



UNIVERSITY OF PRISHTINA
HASAN PRISHTINA
MEDICAL FACULTY

Swiss TPH



MEMORANDUM OF UNDERSTANDING

between

Swiss Tropical and Public Health Institute

Socinstr. 57

CH-4002 Basel

Switzerland

(hereinafter referred to as "Swiss TPH")

and

University of Prishtina "Hasan Prishtina", Medical Faculty

Str. Bulevardi i Dëshmorëve p.n.

10 000 Prishtinë

Republic of Kosovo

(hereinafter referred to as "UP")

and

National Institute of Public Health of Kosovo

Str. Nëna Terezë p.n., Rrethi i Spitalit

10 000 Prishtinë

Republic of Kosovo

(hereinafter referred to as "NIPH")



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WHEREAS, the parties to this MoU are also hereinafter collectively referred to as "Parties" or individually as a "Party";

WHEREAS, Swiss TPH is carrying out scientific research concerning public health and UP is carrying out scientific research concerning medical research and public health and NIPH is carrying out scientific research concerning public health, respectively;

WHEREAS, the Parties recognise the importance of closer collaboration in common fields of non-communicable diseases as well as their respective etiological and prognostic risk factors related to lifestyle as well as physical and social environment and therefore, desire to expand scholarly ties and facilitate academic and institutional collaboration;

NOW THEREFORE, the Parties hereby agree as follows:

1. Objectives

Collaboration between the Parties shall be directed toward finding solutions to mutually agreed problems and to exchanging information developed during the resolution of these problems. This collaboration may include exchange of experiences and results of theoretical, experimental and development projects. Collaboration between the Parties shall be on the basis of mutual benefit, equating and reciprocity.

2. Scope of Collaboration

The Parties shall collaborate in common fields of epidemiology, public health, mental health, health system research, mutual learning and training. The scope of collaboration may include the areas described in ANNEX 1 hereto.

Other collaboration items can be added upon mutual agreement between the Parties.

3. Forms of Collaboration

Collaboration shall cover the following forms:

- Exchange of information;
- Participation of experts in research and development, performing at the facilities of the Parties; and
- Organisation of technical meetings, symposia and/or training courses.
- Supervision of PhD students
- Faculty and staff exchange
- Joint development of grants and conduct of projects



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4. Specific Collaboration

The execution of any specific collaboration decided upon by the Parties shall be subject to a separate written agreement. Each separate agreement shall contain all major details of the execution of the collaboration. These shall include provisions regarding:

- Financial provisions;
- ~~Delegation/exchange of staff;~~
- Warranty and liability;
- User rights of patentable and non-patentable results of work;
- Confidentiality and use of information;
- Publication rights.

A Board of Collaboration shall take decisions on specific collaborations including the exchange of students and their selection. The board shall consist of two representatives of Swiss TPH two representatives from the UP and two representatives from NIPH. Decisions are taken unanimously. The respective institutions nominate the board members.

The ethical approval process for any joint studies will be facilitated by the members of the Board of Collaboration whereas Swiss TPH facilitates the process at the level of the respective Swiss ethics commission (EKNZ – Ethikkommission Nordwest- und Zentralschweiz) and the UP facilitates the process for Kosovo.

Parties.

5. Costs

Except when otherwise specifically agreed in writing, all costs resulting from cooperation shall be borne by the Party that incurs them. In particular, whenever a delegation / exchange of staff is contemplated under this MoU, the sending Party shall be responsible for the salaries, insurance, benefits, travel expenses, and allowances to be paid to its personnel.

6. General Provisions

The provisions of this MoU shall be applied in accordance with the laws and regulations in force in each country.

This MoU shall enter into force upon signature of both Parties and shall be effective until April 2025. This MoU may be extended by prior written agreement between the Parties.

Either Party may, at any time, terminate this MoU by giving the other Parties a 6 (six) months' notice in writing. In the event of termination or expiration, obligations and commitments already agreed upon shall be honoured and continued by the Parties until full completion.



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Either Party may, at any time, terminate this MoU by giving the other Parties a 6 (six) months' notice in writing. In the event of termination or expiration, obligations and commitments already agreed upon shall be honoured and continued by the Parties until full completion.

This MoU may be amended and supplemented upon mutual written agreement. Any mutually agreed annex to this MoU or removal of it will form part of the agreement and does not limit the validity of this MoU.

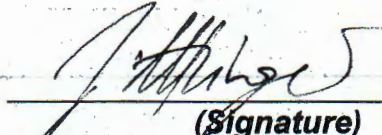
This MoU shall be construed under the laws of Switzerland; the venue for all Parties shall be Basel.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in two originals by their duly authorised representatives.

