MEMORANDUM OF UNDERSTANDING
FOR EDUCATIONAL AND SCIENTIFIC COOPERATION

Between

the Istituto Superiore di Sanità of the Italian Republic
and
the National Center for Disease Control and Public Health of Georgia

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The **Istituto Superiore di Sanità of the Italian Republic** and the **National Center for Disease Control and Public Health-of Georgia** (hereinafter referred to as "Parties"),

guided by the willingness to develop, within the areas of their own competences, a fruitful cooperation in the areas of public health and research,

HAVE entered into the following Memorandum of Understanding:

ARTICLE 1

The Parties will encourage cooperation in the areas of public health and research, on the basis of equality, gender parity, reciprocity and mutual benefit.

The Parties will cooperate, in particular, in the following areas of common interest:

1. Bilateral exchange of staff of the Istituto Superiore di Sanità (ISS) and the National Center for Disease Control and Public Health (NCDC) for study visits, research, trainings, technical assistance, lecturing, including the possible provision of sabbatical terms (if/where applicable) in the following areas: health promotion, immunization, non-communicable diseases (NCDs), disease prevention and control, registries of diseases (such as cancer, diabetes mellitus, acute cardiovascular diseases, acute cerebro-vascular diseases, illicit drug abuse, children with disabilities, injuries, hepatitis etc.), environmental health, health statistics, health system strengthening, including strengthening of public health laboratory network, nutrition/eating disorders, water and food safety, rare diseases, autism spectrum disease, and others as included by the Parties;

2. Research in the field of public health, covering but not limited to: NCDs and their risk factors, evaluation and improvement of early detection of emerging infections and improvement of the surveillance system, evaluation of vaccines' impact, antimicrobial resistance, health impact assessment of the environmental factors, maternal and Child health, mental health, big data for surveillance and modelling, identification of biomarkers and risk factors to support clinical evaluation, clinical and preclinical studies to set the ground for early detection of diseases and public health threats, assessment of laboratory capacities, protection of population health from climate change, etc.;

3. Design and development of projects, covering different areas of the health system, development of training activities on health care management and application of pedagogical tools (such as evaluation tools, educational guides, management systems, etc.) in collaboration with selected Universities for the delivery of credited training programs in the public health sector, with special emphasis on the development and management of EU funded projects (e.g. Horizon 2020);

4. Exchange of scientific data, including but not limited to exchange of training materials, research publications, case studies and online training modules.

ARTICLE 2

The Parties will use their best endeavours to promote:

- Exchange of relevant information and documentation in the fields of common interest;
- Supervised exchange of specialists for the purpose of studies and consultations, as specified in the Action Plans of Cooperation referred to in article 4 of this Memorandum of Understanding;
- Direct contacts between them;
- Other possible forms of cooperation in the field of public health e. g. twinning projects and technical assistance calls promoted by the European Union.

ARTICLE 3

The Parties will support the mutual exchange of the most updated and relevant data, literature and audio-visual informative materials in the field of Public Health.

ARTICLE 4

To implement this Memorandum of Understanding, the Parties will adopt Action Plans of cooperation describing the activities to be carried out.

ARTICLE 5

The activities foreseen under this Memorandum of Understanding will be implemented by the Parties according to their ordinary budget availability without any additional cost for the State budgets of the Italian Republic and Georgia.

ARTICLE 6

ISS will appoint for the coordination of the activities envisaged in this MoU Professor Luca Rosi, Director of the International Affairs Unit. NCDC will appoint for the coordination of the activities envisaged in this MoU Dr. Nana Kavtaradze, Head of the International Relations Division.

ARTICLE 7

The Parties will establish a Joint Commission which will include up to three representatives of each Party, excluding the chief executives, and will be coordinated by a scientific coordinator for each Party. The Joint Commission will meet on a regular basis and not less than once a year and will be independently able to consult with specific experts on topics of mutual interest.

ARTICLE 8

1. The implementation of this Memorandum of Understanding and all activities undertaken will be subjected to the respective rules and regulations of each Party.

2. The Parties will cooperate on the basis of equality, mutual benefit, results sharing and protection of intellectual property rights in conformity with applicable international law, the Italian and Georgian legislations, as well as the obligations arising from Italy's membership of the European Union.

3. All the information relayed by the Parties under this Memorandum of Understanding will be considered as strictly confidential and will not be disclosed to third parties without the prior written consent of both Parties.

ARTICLE 9

1. The present Memorandum of Understanding takes effect on the date of signature;

2. The Memorandum of Understanding will remain valid for a period of 5 (five) years, and will be automatically renewed for additional periods of 5 (five) years unless terminated by either Party giving at least a six-month written prior notice to the other Party of its intention to terminate this Memorandum of Understanding.

ARTICLE 10

The provisions of this Memorandum of Understanding may be amended in writing by mutual consent of the Parties.

Any difference in the interpretation and/or implementation of this Memorandum of Understanding will be solved amicably by means of direct consultations and negotiations between the Parties.

Done at Tbilisi on 16th of July 2018 in two originals, in the English language.

