PROJECT "IMPROVEMENT OF RETENTION IN CARE OF PEOPLE WITH HIV NECTION 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 **Tigray Health Bureau** hereinafter referred to as "Bureau", established in Mekelle, Tigray, Ethiopia – T Number 0001451962 –represented by its legal representative, Mr. Hagos Godefay

### **WHEREAS**

- the ISS and the Tigray Health Bureau, 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 Bureau" 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.

Mr. Hagos Godefay is the scientific coordinator for the "Bureau".

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 171.710,40.

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

- ⇒ First year of the project:
- ⇒ € 61.519,64 after stipulation of the first year agreement
- ⇒ € 21.545,56 at the end of the first year of the project
- ⇒ Second year of the project:
- ⇒ € 62.051,64 after stipulation of this Amendment
- ⇒ € 26.593,56 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 Martoco

MINA.

For Tigray Health Bureau

Legal Representative Mr. Hagos Godefay

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

### DOCUMENT A (15 February 2019 – 14 February 2020)

### Tigray Health Bureau

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

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

- A. Operational research
- B. Involvement of Adherence Supporters
- C. Training activities

### A. Operational research

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 top-up and salaries of the health workers involved in the project:

- 1. Nurses/Health officers
- 2. Data managers
- 3. Local project supervisor
- 4. Local project administrator
- 5. Tigray Health Bureau members
- 6. Tigray Health Research Institute members

Data will be collected by using specific paper forms. **Nurses** [1] will fill-in the paper forms with data produced during the daily clinical practice. Collected data will then be entered into an electronic database by trained **Data-managers** [2].

and, more generally, between the Ethiopian and Italian Institutions involved in the project. A Local project administrator [4] will take care of the administrative aspects of the project, especially by ensuring the correct execution of periodic reports on expenses incurred for the project activities.

Tigray Health Bureau [5], as Ethiopian Institution of reference for the project (having full ownership of data), will guarantee the normal performance of all the planned activities.

Tigray Health Research Institute (THRI) is a regional institution that will join our project in 2018. THRI will be able to provide essential laboratory data not detectable at the other participating HFs. The drafting of a Memorandum of Understanding between THRI and ISS is underway.

### B. Involvement of Adherence Supporters (local associations of HIV patients)

The project aims to improve "retention" of HIV-patients, through a model of care based on the active involvement of Adherence Supporters (AS) in following and supporting patients. The AS will provide practical and psychological backing to patients, also giving basic information on HIV/AIDS and explanations about the importance of retention and adherence to therapy. A close collaboration between AS and HFs healthcare workers will be crucial to improve patients retention. The AS will trace patients through phone calls or directly, going to the patient's home. They will also try to understand the reasons for patients' poor compliance and possibly persuade them to resume their prescribed treatments. For such purpose, the acquisition of good communication skills will be essential for AS to succeed in their tasks. Therefore, specific trainings addressed to AS, giving recommendations on how to approach lost or not compliant patients, have been carried out (from 2013 to 2016) and planned for the next three years. AS will receive adequate financial support for their tasks.

### C. Training activities

The project includes intense training activities addressed to healthcare workers (mostly Nurses) and Adherence Supporters. The topics of the courses are "Communication" and "Clinical Aspects of HIV Infection". The planned training for the next three years will be based on the same topics as in past (Communication and HIV/AIDS), but didactic programs will be more elaborate and complete, suitable to train selected people destined to become teachers.

Basically, the planned 3-year training will be the "second phase" of an educational process began in 2013 and ended in October 2016 with final exams to verify the acquired benefits. Based on results of the exams (officially recognized and certified by THB), the most skilled and motivated learners were selected to be further trained and become trainers (the "train the trainer" approach). In this way, the sustainability of the project is expected to be guaranteed.



