ANNEX A to the AMENDED AND RESTATED PROGRAM GRANT AGREEMENT

Program Implementation Description

Country:	**Georgia**
Program Title:	**Sustaining Universal Access to Quality Diagnosis and Treatment of All Forms of TB Including M/XDR-TB**
Grant Number:	**GEO-T-NCDC**
Disease:	**Tuberculosis**
Principal Recipient:	**National Center for Disease Control and Public Health**

Capitalized terms and acronyms used but not defined in this Annex A or the attachments to this Annex A have the meaning given to them in the Standard Terms and Conditions of this Agreement.

In the event of any conflict between the terms of this Annex A and any provision of the Standard Terms and Conditions of this Agreement, the terms of this Annex A shall prevail.

A. PROGRAM DESCRIPTION

1. Background and Summary:

Georgia is a former Soviet Republic, located in the South Caucasus, with a population of 4.4 million. Georgia is an Upper-Low-Middle Income Country with a severe tuberculosis (TB) burden.

According to the WHO estimate, TB incidence for 2012 was 116 cases per 100,000 population, which is the fifth highest rate among the 53 countries of the WHO European Region (Global tuberculosis report 2013, WHO). The rate of new TB cases and relapse notifications in 2011 was 105 cases per 100,000 population (TB surveillance and Monitoring in Europe 2013, European Centre for Disease Prevention and Control and WHO joint report). The TB case detection rate has increased from 58% in 2005 to 84% in 2011. WHO estimated prevalence was 158 cases per 100,000 population in 2012 (Global tuberculosis report 2013, WHO). Historically, the estimated prevalence has shown a positive trend of decline.

From 1990 to 2012, the estimated TB mortality rate has decreased from 8.3 to 4.5 cases per 100,000 population. During the last three years, the estimated mortality rate has shown a positive trend of decline from 15 in 2010 to 4.5 in 2012, in each case per 100,000 population (Global tuberculosis report 2013, WHO).

The treatment success rate for new smear-positive cases increased from 63% in 2000 to 76% in 2011. The treatment failure rate remains high at 12% in 2010, with an increase up to 15% in 2011.

Currently, the National TB Control Program (NTP) routinely conducts drug resistance surveillance and according to the NTP data, in 2011, MDR-TB was found in 10.9% of newly diagnosed pulmonary TB cases and in 31.7% previously treated pulmonary TB cases. The treatment success rate for MDR-TB patients is 53.7% (2009 cohort, TB surveillance and Monitoring report in Europe, 2013). In 2011, there were 475 cases (65% of estimated cases of TB) with confirmed MDR-TB and 737 started Second Line Drugs (SLD) (there is no waiting list for second-line treatment). It is important to emphasize a high rate of default rate of 28% among MDR-TB cases treatment outcomes.

According to the latest Green Light Commission (GLC) mission report (June 2012), every year in Georgia there are approximately 200 - 240 new MDR-TB cases and 185 – 214 retreatment cases from 2009 -2011.

Additionally, Georgia has a concentrated HIV epidemic (13% prevalence among MSM according to 2012 IBBS). The HIV testing for TB patients in 2012 was 38% compared to 46% in 2011; 1.8% of tested TB patients (33 cases) were HIV positive, 79% of HIV positive TB patients were on cotrimoxazole preventive treatment (CPT) in 2012 compared to 56% in 2011.

The overall goal of the program is to reduce the burden of tuberculosis in Georgia by sustaining universal access to quality diagnosis and treatment of all forms of tuberculosis.
The interventions included in this Grant Agreement are aligned with the priorities of the National TB Strategy and continue to have focus on strengthening the programmatic management of TB, including drug-resistant TB, supporting patients and consolidating health services' capacities for successful TB case management, with a special focus on groups at high risk such as prisoners.

