

H5N1 Infections of Humans: *WHO Research Initiatives*

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Global Influenza Programme



**World Health
Organization**

WHO Human H5N1 Research Initiatives

- **H5 Clinical-Treatment Outcomes Database**
- **SouthEast Asia Influenza Clinical Research Network**
- **Influenza Research Coordinator**



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The Second WHO Consultation on Clinical Aspects of Human Infection with Avian Influenza A (H5N1) Virus

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Antalya, Turkey, 19-21 March 2007

Alert & Response Operations

[Summary of the second WHO consultation on clinical aspects of human infection with avian influenza A \(H5N1\) virus](#)

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BACKGROUND AND OBJECTIVES

Global Outbreak Alert & Response Network

In May 2005, WHO convened the 1st Meeting on Case Management and Research on Human Influenza A/H5 in Hanoi, Viet Nam in May 2005. Despite increased awareness at community level and efforts made by the agricultural and human health sectors to contain the disease, the number of cases of influenza A (H5N1) virus infection in humans, who die from this infection, is still high. The World Health Organization is now convening a second meeting of experienced clinical practitioners from hospitals that have treated H5N1 patients.

International Health Regulations

Biorisk Reduction

The objectives of the meeting:

- Summarize clinical manifestations, laboratory findings, and pathological findings associated with influenza A (H5N1) virus infections in humans,
- Summarize current knowledge about the management of H5N1 infections,
- Identify important gaps for additional research in the knowledge about, and treatment of, H5N1 infections.

WHO Human H5N1 Clinical - Treatment Outcomes Database

- **Current WHO H5N1 database has only basic demographic, risk factor, and overall outcomes data.**
- **Need integrated database for timely risk assessments**
 - **Changes in clinical presentation or course**
 - **Prognostic features**
 - **Treatment effectiveness and safety**
- **Proposed database**
 - **Retrospective and prospective data collection**
 - **No release of individual patient data**
 - **Regular updates on web or in WER**

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Clinical management of human infection with avian influenza A (H5N1) virus

15 August 2007

- [Full text - English \[pdf 119kb\]](#)
- [WHO H5N1 Clinical Case Summary Form \[pdf 41kb\]](#)
- [Supplementary WHO H5N1 Clinical Case Data \[pdf 22kb\]](#)

This document replaces the *WHO interim guidelines on clinical management of humans infected by influenza A(H5N1)* published in March 2004

The present advice is applicable for the current situation with sporadic A(H5N1) virus human infection. As more data become available or if the disease patterns change, this advice will be modified as appropriate



SEA Influenza Clinical Research Network

Supported by the Center for International Research Assistance & Support

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What's New?

Our URL address has changed from ciras-sea.org to: seaclinicalresearch.org

[Publications](#) (updated)

[Calendar of Events](#)

[Second Annual Conference Details](#)

[Bamrasnaradura Infectious Disease Institute Laboratories Accreditation](#)

[Siriraj Labs Accredited](#)

[CIRAS Sharepoint Site](#)
(permission required)

Mission Statement: The mission of the Southeast Asia Influenza Clinical Research Network (Network) is to advance the scientific knowledge and management of human influenza through integrated, collaborative clinical research.

Description of the Network: The Southeast Asia Influenza Clinical Research Network [SEA ICRN] is a multi-lateral, collaborative partnership of hospitals and institutions in Indonesia, Thailand, United Kingdom, United States, and Vietnam. International partners currently include US National Institute of Allergy and Infectious Diseases, Oxford University, Wellcome Trust, and WHO.

