biosafety measures. The laboratory should adhere to all policies and guidelines of the NTLP and have low risk of false-negative results and laboratory cross-contamination. Shipping of samples will probably to a laboratory for whole genome sequencing (to be determined), probably outside Tanzania.
	3. Participate in computationally intensive analyses (bioinformatics) of sequencing data.
3. For the second sub-study, the TST-surveys:
	1. Identifying appropriate cohorts of school children.
	2. Organizing the testing logistics
	3. Performing TST of schoolchildren (two surveys in 2 areas at the same time in year 1 and again in year 3)
	4. Utilizing appropriately trained personnel to place and read the TSTs in a standardized way
	5. Ensuring proper care for children with TST induration above 15 mm

This scope of work will be a collaborative effort between the organizations, KNCV, ATS, USAID and Tanzania NTLP. A list of possible publications will be prepared and authorship will be agreed upon, according to guidelines of scientific journals. Any publications and presentations on this scope of work must be submitted to Institute (as owner) AND KNCV (and via KNCV to USAID) for approval. These conditions will be further detailed in the sub-agreement.

The protocols and most of the data collection tools for the 2 sub-studies have been developed (abstracts annex 1). The organization local partner will have the opportunity to propose adaptations. The scope of work will be worked out in detail and can only be adapted with mutual agreement between KNCV, ATS, USAID and the Institute.

# Geographic focus

The project needs to be implemented in a community where CTB pilot interventions are planned in fiscal year 2 (October 2015-September 2016). The proposed study area is a geographically connected group of NTLP districts within the NTLP region of Kinondoni. This area has been selected since it is a CTB pilot area, an urban area, with research experience and appropriate TB burden. The first study requires a sample size of 1045 culture confirmed pulmonary TB patients per year. Such numbers can be achieved in an area with a current notification of at least 750 bacteriologically confirmed pulmonary TB patients per year (or 1500 total pulmonary TB patients), excluding patients from outside the district. Bacteriological confirmation includes positive smear and/or culture and/or Xpert.

For the TST surveys the proposed intervention area is the same as above and the proposed control area is Morogoro urban, selected since it is also an urban area, with no or limited TB control interventions besides the standard NTLP TB control activities.

# Application process

The proposal must be prepared in accordance with the instructions provided in below section. Each organization shall submit only one proposal.

Issuance of this RFP does not in any way constitute an award or commitment on the part of the CTB nor does it commit to pay for costs incurred in the preparation and submission of proposal.

To ensure you receive modifications to the RFP, send an email to coretransmission@kncvtbc.org requesting that your organization be put on the distribution list.

# General guidelines for developing requests for proposals

Applicants shall consider the following guidelines for developing the proposal:

* The proposal should address all activities under section ‘Scope of Work’.
* Proposed activities described in the proposal should be for the proposed geographic area.
* Applicants can receive funding for similar activities from other donors. However, proposed activities must not be duplication of activities that are covered or planned under the other funding source, and the organization must make clear how the different funding sources will be used for distinct objectives or distinct geographic areas.

# Eligibility criteria

The organization submitting the proposal should meet the following eligibility criteria:

* Is a large reputable university or other medical research organization legally registered in Tanzania. The organization can subcontract parts of the work to third parties; however the organization remains responsible towards KNCV
* If a subcontractor is included, partners should have a track record of successful collaboration.
* Have demonstrated collaborative interactions with the NTLP
* Have demonstrated capability for TB field research (including engagement of the local TB control program, local private sector, and local community)
* Have demonstrated data management capacity
* Have demonstrated capacity to manage sub-award and/or research contracts funds
* Have demonstrated presence with research activities in the proposed geographic area
* Possess audited financial statements of last 3 fiscal years
* The organization or its subcontracted partner within an existing collaboration should have access to an acceptable biosafety level 2+ laboratory to do *M.tb.* culture and DNA extraction. The laboratory should be within 1 day transport distance of the selected community (see geographic focus)

# Budget and funding period

A budget should be added in the attached format. See annex 1 and 2 for study details. The budget should be split per sub-study; but staff can work (part-time) on both projects. The budget should specify all staff levels and numbers needed full-time/part-time %, equipment, maintenance, consumables[[1]](#footnote-2), training, communication, transport, database set-up and maintenance, conference attendance, publication fees, cost for IRB permission, cost for audit, legal fees, bank fees, translation and dissemination. The following categories of cost should be used: salary and wages, fringe benefits, travel and transportation, equipment, supplies, contractual, other direct costs, indirect costs. [[2]](#footnote-3) All items should be specified and justified.