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FOR THE ISTITUTO SUPERIORE DI SANITA'

Name: Luca Rosi

Title: Head of International Affairs

Signature _____

FOR THE NATIONAL CENTER FOR DISEASE CONTROL AND PUBLIC HEALTH

Name: Amiran Gamkrelidze

Title: Director General

Signature _____

ANNEX of the

MEMORANDUM OF UNDERSTANDING FOR EDUCATIONAL AND SCIENTIFIC COOPERATION

BETWEEN

ISTITUTO SUPERIORE DI SANITÀ, ITALY

AND

NATIONAL CENTRE FOR DISEASE CONTROL AND PUBLIC HEALTH, GEORGIA

Action Plan: Evaluation of the lead exposure in the Georgian children.

Background

Lead is one of the most dangerous toxicants with devastating long-term effects on public health, environment, and, then, on economic and social development. According to the Institute for Health Metrics and Evaluation estimates based on 2015 data, lead exposure accounts up to half a million deaths, loss of 9.3 million disability-adjusted life years (the highest burden in low and middle-income countries); 12.4% of the global burden of idiopathic developmental intellectual disability, 2.5% of ischemic heart disease and 2.4% of stroke.

Safe Blood Lead Levels (BLLs) cannot be identified in children. Children with high BLLs (≥700 µg/L) display severe neurologic problems, including seizures, comas, and death. Behavioral and cognitive disorders as well as non-reversible neurologic damages are associated with BLLs lower than 50 µg/L. The current US Reference Value of 50 µg/L (based on the 97.5th percentile of the National Health and Nutritional Examination Survey, NHANES) is used by clinical and public health care providers to identify children with elevated BLLs.

Children aged <5 years are at increased risk because their bodies are growing rapidly and they tend to put their hands or other objects, which might be contaminated with lead dust, into their mouths.

- Indicative Evidence of Lead Contamination in Georgia

In recent years, reports of lead poisoning/contamination have dramatically increased in Georgia. In response, Georgia's National Center for Disease Control (NCDC) and the US CDC office in Tbilisi conducted a small sample lead survey in November-December 2015. They identified Iashvili Children's Hospital in Tbilisi and tested 254 children 2-5 years of age, with the following serious

results: i), **33%** of children having BLLs ≥ **50** µg/L; ii), **9.5%** ≥ **100** µg/L; iii), **2.8%** ≥ **20** µg/L andiv), **0.4%** ≥ **45**µg/L. In total, **over 45%** of participants had high or especially high blood lead levels (BLL).

In March 2018, paints and toys were tested in randomly selected schools and kindergartens in Tbilisi and neighboring city of Rustavi, even recently constructed school/kindergarten classrooms appeared to be colored with lead paint, while the toys used for kids to play contained excessive levels of lead. The Georgia's Health Minister's February 2018 address to the country's Parliament further corroborates this.

Tbilisi State University conducted two studies in 2014 and 2017 in Southern part of Georgia (Bolnisi and Dmanisi) showing that already high contamination of soil by lead, mercury and cadmium increased several times in 2017 compared with 2014. Research on water and air quality conducted in the same area indicated that both water and the air are contaminated, with lead concentration in the air 10 times in excess of acceptable threshold prescribed by Georgia's environmental regulations.

The Public Defender (Ombudsman) of Georgia in its 2017 Annual Report on Human Rights presented to the Parliament described the instances of lead poisoning/contamination in Georgia as a dramatic problem for the country and qualified it as a serious impediment to effective realization of right to life, health and development of a child. The Public Defender highlighted the need of a nationally representative lead study as a basis to design and enforce effective measures against lead.

- Georgian Government Request to *UNICEF* on Lead Survey

In December 2017, Georgian NCDC on behalf of Georgian government sent an official letter to the UNICEF requesting to include a nationally representative lead prevalence survey into the Multiple Indicator Cluster Survey (MICS), fieldwork of which is planned to be conducted by UNICEF and the National Statistics Office (GeoStat) in September-December 2018. The MICS is one of the largest household surveys globally generating 188 indicators (including 48% of household related SDG indicators) related to environment (e.g. water quality or energy use); child health, nutrition, development and education; maternal health; etc.

Including lead testing in the MICS has two advantages: i), it can help reduce costs of conducting a separate lead survey by making use of transportation, training venue or vast communication resources of MICS; ii), the cross-sectional analyses of lead results with the comprehensive MICS data will make the lead testing more informative and thus more useful to inform policy.

- Georgian NCDC Request to ISS on technical support for lead survey

During the implementation of the EU-Twinning Project GENVHE ('Institutional strengthening of Environmental Health System in Georgia') the Georgian NCDC asks experts of ISS (partner of

GENVHE) to contribute to lead survey giving technical support for a lead biomonitoring campaign and evaluation of the results on a cohort of Georgian children.

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To implement the Memorandum of Understanding (article 4), the ISS and Georgian NCDC will adopt the present action plan of cooperation for evaluating the children exposure to environmental contaminants, lead in particular, and agree to join the Working Group formed in response to the NCDC's requests.

