



PROJECT "IMPROVEMENT OF RETENTION IN CARE OF PEOPLE WITH HIV INFECTION IN TIGRAY, ETHIOPIA: INVOLVEMENT OF PATIENT ASSOCIATIONS TOWARDS DECENTRALIZATION OF CURES (PROJECT - CASA) II PHASE

Amendment to Agreement executed on the 15 February 2018

between

The **Istituto Superiore di Sanità** hereinafter referred to as "ISS", established in Italy – Rome Viale Regina Elena, 299 – 00161, legal registration number 80211730587 represented by its Financial Manager Dr. R. M. Martoccia

AND

The **Mekelle University College of Health Sciences, Ayder referral Hospital** hereinafter referred to as "University", established in Kebele 03 woreda : semene , Mekelle, Tigray, Ethiopia – Tax Code: T Number 0016256904 – represented by its legal representative , Dr. Amanuel Haile

WHEREAS

- the ISS and the Mekelle University College of Health Sciences, signed a collaboration agreement on 15 february 2018, for the realization of the activities of the project "Improvement of retention in care of people with hiv infection in Tigray, Ethiopia: involvement of patient associations towards decentralization of cures (project - casa) II phase";
- the above mentioned project lasts 24 months;
- the parties desire to agree on the activities of the second year of the project, the related financing and the extension of the duration of the contract.

NOW THEREFORE

Both of the parties hereby have agreed to amend the Agreement as follows:

- Article 2 (Objectives);
- Article 4 (Financing the research) (MANAGEMENT OF THE FINANCING);
- Article 7 Length of the Agreement;
- Annex (Document A and Document B - 15 February 2019 – 14 February 2020).

1) AMENDMENTS TO AGREEMENT.

a) The Article 2 of the Agreement is hereby added with the following:

**Article 2
(Objectives)**

The present agreement regulates the collaboration between ISS and University



for the realization of activities of the research project improvement of retention in care of people with hiv infection in Tigray, Ethiopia: involvement of patient associations towards decentralization of cures (project - casa) II phase .

Dr. Raffaella Bucciardini is the scientific coordinator for ISS.

Dr. Amanuel Haile is the scientific coordinator for the "University".

The objectives of the agreement are detailed in the technical Annex (document A and document B) which has to be considered as integral part of the current agreement.

b) The Article 4 of the Agreement is hereby added with the following:

Article 4
(Financing the research)
(MANAGEMENT OF THE FINANCING)

The maximum contribution the ISS will recognize in toto to finance the activities relative to the present agreement is set for the duration of the present act in the amount of Euro 35.161,00.

The above contribution will be paid, after receiving the relative invoices as follow:

- ⇒ First year of the project:
- ⇒ € 17.840,90 after stipulation of first year agreement
- ⇒ € 650,10 at the end of the first year of the project

- ⇒ Second year of the project:
- ⇒ € 11.669,00 after stipulation of this Amendment
- ⇒ € 5.001,00 at the end of the second year of the project

- The contribution must be used exclusively for expenses incurred during the duration of the research project and for expenses strictly pertinent to the realization of research activities.
- In all cases, expenses not foreseen by the budget (document B), attached to the present agreement, may neither be undertaken nor, as a consequence, be recognized.
- It is allowed to pay permanent staff only if allowed by the Institution rules for personnel recruitment.
- The University must justify the overhead cost at the end of the projects with a declaration of the Institution Legal Representative.
- A sole variation on the budget, will be permitted. This may take place exclusively within the limits of the overall contribution as constituted by each single entry in the budget and must be signed by the scientific manager and by legal representation.
- The same must be formally authorized by ISS.
- At the expiration of the present act the Institution must present a financial report of all expenses incurred, accompanied by documentation, either in the original or exact copies of the same, relative to the expenses effectively incurred, in order of the individual expense entries, and corresponding to the budget as presented.
- The aforementioned financial report must be approved by the scientific manager and the Institution's legal representative, or by a delegate of the same (should the signature be delegated, a copy of the delegation decree must be attached.)

c) The Article 7 of the Agreement is hereby added with the following:

Article 7
(Length of the agreement)

The effectiveness of this Act is subject to its publication on the ISS website according to the law art. 18, comma 5, D.L. n. 83/2012.

The present agreement will run from the signing of the act, and expires on 14.02.2020.