Subject to the availability of funds and technical evaluation outcomes, KNCV intends to award one sub-award to a local Tanzanian research institute under the CTB project. Funding amount for the sub-award will be commensurate with the proposed geographic area, population coverage, and outcomes in terms of case finding and management.

The funding period of the sub-award is maximum 3.5 years, depending on the signature date, and the contract will end September 2019. Funding will depend on USAID funding for this project and therefore funding commitments can only be given for 1 year periods, with the intention to fund the complete period.

# Questions and answers

Questions can be submitted to the following email address until a week before the application deadline: coretransmission@kncvtbc.org. Responses will be provided within 3 working days to all organizations that have shown interest to apply.

# Request for proposals format

The proposal should be prepared in English. Applicants are requested to use A4 size paper, with single space, 9 point font Verdana. The proposal should not exceed 10 pages excluding the cover page.

The organization will develop a proposal which describes:

1. Applicant information (Name of Applicant Institute, Name and title of contact person, Mailing Address, Telephone (including mobile), Email address)
2. Number and type of health facilities in the proposed site diagnosing or treating TB patients, including private facilities
3. Experience in community-based and health facility-based TB research, including
	1. Experience in obtaining ethics and administrative approvals to work in facilities and communities
	2. Experience in data management, maximum number of TB patients included in previous/current studies.
	3. Experience in tuberculin skin test surveys in defined populations such as school children.
	4. Research experience in the proposed site
4. Experience in working with the Tanzanian NTLP
5. Experience in working with private sector (including NGO/non-for profit)
6. Specific proposal on:
	1. How to ensure achieving the sample size for the community study
	2. How to engage the private sector to find maximum number of patients & and experience with private sector engagement
	3. How to recruit school children for a TST survey and ensure proper follow-up of those with a positive TST.
	4. Time plan to finish both studies and report by August 2019
	5. How the project will be managed, which partners will be involved and their responsibilities
7. Collaboration with an identified TB laboratory, and the experience of the identified laboratory in:
	1. System for transporting specimens from sputum collection sites to the study laboratory
	2. Quality assurance and biosafety measures (including appropriate disposal of hazardous material) for central and peripheral laboratories.
	3. Culture capacity (maximum number done per month/year currently, plus maximum capacity possible with current facilities and staff), specimen processing for culture and media inoculated within 1-2 days of receiving the sample; and measures in place to prevent lab cross-contamination. If the lab has not achieved 1500 culture samples in the past, indicate staff, equipment, space and time requirements to achieve these within 3 months (no new construction allowed).
	4. Smear microscopy and cultures performed using standardized methods recommended by the Global Laboratory Initiative
	5. DNA extraction capacity and method used
	6. Capacity to store *M.tb* cells (in a -20, or preferably, -80 freezer) and *M.tb* DNA (-20 freezer) or capacity to place a -80 freezer with generator back-up

#

# Evaluation criteria

KNCV will establish a Technical Evaluation Panel (TEP), including KNCV and ATS, to review and evaluate all proposal papers received before the deadline. *Only proposals that meet the eligibility criteria will be considered.* The TEP will evaluate the proposal using the following criteria and scoring as described below. The TEP will assign maximum 100 points. Behind each item is the maximum number of points that can be obtained:

1. Laboratory capacity and experience, as specified above (30 points)
2. TB Research experience, as specified above (30 points)
3. Suitability of specific proposal, as specified above (20 points)
4. Budget (20 points)

The organization that has been selected to collaborate for developing a full proposal and budget based on their proposal will be notified within 1 month after the closing date for submission.