Network Partners

 wellcome trust



www.seaclinicalresearch.org

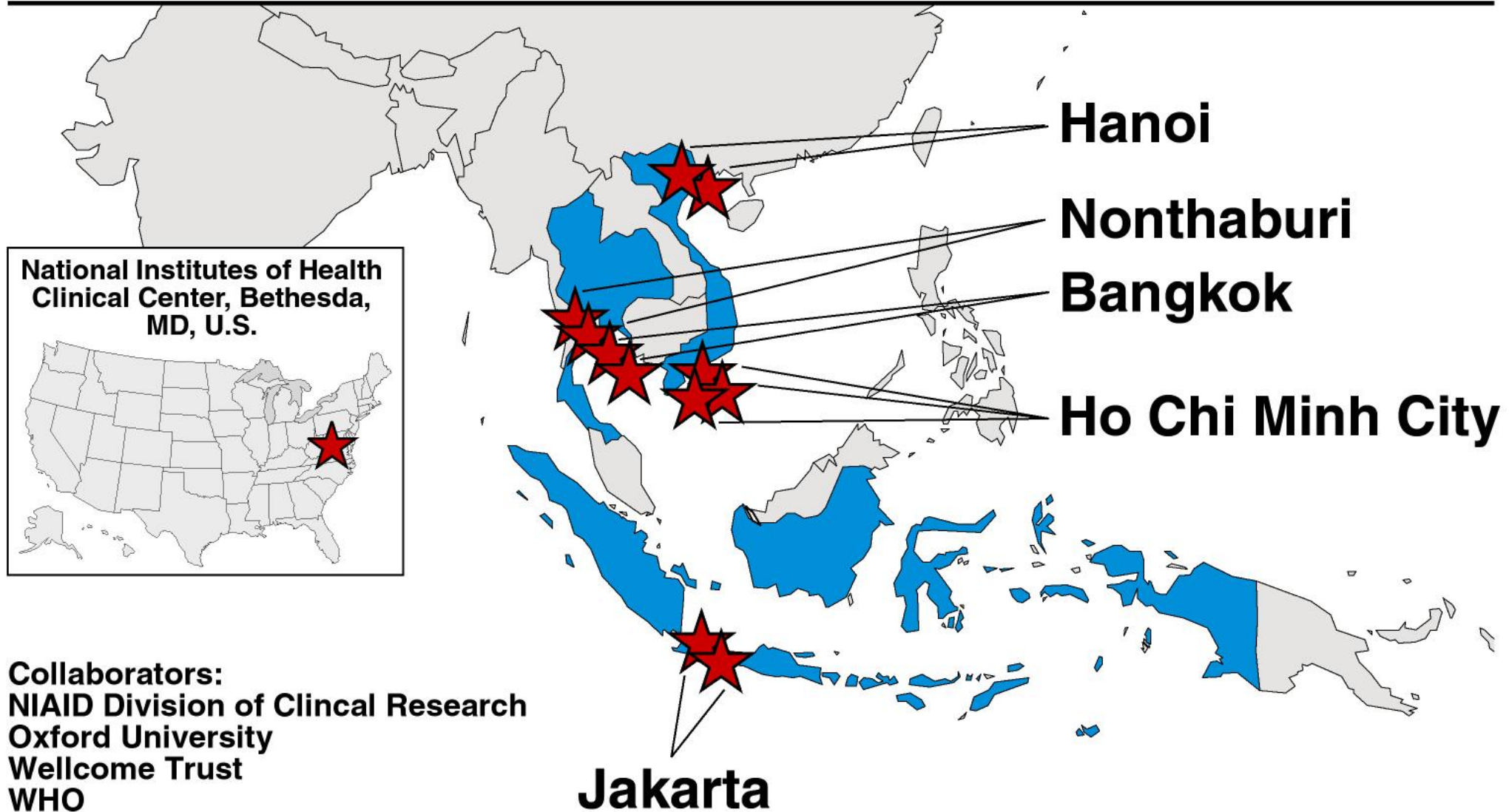
SEA Influenza Clinical Research Network

- Collaborative partnership of hospitals and institutions in Indonesia, Thailand, Viet Nam, UK, and USA.
- International partners currently include US National Institute of Allergy and Infectious Diseases, Oxford University, Wellcome Trust, and WHO.
- Mission of the Network is to advance scientific knowledge and management of human influenza through integrated clinical research with the aim of improving patient care and human health.

SEA Influenza Clinical Research Network Principles

- **Develop knowledge on influenza pathogenesis, therapeutics, diagnostics, and prevention through protocol-based studies**
- **Strong emphasis on building independent research capacity of investigators/institutions**
- **Compliance with international standards for clinical research**
- **Prompt sharing of data and isolates with approval of relevant national authorities**
- **Publication guidelines that are inclusive**

SEA Influenza Clinical Research Network



Collaborators:
NIAID Division of Clinical Research
Oxford University
Wellcome Trust
WHO



**SEA ICRN
Network Steering
Committee**
WHO, US NIAID, Wellcome Trust,
Oxford University,
Representatives of Vietnam, Thailand
and Indonesia