The National Center for Disease Control and Public Health (NCDC) will serve as the Principal Recipient of the Grant, having accepted this role from the Global Projects Implementation Center, following the Periodic Review of this Grant. The NTP Central Unit (National Centre for Tuberculosis and Lung Disease (NCTBLD)) through the network of public health care institutions and providers will be responsible for implementation of the majority of planned activities as a Sub-recipient.

2. **Goal:**

To reduce the burden of tuberculosis in Georgia by sustaining universal access to quality diagnosis and treatment of all forms of tuberculosis including M/XDR-TB.

3. **Target Group/Beneficiaries:**

- All TB patients in the country including M/XDR-TB patients and prisoners; and
- All Medical personnel of NTP and Regional units.

4. **Strategies:**

- To strengthen the NTP management, coordination, monitoring and evaluation;
- To improve diagnosis of TB including M/XDR-TB;
- To ensure quality treatment of all forms of TB; and
- To ensure adherence to TB treatment by intensive patient support and follow up.

5. **Planned Activities:**

To strengthen the NTP management, coordination, monitoring and evaluation

- To be performed in both civilian and penitentiary sectors; and
- By provision of technical assistance with priority issues in TB control and M&E system management, central and regional NTP supervision of TB and PHC facilities, penitentiary institutions, and program management of NTP Central and Regional Units.

To improve diagnosis of TB including M/XDR-TB

- Strengthening the laboratory capacities for TB and M/XDR-TB diagnosis, including sputum smear microscopy, culture, LED microscopy and DST (drug susceptibility testing) to first-line drugs;
- Sustaining reliable routine drug resistance surveillance, a regular specimen transportation system country-wide, upgrading reference and regional laboratories for rapid DR-TB diagnosis and ensuring external laboratory quality control and quality assurance; and
- Targeted support of case-finding activities among at-risk population groups, such as screening of IDUs for TB, entry screening for TB in penitentiary institutions, and HIV counselling and testing among TB patients.

To ensure quality treatment of all forms of TB

- Sustaining universal access to quality treatment of all forms of TB, including M/XDR-TB;
- Procurement of anti-TB drugs (first-line, second-line and third-line for TB and M/XDR-TB patients and side effect drugs; and
- Laboratory and clinical monitoring of effectiveness of TB treatment including DST to second-line drugs, and ensuring individual infection control and protection measures for staff.

To ensure adherence to TB treatment by intensive patient support and follow up

- Incentives for TB and M/XDR-TB patients including transportation of visiting Directly Observed Therapy (DOT) supporters and patients to DOT center; and
- DOT incentives for PHC nurses and monitoring visits

B. CONDITIONS PRECEDENT TO DISBURSEMENT

1. Condition Precedent to Use of Funds for procurement of Second-Line Anti-Tuberculosis Drugs

Prior to the use of Grant funds by the Principal Recipient to finance the procurement of second-line anti-tuberculosis drugs, the Principal Recipient shall deliver to the Global Fund the following items, each in form and substance satisfactory to the Global Fund:

a. A current detailed MDR-TB expansion plan (including the number of MDR-TB patients to be treated and the list and quantifications of the medicines to be procured for the MDR-TB program reflecting the Principal Recipient's finalized forecast for the Grant implementation period covered by this Agreement); and

b. The national guidelines for programmatic management of MDR-TB, both of which have been developed in collaboration with a technical partner acceptable to the Global Fund.

C. SPECIAL TERMS AND CONDITIONS FOR THIS AGREEMENT

1. No later than 31 March 2015, the CCM shall, or the Principal Recipient shall cause the CCM to, submit a Budgeted Sustainability Plan for governmental take-over of financing for the first line TB medicines during the second year of the implementation, and gradual take-over of financing for the NTP by the end of the second implementation period, which at a minimum shall include the financing of second-line anti-tuberculosis medicines and patient support.

2. No later than 30 days prior to a scheduled cash transfer that includes funds for the procurement of MDR-TB medicines, the Principal Recipient shall deliver to the Global Fund a pro forma invoice issued by the designated Procurement Agent of the Global Drug Facility, as delegated by the Green Light Committee Initiative.