# Annex 1. Research summaries

**Sub-study 1[[3]](#footnote-4). Impact of interventions to prevent transmission of Mycobacterium tuberculosis in Kinondoni District, Dar es Salaam, Tanzania**

**Population**: The study population will consist of all persons living in Mwananymala and Magomeni tuberculosis control districts, Kinondoni District, Dar es Salaam, Tanzania who are identified as having tuberculosis.

**Number of Sites**: Two: Mwananymala and Magomeni tuberculosis control districts, Kinondoni District, Dar es Salaam

**Study Duration**: 3.5 years

**Subject Duration**: Each subject will be in the study for approximately 2 months.

**Objectives and aims**:

**Overall Objective.** The overall objective of the study is to determine the impact of tuberculosis control interventions supported by the United States Agency for International development (USAID) on the transmission of *Mycobacterium tuberculosis* (*M.tb)* in defined populations.

**Objective 1.** To utilize whole genome sequencing (WGS) to construct transmission trees of *M.tb* isolated from patients in Mwananymala and Magomeni tuberculosis control districts of Kinondoni District and from these trees identify source and secondary cases.

**Aim 1**. To perform next-generation WGS of *M.tb* isolates from all patients with pulmonary tuberculosis (new and retreatment) in Mwananymala and Magomeni tuberculosis control districts, Kinondoni District of Dar es Salaam during a 3.5-year period.

*All persons for whom treatment for tuberculosis is initiated will have a sputum sample sent to a laboratory able to perform cultures in Dar es Salaam. All patients who have a positive culture for M.tb and who consent to participate will be included in the study. All M.tb isolates will undergo WGS.*

**Aim 2**. To compare secondary case rates determined by WGS between discrete time periods in relation to the implementation of control interventions in the community.

*A calendar of intervention implementation (interventions during the past 3 years and during the study period) will be developed. Year-to-year trends in secondary case rates will be compared in relation to new or modified control interventions. The degree to which the interventions have been implemented will be assessed.*

**Aim 3**. To compare transmission patterns and characteristics of source and secondary cases to identify risk factors for transmission and for tuberculosis due to recent transmission.

*Study staff will collect information on factors related to the putative source and secondary cases, the settings in which exposure could have occurred, and features of presumed secondary cases.*

**Aim 4.** To utilize WGS together with expanded case interviews to identify possible sites of transmission within the community.

*Study staff will conduct an expanded interview to identify contacts (household and other) and to obtain an estimate of time spent in various settings (household, health care facilities, social gathering places, religious gatherings, etc.)*

**Objective 2.** To utilize community wide WGS to examine the impact of specific interventions, such as active screening for tuberculosis in high risk groups, contact investigation, and facility-based infection control, on secondary case rates within the community

**Aim 1.** To compare secondary case rates associated with cases identified by active screening for tuberculosis in high risk groups, contact investigation, and facility-based infection control with self-referred cases.

*This aim is intended to be illustrative of possible questions to be addressed by the study. Additional comparisons (aims) will be determined based on the interventions implemented. Possible interventions might include contact investigation, facility based screening of risk groups, infection control in healthcare facilities, TB/HIV integration.*

**Objective 3**. To measure total delay in diagnosis and treatment initiation (See Figure 1) and compare delays between discrete time periods in relation to the implementation of TB control interventions in the community.

*Staff will collect information on the components of total delay in establishing a diagnosis and initiating treatment (Figure 1) from study participants.*

**Aim 1**. To determine the association of changes in total delay with secondary case rates.

*The trend median total delay will be determined and will be compared with the trend in secondary case rates.*

**Sub-study 2[[4]](#footnote-5): Estimating the effect of TB control interventions on TB transmission as measured by tuberculin school surveys in Tanzania**

**Background:** This project intends to measure the effects of tuberculosis (TB) control interventions on transmission. It is linked to a multi-country project in the same area that will use genotyping (whole genome sequencing, WGS) to reflect person-to-person transmission of *Mycobacterium tuberculosis* (MTB). The project is part of the Challenge TB project funded by USAID.

