LETTER OF INTENT

between
The Centers for Disease Control and Prevention
Department of Health and Human Services
United States of America

and
The Department of Animal Health
Ministry of Agriculture and Rural Development
Socialist Republic of Vietnam

regarding
Research of Influenza Viruses and Other Zoonotic Diseases

1. Purpose

This Letter of Intent evidences the intention of the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) to cooperate with the Department of Animal Health (DAH) of the Vietnam Ministry of Agriculture and Rural Development (MARD), in a partnership for research at the animal-human interface (AHI), on influenza viruses including highly pathogenic avian influenza A/H5N1, pandemic influenza A/H1N1 2009, and on other zoonotic diseases of public health and animal health importance in Vietnam.

2. Background

CDC recognizes the mutual fundamental benefits to be gained through research cooperation and in building on the success of partnerships between CDC, the MARD Department of Animal Health, the DAH National Centre for Veterinary Diagnostics (NCVD), the MARD National Institute of Veterinary Research (NIVR), and the National Institute of Hygiene and Epidemiology (NIHE) of the Vietnam Ministry of Health (MOH), in the fields of prevention and control of influenza and other zoonotic diseases. It is therefore desirable that the two agencies further develop this research cooperation to achieve improved health promotion and disease prevention for animals and people of the two countries.

In furtherance of this cooperation, CDC and MARD intend to strengthen the capacity in Vietnam to develop and implement AHI activities related to influenza and other zoonotic diseases. There is a need to better identify and apply new scientific and health knowledge related to gaps in this area, such as variables related to intra- and inter-species transmission, environmental risk factors, co-habitation and geo-spatial risk factors, virus genetic mutations and re-assortment; and to...
provide knowledge and data to support recommendations for better surveillance, response and control efforts of influenza and other zoonotic diseases.

In addition, CDC and MARD envision opportunities to further identify the risk factors for animal and human infection and disease and to evaluate interventions that may offer approaches toward their prevention and control, including new diagnostics, vaccines, pharmaceuticals and non-pharmaceuticals, and other interventions on highly pathogenic avian and human influenza, pandemic influenza, and other zoonotic diseases of animal and public health importance.

3. Activities

CDC activities for this program are expected to

- Provide assistance and technical consultation on aspects of program planning, implementation, monitoring and evaluation, and coordination between projects and activities as needed. This may include:
  - evaluating existing surveillance, epidemiologic, and laboratory systems;
  - providing guidelines and training for disease surveillance, outbreak investigations and epidemiological studies;
  - assisting in the conduct of epidemiological field studies to identify modifiable risk factors, and to define burden of disease in relevant animal and human populations;
  - evaluating prospectively MARD proposals
  - providing material support, technology transfer, and training in laboratory diagnosis and research methodologies;
  - providing assistance in study protocol development, and data management and analysis; and
  - disseminating information by relevant means such as presentation at meetings, preparation of reports, and drafting scientific articles.
- Provide scientific support in the development and periodic review of a research agenda.
- Coordinate and support collaboration between other CDC-supported international and domestic programs where relevant.
- Provide special reagents or other materials to conduct surveillance and research.
- Conduct laboratory tests on specimens and epidemiologic analysis of data collected during outbreaks or studies.
- Assist in the development of research protocols for ethical human and animal review by U.S. Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or independent Vietnam Ethical Review Committee, or as required by all participating institutions. The U.S Government will review and consider approval or update, on at least an annual basis, or defer authority for protocols until research projects are completed, all consistent with appropriate U.S. laws, regulations and policies.

MARD activities for this program are expected to

- Strengthen the capacity to detect influenza viruses and other zoonotic pathogens and related diseases through implementation of surveillance, and development and evaluation of sensitive and specific diagnostic tests.
• Isolate and conduct genomic analyses of influenza viruses and other zoonotic infectious agents, and characterize features such as immunogenicity, pathogenicity, transmissibility, genetic mutations and re-assortment, susceptibility to pharmaceuticals, and preventability by vaccines.
• Investigate outbreaks of influenza and other zoonotic diseases in Vietnam and, as possible, elsewhere in the region as they may threaten the public health of Vietnam.
• Conduct epidemiological studies, including in conjunction with epidemiologic and laboratory training programs when possible, to identify modifiable risk factors such as animal-human co-habitation and geo-spatial variables, intra- and inter-species transmission, and environmental variables, and to define burden of disease in relevant animal populations.
• Develop and evaluate prevention and control strategies, including the evaluation of new vaccines to prevent influenza in animals and other zoonotic infectious diseases.
• Assess and monitor antimicrobial resistance of influenza viruses and other zoonotic infectious disease agents in Vietnam.
• Assure coordinated management and administrative support for the various projects and studies, as many activities addressing the above requirements are likely to be related (such as add-on projects to common existing surveillance systems).
• Maintain research data in compliance with internationally accepted safeguards, including compliance with appropriate U.S. laws, regulations and policies for both human subjects-related data and for animal subjects humane data.
• Work with CDC to develop research protocols.
• Specify in research protocols the role and responsibility of all investigators, including development and dissemination of data, reports, manuscripts, and special studies, prior to initiation of the work.

4. Approvals

This Letter of Intent is not intended to create obligations under international or other law, and all cooperation is subject to the availability of appropriated funds, personnel, and other resources. Either CDC or MARD may terminate this cooperation on 30 days written notice to the other. The cooperation under this Letter of Intent is expected to commence on the date of signature and continue for a period of five years. It may be extended for additional periods upon mutual consent by CDC and MARD.

This letter is intended to be fully consistent with previous agreements and nothing herein should be construed to be in conflict with those agreements. Specifically, this letter follows the Agreement between the Government of the United States and the Government of the Socialist Republic of Vietnam on Health and Medical Sciences Cooperation, signed in 2006; the Agreement for Economic and Technical Cooperation between the Government of the United States and the Government of the Socialist Republic of Vietnam, signed in 2005; the Letter of Intent on Cooperation between the Ministry of Health of the Socialist Republic of Viet Nam and the Department of Health and Human Services of the Department of Health and Human Services of the United States of America, signed in 2005; the Agreement between the Government of the United States and the Government of the Socialist Republic of Vietnam on Scientific and Technical Cooperation, signed in 2000; and the original Joint Statement of Cooperation in the Field of Health and Related Endeavors between the Department of Health and Human Services

For the International Cooperation Department For the Office of the Assistant Secretary for Health
Ministry of Agriculture and Rural Development Department of Health and Human Services
The Socialist Republic of Vietnam United States of America

Luong The Phiet Bruce G. Gellin
Acting Director General Deputy Assistant Secretary for Health
International Cooperation Department Office of the Assistant Secretary

Date Date

For the Department of Animal Health For the Centers for Disease Control and Prevention
Ministry of Agriculture and Rural Development Department of Health and Human Services
The Socialist Republic of Vietnam United States of America

Hoang Van Nam R.J. Simonds
Acting Director General Acting Director
Department of Animal Health Center for Global Health

Date Date