3. The Principal Recipient shall cooperate with the Green Light Committee (the "GLC") in GLC's efforts to provide technical support and assistance to the Principal Recipient with respect to monitoring and the scaling-up of MDR-TB-related services provided in Georgia. Accordingly, the Principal Recipient shall budget and authorize the Global Fund to disburse up to a maximum of US$ 50,000, or such lower amount as may be agreed between the GLC and the Global Fund, each year to pay for the GLC services.

4. No later than 31 March 2015, the Government of Georgia shall, or the Principal Recipient shall cause the Government of Georgia to, prepare and provide a formal document describing the tuberculosis program coordination mechanisms, with clear segregation of the roles and responsibilities among the implementing entities in Georgia.

5. No later than 31 March 2015, the CCM shall, or the Principal Recipient shall cause the CCM to, deliver the National Tuberculosis Strategy, approved by the relevant government bodies, which shall clearly specify and describe the full organizational structure, including a central body responsible for TB services in Georgia.

6. Notwithstanding the delivery of the OM pursuant to Section B(3) of this Agreement, no later than 31 August 2014, the Principal Recipient shall deliver to the Global Fund, in form and substance satisfactory to the Global Fund, the revised OM which shall include procedures in respect of Financial management, Sub-recipient management, and shall address any weaknesses identified by the Principal Recipient assessment and regular progress updates, including but not limited to the following:

a. Selection and contracting of Sub-recipients, reporting requirements, procedures for verification of Sub-recipients' financial and programmatic data, frequency and scope of monitoring visits, Sub-recipients' audit arrangements;

b. SOPs for budgeting, budget management, variance reporting, bookkeeping, administrative procurement and treasury management of the Principal Recipient; and

c. Details of the accounting and finance organizational structure of NCDC, all adequate policies and procedures to guide activities in financial management and accounting and ensure staff accountability for the Global Fund grants. The OM shall contain SOPs for financial management and accounting procedures. The OM shall further contain the requirements for financial management of the grants, including but not limited to the new Global Fund requirements mandated by the revised structure and funding process, and composition of financial management function of NCDC. The OM may incorporate by reference the Public Financial Management legislation, rules and regulations of Georgia which are presently followed by the Principal Recipient.

In addition, the Principal Recipient shall confirm (as verified by the LFA) that each Sub-recipient contract complies with Articles 14, 18 (d) and 20 (a) of the Standard Terms and Conditions of this Agreement.

D. FORMS APPLICABLE TO THIS AGREEMENT

For purposes of Article 15(b) of the Standard Terms and Conditions of this Agreement entitled "Periodic Reports," the Principal Recipient shall use the "On-going Progress Update and Disbursement Request", available from the Global Fund upon request.

E. ANTICIPATED DISBURSEMENT SCHEDULE

For purposes of Article 10(a) of the Standard Terms and Conditions of this Agreement, the Global Fund shall make disbursement decisions on an annual basis starting from the Grant Starting Date. The Global Fund may elect to transfer the disbursement decision amount to the Principal Recipient through multiple tranches over time, the decision of whether to transfer any funds in a given tranche, and the timing and amount of such tranche, shall be determined by the Global Fund in its sole discretion.

F. THE GLOBAL FUND STAGGERED FUNDING COMMITMENT POLICY

At the time of each annual disbursement and commitment decision by the Global Fund, the Global Fund shall set aside ("commit") funds up to the amount of the annual commitment decision amount, subject to the terms and conditions of this Agreement. Grant funds shall be committed in a manner consistent with the Global Fund's discretion and authority as described in Article 10 of this Agreement, taking into account, among other things, the availability of the Global Fund funding and the reasonable cash flow needs of the Principal Recipient. If a commitment of Grant funds is made, it will be communicated to the Principal Recipient at the time of the annual disbursement and commitment decision through written notice from the Global Fund. The Principal Recipient further acknowledges and agrees that the Global Fund may de-commit Grant funds, in its sole discretion, after the end of the Program Term.