**Aim & objectives**: The aim of this project is to assess the effect of TB control interventions on TB transmission in Tanzania, by relying on measured changes in prevalence of latent TB infections among school children. Objectives are:

1. To assess the trend in prevalence of latent TB infection in school children in an area with extensive TB control interventions (intervention area).
2. To compare this trend between an area with extensive TB control interventions and an area with only standard TB control activities (control area).

**Design**: The change in prevalence of latent TB infection will be compared between an intervention group and a comparison group. Interventions will be a package of TB control interventions, selected for the Challenge TB project that will be implemented over 3 years. Two surveys will take place, one in year 1, and one after 2 years of interventions, in year 3.

**Geographic location**: The intervention study will take place in 3 adjacent districts within Kinondoni region of Dar es Salaam (TB districts Mwananyamala I and II and Magomeni, together accounting for 13 wards). The control area will be Morogoro urban, since it currently has only standard TB control interventions.

**Measurements**: TB infections will be measured using TST in primary school children.

**Inclusion criteria**: The study population will consist of healthy primary school children of ages 6-8 years in school grade 1 and 2 in all public day schools in the selected areas. By including a limited age group, we ensure there will be no children tested both in baseline and in repeat survey.

**Sample size**: The required sample size will be 12,200 primary school children in the intervention area and 12,200 primary school children in the control area in year 1 (to be prepared and completed within 1 year), and another 24,400 children in the repeat surveys, total 48,800 children. In order to allow for non-response and drop-outs and non-eligibles, 25% more will be approached among the study population, or about 15,250 per survey.

**Field work:** Field teams will visit the selected schools and inject children with commercially available and licensed tuberculin in the arm. Two to three days after testing the teams will visit the schools again to read the skin reactions. Children with positive tests will be managed according to existing NTLP policies.

**Data entry and analysis:** Data will be collected using tablets. The 2 trends in prevalence of tuberculosis infection in the intervention and control group will be compared using multivariable logistic regression.

**Ethics**: At least 1 parent per child will be asked written informed consent and the child will be asked for assent. Only children of parents who give informed consent will be included. The survey will start only after administrative and ethical clearance from NIMR, UCSF and AMC. Local leaders will be informed and sensitized in the preparation phase of the survey.

**Training and pilot:** will be done in an area not included in the study.

# Annex 2. Additional protocol items needed for budgeting purposes

**Package of interventions**

The package of interventions is the responsibility of CTB project led by KNCV country office; and not responsibility of the research organization.

**Data collection**

1. For sub-study 1:
	1. Recruitment and written informed consent
	2. Standard TB treatment register information
	3. Extensive contact interview (household, work place, social interactions, health care facilities, TB contacts)
	4. Medical history (health-seeking behavior and TB diagnostic history, prior tuberculosis treatment history, risk factors for tuberculosis, comorbidities)
	5. Mapping of household and frequently visited places by GIS
2. For sub-study 2:
	1. Ensure written individual parental consent and child assent
	2. Limited information as per regular tuberculin surveys (age, sex, BCG scar, TB contact, previous TB, school, grade, induration and for those with induration above 15 mm: TB symptoms, diagnostic result, TB disease status)
	3. Ensure proper case management according to local policy and ethics regulations for children that have a positive TST (>=15 mm; expected 5%).
3. For both studies: Besides study outcomes, also collect intermediate indicators of program quality:
4. Changes in case notification (total, smear-positive, bacteriologically confirmed)
5. Changes in diagnostic delay
6. Changes in treatment outcomes
7. Quality (fidelity) of implementation of TB control activities including yield of screening if this is taking place

**Laboratory** (only for sub-study 1):

* We assume sputum smears are already part of regular care; need to obtain results from regular TB smear lab.
* Sputum culture and *M. tuberculosis* DNA extraction of all included TB patients (ensuring high quality DNA extraction of at least 1045 patients) within 1 week of starting treatment.
* Package preparation of DNA of all positive culture samples for WGS abroad for quarterly shipping, using approved procedures.
* Store frozen samples/isolates.