# CASA PROJECT BUDGET PLAN 15 February 2019 – 14 February 2020 Tigray Health Bureau

Data manager (salary)	One month/Euro	12 months/Euro	
Data manager Mekelle HC	230,00 Euro	2.760,00 Euro	
Data manager Alamata HC	230,00 Euro	2.760,00 Euro	
Data manager Mohoni HC	230,00 Euro	2.760,00 Euro	
Data manager Mekelle Hospital	230,00 Euro	2.760,00 Euro	
Data manager Alamata Hospital	230,00 Euro	2.760,00 Euro	
Data manager Machew Hospital	230,00 Euro	2.760,00 Euro	
Data manager Ayder Hospital	230,00 Euro	2.760,00 Euro	
Sub Total	1.610,00 Euro	19.320,00 Euro	
11% pension contribution	177,1 Euro	2.125,20	
Sub Total	1.787,1 Euro	21.445,20 Euro	

### Tab. 2

Director (top-up)	One month/Euro	12 months/Euro	
Mehoni Health Center	45,00 Euro	540,00 Euro	
Alamata Health Center	45,00 Euro	540,00 Euro	
Mekelle Health Center	45,00 Euro	540,00 Euro	
Alamata Hospital	45,00 Euro	540,00 Euro	
Mekelle Hospital	45,00 Euro	540,00 Euro	
Machew Hospital	45,00 Euro	540,00 Euro	
Sub Total	270, 00 Euro	3.240,00 Euro	

### Tab. 3

Nurse (top up)	One month/Euro	12 months/Euro
Mekelle HC	220,00 Euro	2.640,00 Euro
Alamata HC	220,00 Euro	2.640,00 Euro
Mohoni HC	220,00 Euro	2.640,00 Euro
Mekelle Hospital	220,00 Euro	2.640,00 Euro
Alamata Hospital	220,00 Euro	2.640,00 Euro
Machew Hospital	220,00 Euro	2.640,00 Euro
Sub Total	1.320,00 Euro	15.840,00 Euro

### Tab. 4

Adherence supporter [(Network of Charitable Societies of HIV Positives in Tigray TNEP+)] monetary contribution	N. of employees	One month/ Euro	12 months/Euro
Mekelle HC	2	30,00 x 2 (60,00)	720,00
Alamata HC	2	30,00 x 2 (60,00)	720,00
Mohoni HC	2	30,00 x 2 (60,00)	720,00
Mekelle Hospital	2	30,00 x 2 (60,00)	720,00
Alamata Hospital	2	30,00 x 2 (60,00)	720,00
Maichew Hospital	2	30,00 x 2 (60,00)	720,00
Ayder Hospital	2	30,00 x 2 (60,00)	720,00
District health focal person	4	30,00 x 4 (120,00)	1.440,00
Regional health bureau focal person	1	50,00	600,00
Sub Total		500,00 Euro	7.080,00 Euro

### Tab. 5

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Local Supervisor (salary)	One month/Euro	12 months/Euro	illa i
Atakilt Halifom	1.300,00 Euro	15.600,00 Euro	
11% pension contribution	143,00 Euro	1.716,00	
Sub Total	1.443,00 Euro	17.316,00 Euro	

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Financial administrator (salary) (CASA-project)	One month/Euro	12 months/Euro
Financial member	500,00 Euro	6.000,00
11% pension contribution	55,00 Euro	660,00
Sub Total	555,00 Euro	6.660,00 Euro

Special training	Days/Year /Cost per day	Training / Euro
Special training for CASA nurses	8 days per year / 22 EURO per day	
4 days/2 times a year	(20 persons)	3.520,00
Sub Total		3.520,00 Euro
Tab. 8		
Special training	Days/Year /Cost per day	Training / Euro
Special training for CASA Adherence supporter 3 days/2 times a year	6 days per year / 22 EURO per day (14 persons)	1.848,00
Sub Total		1.848,00 Euro
Tab. 9		
Plenary session	Days/Year /Cost per day	Training / Euro
Plenary session CASA members 3 days/2 times a year	6 days per year / 22 EURO per day (4 person per 7 HF)	3.696,00
Sub Total		3.696,00 Euro

THB operating expenses	Euro
THB operating expenses for 12 months	3.500,00 Euro
Şub Total	3.500,00 Euro

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Training expenses Expenditure reserved for fraining in Italy	12 months/EURO	
To get VISA: Flight Mekelle-Addis Abeba-Mekelle, Food and accommodation in Addis Abeba; Insurance	800,00 (1 person)	
Food for a week	490,00 (1 person)	
Per diem for a week (general expenses)	210,00(1 person)	
Subtotal	1.500,00 EURO	
Subtotal (3 people)	4.500,00 EURO	

TOTAL BUDGET FOR 12 MONTHS: 88645,20 EURO