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Letter of Intent

between

The Ministry of Healthcare of Armenia

and

US Army Medical Research Directorate – Georgia (USAMRD-G)

With this Letter of Intent (LOI), the US Army Medical Research Directorate-Georgia (USAMRD-G) offers research cooperation to the Ministry of Healthcare (MOH) of Armenia within the framework of the project entitled: "Hospital-based Surveillance of Selected Zoonotic and Vector-borne Etiologies among Febrile Patients in Armenia" (hereinafter referred to as the Febrile Illness Study). USAMRD-G is the newest overseas laboratory of the Walter Reed Army Institute of Research (WRAIR) and is a tenant embedded in the Lugar Center in Tbilisi, Georgia. USAMRD-G initiated wet laboratory operations in late 2012 and continues to build capabilities for research and surveillance in the region of South Caucasus. US scientists are working at USAMRD-G in support of various research studies. Febrile Illness is one of the research interests of USAMRD-G, and it will be the first collaborative project with Armenian institutions.

In recent years, several studies have reported that endemic and emerging zoonotic infections, such as anthrax, leptospirosis, leishmaniasis, brucellosis, Crimean–Congo hemorrhagic fever, and hantavirus infection are circulating in the South Caucasus region. Despite the growing evidence suggesting that Armenian residents may be exposed to these zoonotic infections, little is known about the probable causes of febrile illness in the country.

The primary objective of this study is to determine the relative frequency of the infectious etiologies for undifferentiated febrile illnesses in Armenia to improve the detection, treatment, prevention, and control of these pathogens.

Secondary objectives are to:
1. Determine the epidemiological risk factors for specific pathogens.
2. Build awareness on the relevant infectious causes of febrile illnesses in Armenia.
3. Provide baseline information for future clinical studies in Armenia.

This project aims to establish an active hospital surveillance system for undifferentiated acute febrile illness syndrome to identify relative frequency of the following pathogens: *Leishmania* spp., *Leptospira* spp., *Rickettsia* spp., *Borellia* spp., *Brucella* spp., *F. tularensis, C. burnetii*, Crimean-Congo Hemorrhagic Fever Virus (CCHFV), Hantavirus, and West Nile Virus (WNV).

In order to obtain a comprehensive understanding of the etiology, clinical outcomes, and epidemiological patterns of hospitalized febrile patients, the study site would be the Nork Hospital – it will be the primary implementer of the study. A second regional clinical site will be added during the 2nd year of surveillance. It is estimated that 600 patients will be enrolled in the study over three years. Screening, enrollment,

sample and data collection and sample testing will take place at the Nork Hospital. Findings from this study provide useful epidemiological and clinical information for relevant public health officials for future planning. In addition, results from this study will provide baseline data for future research in Armenia.

The National Center for Disease Control and Prevention (NCDCP) of Armenia will also be involved in the study, namely, in the data analysis process.

USAMRD-G physician researchers will serve as co-investigators on this study. USAMRD-G will provide assistance in drafting the human use study protocol, on-site support for field implementation, and personnel to perform the function of monitoring to ensure ethical and safety compliance according to applicable Armenian and US regulations. USAMRD-G lab scientists will provide laboratory expertise for the study.

USAMRD-G is funded by Global Emerging Infectious Diseases Surveillance Program (GEIS) to conduct this study. From the study budget, the study site (Nork Hospital) will receive all the supplies (consumables, general laboratory supplies, reagents) for sample collection, processing and testing. At the Nork Hospital, four physicians and three laboratory specialists will be involved in the study. Two epidemiologists will be involved from NCDCP at the data analysis stage. USAMRD-G will provide study initiation training and refresher trainings regarding study-related procedures and ethical conduct of the study.

We anticipate having at least one manuscript published in a peer-reviewed international journal. Armenian investigators involved in the study will be the leading co-authors of the manuscript. All outcomes of this project will be used to develop recommendations for the Ministry of Healthcare. We hope that this will be the first among many other collaborative projects between the Ministry of Healthcare of Armenia, USAMRD-G and WRAIR.

USAMRD-G requires CVs for the MOH personnel involved with this proposed work to evaluate their experience and competence.

An official letter with the responses should be sent to the USAMRD-G no later than 30 April 2017.

Upon approval of the proposed study and provision of the final and complete staffing form by the Ministry of Healthcare of RA (which will be approved by USAMRD-G), USAMRD-G will send a draft Cooperative Research and Development Agreement (CRADA) along with the project's full proposal. Once the CRADA is executed, USAMRD-G will work with the project manager and collaborators to initiate the project. If all parties are in agreement, we expect to start the project in May 2017.

USAMRD-G is looking forward to working with the Ministry of Healthcare of the Republic of Armenia to address this matter of high public health concern.

Sincerely,

Karen Peterson

Karen Peterson, PhD
Chief Science Officer