For Swiss TPH

Date: 3/12/2019

By: Prof. Dr. Jürg Utzinger/
Director


(Signature)

Date: 3/12/2019

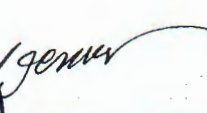
By: Prof. Dr. Nicole Probst-Hensch/
Head Department of Epidemiology & Public Health


(Signature)

For University of Prishtina "Hasan Prishtina", Medical Faculty

Date: _____

By: Prof. Dr. Marjan Dema/
Rector of the University of Prishtina



(Signature)



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Date: _____

By: Prof. Dr. Suzana Manxhuka-Kërliu/
Dean of Medical Faculty, University of Pristina

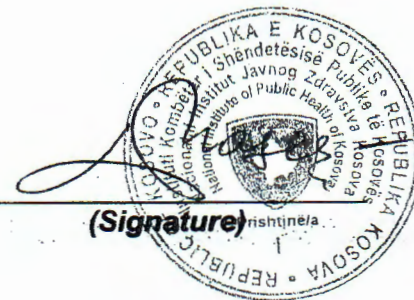
(Signature)

For National Institute of Public Health of Kosovo

Date: _____

By: Prof. Dr. Naser Ramadani/
Director of NIPH

(Signature)



Date: _____

By: Prof. Ass. Dr. Naim Jerliu/
Medical Director, NIPH

(Signature)

(Signature)



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Annex 1: Possible Areas for collaboration covered by this MoU

1. Interdisciplinary public and global health research
 - a. Surveys and cohort studies
 - b. Diabetes
 - c. Cardiovascular diseases
 - d. Health system research
 - e. Non-communicable disease risks (e.g. obesity, physical activity,
 - f. ~~Data management and biostatistics~~ smoking)
 - f. Health behaviours
 - g. Respiratory health
 - h. Environmental epidemiology and exposome research
 - i. Mental health
2. Training and capacity building
 - a. Supervision of PhD students
 - b. Student and faculty exchange
 - c. Facilitating research and field work activities
 - d. Platform for development of joint faculty and student research projects
 - e. Data capture technologies for research and clinical applications
 - f. Data management and biostatistics
3. Joint research grant applications
4. Additional areas to be identified as opportunities of mutual interest arise



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Annex 2: ToR of Collaboration Board

TERMS OF REFERENCE

Board of Collaboration

related to the scientific collaboration between the University of Pristina, the National Institute of Public Health and Swiss TPH

Preamble: The scientific collaboration between the University of Pristina, the National Public Health Institute of the Republic of Kosovo and the Swiss Tropical and Public Health Institute is guided by an MoU, which describes the relationship between the aforementioned Institutions. Specific collaboration projects are overseen by the Board of Collaboration foreseen in the MoU.

Purpose: The Board of Collaboration acts as a forum to routinely exchange about, plan, and decide on current and future scientific activities and projects including cohorts, implemented and evaluated under the MoU between the three organizations. It promotes and supports academic collaboration. It facilitates the identification, conceptualization, ethical clearance, management and exchange about ongoing and new joint research projects. It promotes the exchange of students and decides on their selection. It nominates scientific advisors for studies involving PhD and master students. It ensures ownership of individual research projects including cohorts and promotes and guarantees the accessibility to research data and the active research conduct for Kosovo citizens and members of the signatories of the MoU. It enforces the adherence to international publication guidelines.

The respective institutions nominate the board members. All board members act transparently and on an informed basis, in good faith, with due diligence and care. They also serve as spokespersons and representatives and communicate the views of their organisations to the Board and make decisions in the best interest of the MoU and the collaboration.

Procedures: The operation procedures and project specific procedures are approved by the Board and can be amended from time to time to best suit the MoU. In case of conflict the original regulations stipulated by the MoU apply.

Composition and meeting frequency: The Board of Collaboration shall consist of two representatives from the UP, two representatives of Swiss TPH and two representatives from NIPH. The respective institutions nominate the board members. Decisions are taken unanimously. Board members are the original signatories of the MoU. Institutions may delegate Board membership to other representatives of the



Institutions on a permanent and temporary basis. The Board appoints a chairperson and a secretariat to protocol meetings in order to guarantee transparency of its work. The Board can invite external experts to its meetings but without voting right. Representatives of specific projects are automatically represented in Board meetings without voting right if the Board meeting is dealing with a specific project.