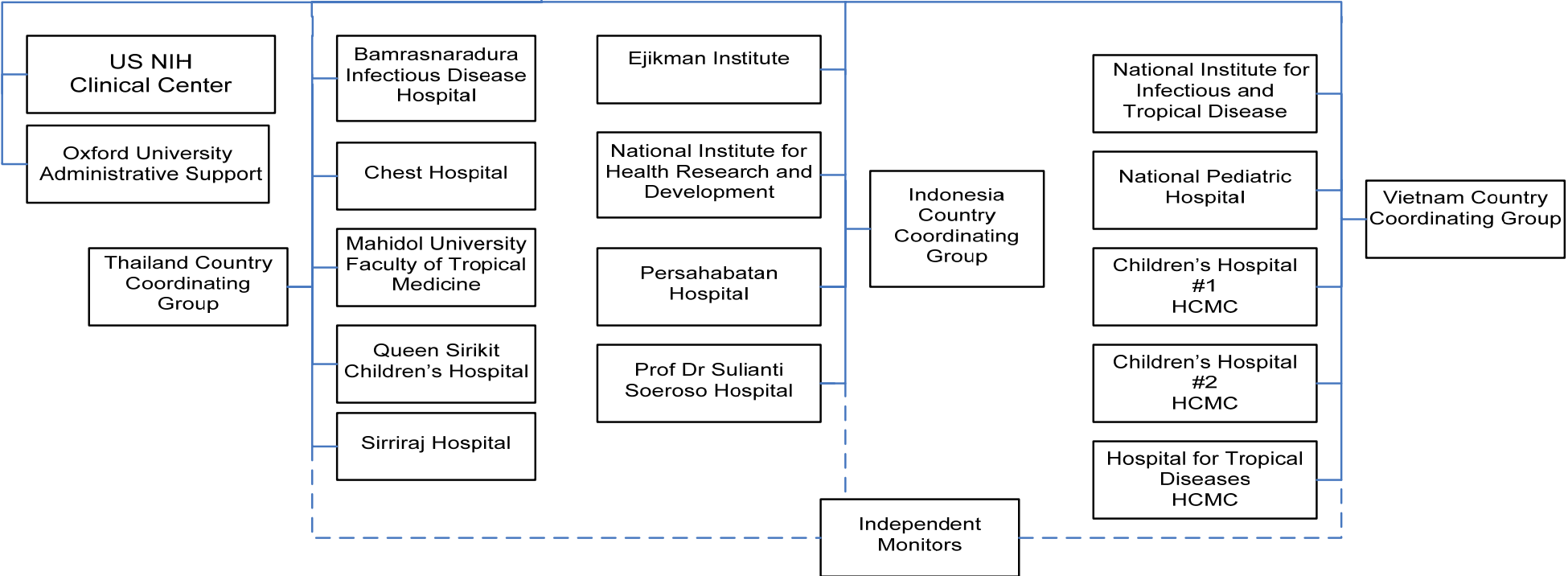
DSMB

- ADVISORY COMMITTEES**
- Data Management
 - Laboratory
 - Pharmacy
 - Pharmacokinetics
 - Regulatory Affairs
 - Site Management
 - Training

Network Coordinating
Center
OUCRU CIRAS

**Trial Operations
Committee**

Protocol Teams



SEA ICRN Antiviral Studies

- **Loading-dose oseltamivir with probenecid (phase 1)**
- **Double-blind, randomized, controlled trial to compare standard and higher dose (150 mg bid) oseltamivir therapy**
 - **Avian influenza or severe human influenza**
- **IV zanamivir and oseltamivir interaction (phase 1)***
- **IV zanamivir/peramivir in avian influenza (phase 2)***
- **Long-term neuraminidase inhibitor prophylaxis***

