PROJECT "COMORBITIES IN ADULT HIV-INFECTED PATIENTS ON ANTIRETROVIRAL THERAPY IN TIGRAY, ETHIOPIA, WITHIN CO-CASA STUDY: A PROSPECTIVE OBSERVATIONAL COHORT STUDY"

AGREEMENT
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

- Within the context of the "Comorbidities in adult Hiv-Infected patients on antiretroviral therapy in Tigray, Ethiopia within Co-Casa Study: a prospective observational cohort study (Co-Casa), the scientific coordinator to realize objectives has proposed to underwrite an agreement with Tigray Health Bureau
- This agreement establishes and defines the collaboration between ISS and Tigray Health Bureau as established by the technical annex (document A) which has to be considered as integral part of the current agreement,

THE FOLLOWING IS AGREED AND STIPULATED

Article 1
(Preamble)

The above preliminary remarks are an integral part of the present agreement.
Article 2
( Objectives )

The present agreement regulates the collaboration between ISS and University for the realization of activities of the research line called CO-CASA project.
Dr. Stefano Vella 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) which has to be considered as integral part of the current agreement.

Article 3
(Direction and coordination)

1. The parties may agree to variations in the activities that may become necessary for the optimal achievement of the objectives. The aforementioned variations cannot affect or modify in any way the amount mentioned in article 4.
2. The ISS may at any time undertake verifications with the aim of ascertaining the state of advancement of the Institution's activities and their connection to carrying out the pre-established objectives.
3. The Bureau, in the person of the scientific coordinator, will deliver to ISS, at the end date of this agreement, a final report on the activities undertaken during the entire length of the research line and a financial report, accompanied by supporting documentation, signed by the legal representative.

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

The maximum contribution that the ISS will fully recognize to finance the activities of this agreement is fixed for the duration of this Act for Euro 7,388,40.
- The above contribution will be paid after receiving the relevant invoice after the stipulation of this agreement
- 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 Bureau 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.)

**Article 5**

_(Ownership of the scientific results)_

1. All scientific results developed under this Agreement shall be owned by ISS.

2. The Bureau can publish, present, or use any results arising out of this Study for their own instructional, research, or publication objectives, provided that such publication does not disclose any of ISS’s Proprietary Information.

**Article 6**

_(Unilateral withdrawal)_

1. This agreement may be terminated by ISS or the Bureau upon at least sixty (60) days prior written notice to the other party that references a material breach of any of the terms and conditions of
this Agreement, which breach the other party fails to cure within sixty (60) days from notice thereof.

2. If the Bureau do not realize the activities mentioned in the document A or do not present the scientific and financial report with all the documentation relative to the expenses effectively incurred, or any other financial documentation requested by the ISS must refund the ISS of the total amount of € 7,388,40

Article 7
(Length of the agreement)

1. 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 by signature of both parties until 30th September 2017.

Article 8
(Disputes)

1. The parties shall attempt to resolve all disputes through informal means. This may include mediation, arbitration, or any other procedures upon which the parties agree. Each party agrees that, prior to resorting to litigation to resolve any dispute, it will confer with the other party to determine whether other procedures that are less expensive or less time consuming can be adopted to resolve the dispute, which may include the following. Any and all divergences in the interpretation or the execution of this agreement, if not resolved by the parties will be devolved to the judgment of a board of arbitration composed of three members chosen, one by each party, and the third, who will act as board president, nominated by common agreement by the two arbitrators. The board of arbitration will decide without formalities and arbitration itself will take place at ISS

Article 9
(Use of other parties’ names)

1. Neither ISS nor the Bureau shall use directly or by implication the names of the other party, nor any of the other party’s affiliates or contractors, nor any abbreviations thereof, or of any staff member,
faculty member, student, or employee of the other party in connection with any products, publicity, promotion, financing, advertising, or other public disclosure without the prior written permission of the other party.

For Istituto Superiore di Sanità

Financial Manager
Dott.ssa Rosa Maria Martoccia

For Tigray Health Bureau

Legal Representative
Mr. Hagos Godefay