In order to take time sensitive decisions the Board operates face to face meetings, virtual meetings by video or audio calls through zoom, Skype or are any other appropriate platform or by circular e-mails. Face to face meetings happen once annually. Guarantee accessibility of research data to the signatories of the MoU.

Roles and Responsibilities: The Board of Collaboration acts as sounding board for the three member institutions of the MoU. The following roles and responsibilities are subject to regular adaptations depending on the needs of the specific collaborations:

- Promote, support, and decide on academic collaboration and facilitate regular scientific exchanges between the MoU signatories and the identification, conceptualization, ethical clearance, management and exchange about ongoing and new joint research projects;
- Take decisions on specific collaborations including the exchange of students and their selection as well as supervision, taking specific University and funding regulations into consideration;
- Ensure anchorage of research projects involving Kosovo citizens such as cohorts, cross sectional studies, qualitative surveys within Kosovo institutions;
- Ensure alignment of research projects with policy needs and priorities in Kosovo;
- Guarantee accessibility of research data to the signatories of the MoU;
- Enforce the adherence to international publication guidelines.

Conflict of Interest: It is recognized that Board members may have conflicts of interest, resulting from different research activities, grant applications, funding mechanisms that are not part of the MoU. When preparing decisions board members must declare when they are in a conflict of interest situation leading to an exclusion from a specific decision making process.

Key documents:

Meeting agenda

Minutes of meetings

Project specific regulations



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Annex 3: NCD cohort in the framework of the Accessible Quality Health (AQH) project funded by SDC

Collaboration Agreement
between
the implementation of a prospective NCD cohort study within the project
National Institute of Public Health and
Swiss TPH
with regard to the implementation, maintenance and scientific use of
the Kosovo Cohort on Non-Communicable Diseases

Version 05/06/2019

Description of the Kosovo Cohort

The burden of disease in the Balkan region falls heaviest on Kosovo, suggested by a life expectancy well below neighbouring countries. A more detailed picture of the current state of health in Kosovo is not yet available due to limited epidemiological estimates. It is well known however that non-communicable diseases (NCDs) are the greatest contributor to health loss in the world and many health sector stakeholders in Kosovo have focused their efforts on controlling NCDs.

Within the framework of the "Accessible Quality Health" project (AQH), SDC supports the implementation of a prospective NCD cohort study within the project implementation area. It aims at:

- contributing epidemiological evidence for the control of NCDs in Kosovo as the basis for policy and decision making;
- promoting research capacity in the domains of epidemiology and public health in Kosovo;
- providing evidence based information for AQH planning, implementation and evaluation in its successive phases;
- strengthening NCD research capacity in Kosovo partner institutions.

The implementation of the prospective longitudinal study started in March 2019 in 12 Main Family Medicine Centres in Kosovo. Consecutive patients exiting these health facilities are being approached for study participation. The targeted sample size is 1000 participants. Consenting participants aged 40 years and over will undergo an in-person interview conducted by a research nurse followed by a health examination (blood pressure, height, weight, waist/hip/neck circumferences, peak expiratory flow and HbA1c measurements). Participants are followed-up every 6 months, alternating between a telephone interview and an in-person interview with a health examination. Future follow-up assessments of the study participants harbour the potential for broadening the focus of the cohort to include additional risk factors and diseases and for embedding a biobank. Appropriate statistical techniques will be applied in exploring



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the longitudinal relationship between NCDs and their etiological and prognostic determinants.

The cohort will contribute to the limited existing literature on the non-communicable diseases in Kosovo. The study will also bring to light the health needs of the people of Kosovo and thus provide evidence for health sector decision makers to improve service responsiveness.

It will inform AHQ project design and management decisions as well as provide evidence for the efficiency of project interventions, thus strengthen its capacity to support Kosovo PHC managers and policy makers. Cohort data also contribute to the regular half yearly reporting cycles of Swiss TPH to SDC.

It will offer ample opportunity to promote academic careers in the domains of epidemiology and public health. It will increase research capacity at the level of Kosovo institutions and will strengthen international research collaborations and thereby has the potential to attract research funds to the country.

Funding of the Kosovo Cohort

SDC provides funding for the operation of the Kosovo Cohort. The SDC funds are supplemented by Swiss TPH institutional funds for the hiring of the first Swiss TPH PhD student. The salary of the first Kosovo PhD students is funded by a Swiss ESKAS Fellowship. Scientific activities and research projects can provide additional funds in the future (see below). Funding statements in scientific publications must inform about the funding background of the cohort.