**Sample size**

For sub-study 1: Patients to be recruited in the study will be those diagnosed as PTB by a clinician and starting treatment. All patients (smear positive, smear negative) started on treatment will have their sputum specimens collected for culture and DNA extraction, i.e. we expect that cultures need to be done of up to 1500 patients started on TB treatment. In settings with Xpert available, only those Xpert and/or smear-positive will have their sputum cultured. Only those patients with a positive culture (conducted by the research project) will be enrolled. At least 1045 patients should be included with both complete epidemiological data and enough high quality DNA for WGS.

For sub-study 2: see abstract.

**Data collection** **and analysis** (for both sub-studies)

* Where possible use handheld electronic equipment (for example tablets) for interviews and Case report forms (CRFs)
* Using barcodes for samples and paper forms
* Internal Quality assurance (the project may add external quality assurance funded outside this RFP)
* Develop database and ensure proper data management including back-ups and limited access
* Data-analysis will be done locally, with support from international partners
* A local bio-informatics/statistician can be trained in data-analysis on WGS data
* Quarterly, annual and final reports to be written within project time.

**Ethics**

* For sub-study 1 all participants will be asked for written informed consent
* For sub-study 2 see abstract
* Institute will obtain administrative approvals and approval from competent ethics committee; KNCV and ATS as research partners will obtain approvals from their respective institutional ethics committees.
* Tools will be translated in local language.

**Dissemination**

Results will be shared with local and national NTLP and other stakeholders and will be presented at international conferences. Writing of scientific papers is envisioned both during and after the project period.

**Monitoring**

Monitoring indicators on progress will be mutually agreed between parties and include for example:

Sub-study 1:

* Process with respect to protocol approval
* Number of TB patients diagnosed in the selected area since study start
* Out of them how many requested to participate
* Out of them how many gave informed consent
* Out of them how many sputum sample taken for culture
* Number of samples with positive culture
* Number of samples with DNA extraction
* Number of patients with interview
* Number of patients with GIS coordinates of their household

Sub-study 2:

* Process with respect to protocol approval
* Number of schools sharing list of potential participants
* Number of children whose parents gave informed consent
* Number of children recruited and tested for LTBI
* Number of children with induration read

Both:

* Process with respect to collecting intermediate indicators
1. The budget does not need to include tuberculin since the standard tuberculin that has been used in past tuberculin surveys in Tanzania (PPD RT23 from SSI Denmark) is not available till 2017 and KNCV is searching for an appropriate alternative. [↑](#footnote-ref-2)
2. ###  For an indirect cost rate: In accordance with the provisional negotiated indirect cost rate agreement (NICRA) allowable indirect costs shall be reimbursed: 1) on the basis of the negotiated provisional or predetermined indirect cost rates and the appropriate bases (NICRA) or 2) Sub-Recipient can budget an indirect cost rate which can be independent from KNCV’s indirect cost rate provided the following is in place: a) Job cost or activity based accounting system which accumulates indirect costs by pool (e.g. fringe benefits, overhead, indirect, general and administrative); b)Timekeeping system which supports direct and indirect costs; c) Cost policy statement which identifies base and pool, direct and indirect functions/costs; d) Timely (monthly) closing of books and records; and e) Financial statement audit and/or independent review of rates annually to attest to compliance the relevant USAID cost principles. This indirect cost rate needs to be approved by KNCV. For budget purposes, Sub-Recipient shall submit a substantiated indirect rate calculation and a confirmation that the above is in place to KNCV. Reimbursements will be made based on actual rates determined by an audit, if budgets allow.

 [↑](#footnote-ref-3)
3. Copied from version 5 dated 11 February 2016, submitted for UCSF ethics approval [↑](#footnote-ref-4)
4. Copied from version 6 dated 3 March 2016 that will be shared with Scientific Advisory Group of experts of the project [↑](#footnote-ref-5)