2. Continuing Effect of Collaboration Agreement

Except as expressly modified by this Amendment, all of the other provisions of the Agreement executed on the 15 February 2018 shall remain unchanged. Each Party acknowledges that this Amendment is made in accordance with the Agreement, and except as provided in the section 1. of this Amendment or otherwise expressly provided under this Amendment, the provisions of the Collaboration Agreement shall be unmodified and shall continue to be in full force and effect in accordance with the terms thereof and hereof.

3. Entire Agreement.

This Amendment and the Agreement constitute the entire and exclusive agreement between the parties hereto with respect to the subject matter hereof. All previous discussions and agreements with respect to this subject matter are superseded by the Agreement executed on the 15 february 2018 and this Amendment. This Amendment may be executed in one or more counterparts, all of which together shall constitute one and the same agreement, and may be executed through the use of facsimiles or .pdf or other electronically transmitted documents.

For Istituto Superiore di Sanità

Financial Manager
Dott.ssa Rosa Maria Martocchia

For Mekelle University College of Health
Sciences, Ayder referral Hospital

Legal Representative
Mr. Dr. Amanuel Haile





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DOCUMENT A

(15 February 2019 – 14 February 2020)

Mekelle University

Hereby, we provide information on the project activities where Mekelle University (MU) will mainly be involved, explaining how the funds allocated to MU will be used. Project activities and tasks of the MU members involved in the project will shortly be described.

Funding allocated to MU will be used to carry out the following activities:

- A. Operational research
- B. Training for Research Monitors

A. Operational research activities

The operational research is based on a longitudinal collection of epidemiological data on a cohort of HIV patients taking antiretroviral therapy at seven participating health facilities (HFs). In the next three years, patients will continue to be followed at the HFs in a setting of common clinical practice, without additional visits. Financial support for operational research will mainly be used to pay salaries for three Research Monitors, MU healthcare workers fully involved in the study.

The Mekelle University (MU) will guarantee the availability of specialized health workers as well as a working area for meetings and local coordination of the study. MU will also be the location of the central database of the study, where collected data will be merged and stored.

Research Monitors (RMs) will perform the following tasks:

- Management of the central database
- Database updating, with data collected at the health facilities (HFs).
- Monitoring visits at the HFs, to check the normal course of the study and take the new data
- First data quality control



Sending data to ISS for further quality control

- Resolution of possible queries from ISS

In the next three years, RMs will also be in close contact with the Tigray Health Research Institute, a regional Institution that will produce additional laboratory data for the study.

B. Training activities (addressed to Research Monitors)

Specific training on management and control of epidemiological data will be addressed to RMs, in international settings (usually in Italy). The courses will be aimed at improving RMs management skills. They will be held only once a year and will have a short duration (less than two weeks).



CASA PROJECT
BUDGET PLAN 15 February 2019 – 14 February 2020
MEKELLE UNIVERSITY

Tab. 1

MU Members (Top-up)	One month/EURO	12 months/EURO
Health Informatics support (Teshome Abegaz)	390,00	4.680,00
Data Manager (Micheal Berhe)	220,00	2.640,00
ART Nurse	220,00	2.640,00
Subtotal	830,00 EURO	9.960,00 EURO

Tab. 2

Monitor visits expenses	Days in a month/EURO	Days in a year/EURO
Abroad monitor visit: <i>Alamata Health Center</i> <i>Alamata Hospital</i> <i>Mehoni Health Center</i> <i>Machew Hospital</i>	5 days in a month (22,00 euro: per diem in a month)	60 days in a year (2.640,00 euro: per diem in a year for 2 people)
Subtotal	110,00 EURO	2.640,00 EURO

Tab. 3

Training expenses Expenditure reserved for training abroad	12 months/EURO
To get VISA: Flight Mekelle-Addis Abeba-Mekelle, Food and accommodation in Addis Abeba; Insurance	800,00 (1 person)
Per diem for a week (general expenses)	210,00 (1 person)
Subtotal	1.010,00 EURO
Subtotal (2 people)	2.020,00 EURO

Tab. 4

Project extra- expenses	12 months/EURO
Expenditure reserved for emergency visits or other purchases/activities	700,00
Subtotal	700,00 EURO

Tab. 5

Financial and Administrative costs	12 months/EURO
Overhead: Mekelle University College of Health Sciences Ayder Referral Hospital for financial and Administrative cost	15.320 x 10%= 1.350,00
Subtotal	1.350,00 EURO

TOTAL BUDGET FOR 12 MONTHS: 16.670,00 EURO