Governance of the Kosovo Cohort

Focus, content, and protocols for follow-up assessments of the Kosovo Cohort are approved by the Board of Collaboration.

Coordination of the Kosovo Cohort

The overall coordination of cohort activities is the joint responsibility of the National Institute of Public Health/University of Prishtina (Prof. Dr. Naim Jerliu) and Swiss TPH (Prof. Dr. Nicole Probst-Hensch). These coordinators represent the study team of the Kosovo Cohort in the Board of Collaboration.

The coordination of scientific cohort activities is the responsibility the scientific governing board consisting of the National Institute of Public Health/University of Prishtina (Prof. Dr. Naser Ramadani), and Swiss TPH (Prof. Dr. Nicole Probst-Hensch; Dr. Manfred Zahorka).



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- D. Stevenson

The administrative implementation and coordination of cohort activities is the joint responsibility of the AQH Team in Kosovo (Dr. Q. Ramadani) and in Switzerland (Dr. J. Gerold).

Study Team of the Kosovo Cohort

The Kosovo Cohort was designed and implemented by a study team consisting of members of the AQH Team, the University of Prishtina, the National Public Health Institute and Swiss TPH. These team members are responsible for the development of the study protocol, for its operational implementation in accordance with ethical, legal, quality and scientific standards, and for its scientific output. The expandable Study Team currently consists of:

AQH Team Members:

- D. Stevenson
- Dr. Q. Ramadani
- A. Bytyci
- Medical Directors of the Family Centres in the 12 municipalities participating in the cohort
- Study Nurses (specifically hired for the Kosovo Cohort)

National Institute of Public Health:

- Prof. Dr. N. Ramadani
- Prof. Dr. N. Jerliu

University Clinical Centre of Kosovo (UCCK):

- Dr. S. Statovci
-

Swiss TPH:

- Prof. Dr. Nicole Probst-Hensch
- Dr. M. Zahorka
- Dr. J. Gerold
- K. Obas

The study team must be acknowledged in scientific publications derived from the Kosovo Cohort.

Data and biological material obtained on cohort participants

The instruments obtained for the conduct of the Kosovo cohort remain the property of the cohort for future follow-up assessments.

The data and future biological material obtained on cohort participants remain the property of the Kosovo cohort. If the MoU between the Kosovo institutions and Swiss

Prof. Dr. N. Probst-Hensch. The two supervisors are responsible that the databases



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TPH which forms the basis for this collaboration is cancelled, the Kosovo cohort becomes the property of the Kosovo institutions. Swiss TPH remains represented in the Scientific Governing Board of the Kosovo cohort and maintain its principle right to access data and biological material obtained on participants.

The pseudonymized and de-identified research database will be mirrored and implemented at both, the National Institute of Public Health/University of Prishtina under the supervision of Prof. Dr. N. Jerliu and Swiss TPH under the supervision of Prof. Dr. N. Probst-Hensch. The two supervisors are responsible that the databases meet the legal, ethical and technical requirements of both partner countries.

Biobanking could be an additional component of the cohort in the future. In this case, the pseudonymized biological material will be stored in the biobanks of the National Institute of Public Health under the supervision of Prof. Dr. N. Jerliu and of Swiss TPH under the supervision of Prof. N. Probst-Hensch. Biological sample aliquots from the same study participants will be distributed equally across the two biobanks to prevent sample loss due to incidental thawing. The two supervisors are responsible that the biobanks meet the legal, ethical and technical requirements of both partner countries. Identifying data (names; exact birthdates; addresses) and ID keys linking research data or biological samples to the identifying data will be stored at the AQH study center and only be accessible to researchers in the case of a follow-up examination and future participant contacts or in other ethically justified and approved cases.

All members of the study team and the involved institutions have the right to request data and biological material in the context of scientific projects.

The use of data and future biological material for scientific purposes (publications; grant applications) needs to be approved by the scientific governing board based on an application which details:

- Research objective
- Data or biological material needed
- Junior and senior author; Principle and Co-Investigators
- Funds available/sought for the conduct of the work

The board of collaboration is responsible that a project is respecting ethical and legal requirements. Data and biological material for approved applications is provided to the scientists by the institution in the country which leads the project (University of Prishtina in the case of Kosovo-lead projects; Swiss TPH in the case of Swiss-lead projects). Data and biological material provided to external research groups are accompanied by Data Transfer Agreements and Material Transfer Agreements respectively.

Novel information derived on cohort participants in the context of a scientific project has to be integrated into the Kosovo cohort database.