Participants at the Working Group:

1) *UNICEF Georgia*
2) *Georgia NCDC*
3) *WHO (European Centre for Environment and Health)*
4) *ISS*
5) *GeoStat*
6) *Georgian Ministry of Health*

To realize a participative and more efficient approach also Local Stakeholders will be involved. The Working Group is tasked to decide on the methodology, develop protection protocols, and deal with other matters related to planning, implementation, ethics and quality assurance of the lead survey.

Objective

Conducting the lead survey will have the following main objective: to know the prevalence of lead exposure in children and the possible location of the environmental contamination.

Implications

i), provide evidence for costly environmental health measures to regulate lead (and other heavy metals) content in paint, in other products/materials and the environment;

ii), support the adoption of risk based medical protocols and guidelines;

iii), as it is the first time that lead testing will be conducted together with MICS study, the realization of a successful precedent will allow other countries to replicate it in their MICS. This is especially important as lead remains a serious concern in many low and middle-income countries globally.

Sustainable Development Goals (SDG)

The lead testing will contribute achieving the Sustainable Development Goals, especially SDG Target 3.9 related to *reduction in number of deaths and illnesses from hazardous chemicals*; and Target 12.4, *achieving an environmentally sound management of chemicals/waste to minimize their adverse impacts on human health and the environment*.

Target Population and Sample

The lead survey will focus on children 2-10 years of age as a target population. The survey participants will be selected from over 14,100 households sampled for MICS. The expected net sample size of the lead survey will be 1,500 children (considering anticipated sizable nonresponse rate), which is sufficient for nationally representative results.

Blood Collection

The lead survey will involve taking venous blood from survey participants, administered by NCDC phlebotomists who have prior experience of venous blood collection in households. These phlebotomists will additionally undergo special training in standard operating procedures of the survey related to blood collection, storage; communication with children, parents/caretakers; possible complications and mitigation strategies; ethics.

The phlebotomists will be part of the MICS field teams, in addition to the metal free tubes, needles, heparin, alcohol pads and other material needed for the blood collection, they will be equipped with coolers ensuring that the temperature bellow 4 °C is maintained before depositing them in lab storage facilities at regional centers of NCDC.

The fieldwork will last for three month, twice a month the blood samples will be transported to Tbilisi from NCDC regional centers and shipped to the ISS lab for testing. Blood samples will be labeled with unique codes that would guarantee anonymity but allow the NCDC to identify an individual from whom the sample was collected to communicate test results as well as administer possible treatment if necessary.

Before collecting blood, an informed consent will be obtained by parents/caretakers signing a special consent form containing terms and conditions of the lead testing. Subject to resource availability, lead survey participants might be provided with small gifts e.g. books and toys or in case a child is already of a school age, maybe a low-cost microscope called a foldscope.

Methodology and Lab

Blood samples will be tested using Inductively Coupled Plasma Mass Spectrometry (ICP-MS) which has a lower detection limit of part per quadrillion (10^{-15}) and thus provides extremely precise results. It might be possible to test other heavy metals as well, e.g. mercury, cadmium together with lead. The ISS Lab has the ISO 17025 certificate with excellent HBM inter-laboratory performance test results.

Analysis and Reporting

After the lab test is complete, prevalence, geometric mean and anonymized data will become available to the public. Individual BLLs will be reported to respective households by the NCDC. In-depth cross-sectional analyses of lead testing results with other data that MICS generates will be subject to separate project.

The lead survey results will allow pinpointing locations of possible contamination and thus, making it easier to identify contamination sources during a follow-up research, which also will be subject to a separate project.

Budget

The NCDC and ISS agree to fund the lead survey as follows:

Service	Fee per/item	Unit/Days/Personnel	Fee Total (US$)	Funding Source
Lab and evaluation	$34 per sample	1500 samples	$50,940	**ISS**
Expert Services	$500 per day	15 days	$7,500	**WHO & Twinning**
Shipping of Samples abroad (shipped as 3 installments)	$2	1500 samples	$3,000	**UNICEF**
Phlebotomists	$500 per month	13 phlebotomists (for 3 months)	$19,500	**NCDC**
Blood collection material			$2,000	**UNICEF**
Gifts for children	$4	1500 children	$6,000	**UNICEF**
Blood Storing/Transportation within country			$3,000	**NCDC**
Training Venue	$750	2 days	**$1,500**	**UNICEF**
Training Accommodation	50 per day per person	2 days	**$1,300**	**UNICEF**
Trainers	$100	2 days	**$200**	**UNICEF**
Per Diem	$10	2 days for 13 phlebotomists	**$260**	**UNICEF**
Total			**$95,200**	
Additional UNICEF and ISS support as In-kind contribution (sampling, Person/Months, administration, etc.)			**$120,040**	

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SIGNED IN Tbilisi on 16th July 2018 in two originals, in English language.

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FOR THE ISTITUTO SUPERIORE DI SANITA	**FOR THE NATIONAL CENTRE FOR DISEASE CONTROL AND PUBLIC HEALTH**
Name Luca Rosi	**Name: Amiran Gamkrelidze**
Title Director International Affairs	**Title: Director General**
Signature _____	**Signature** _____