***Protocol under development**

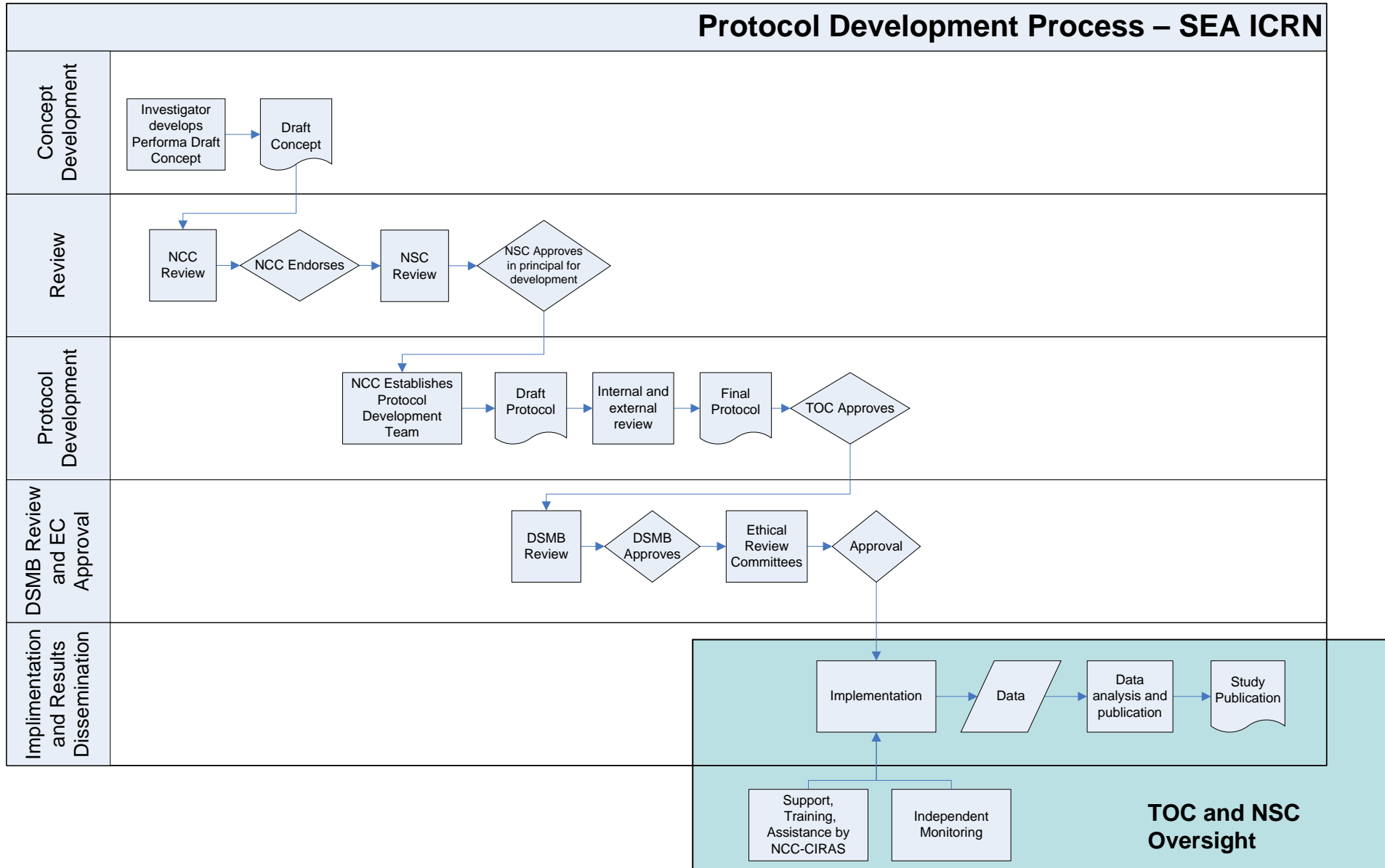
SEA ICRN Immunology Studies

- **Standard vs higher dose (150 mg bid) oseltamivir therapy**
 - Acute measurements of viral loads, cytokines, T and B responses
- **Long-term follow-up of H5 survivors***
 - Clinical, PFTs, chest CT; virus-specific antibody, T and memory B cell responses (up to 4 years)#
 - Development of human neutralizing H5 monoclonals#
 - Cross-reactive antibodies and T cells to avian/human viruses
- **Community cohort study of pre-season antibody, T and B cell responses in relation to risk of influenza infection/illness#**

*Network protocol under development

#In progress in Vietnam (NIHE, HTD)

Protocol Development Process – SEA ICRN





INFLUENZA RESEARCH COORDINATOR

Applications are invited for a 2-year position to be based at the World Health Organization in Geneva and funded by the Wellcome Trust.

This position is to facilitate and coordinate the development of a research agenda related to human influenza, and in particular, to identify the key research needed to reduce the risks from this threat over the next decade.

Key aspects of the role include:

- Ensuring that stakeholders are well-informed about current influenza research activities by developing, maintaining and disseminating a central inventory of funded research activities relevant to human influenza.
- Coordinating a series of road-mapping exercises for identifying key gaps in knowledge to assist funders and researchers with the aim of establishing priorities for research activities with specific focus on vaccines, drug therapies, and epidemiology/population science (e.g. diagnostics, surveillance, transmission, modelling).
- Liaise with external partners to develop a cohesive health research agenda and facilitate implementation of specific projects.
- Work with stakeholders to update, analyse, and prioritize knowledge gaps and assist funding organizations in their efforts to evaluate research activities, so that investments by financial partners will be directed appropriately.
- Facilitate and coordinate interactions between major non-commercial biomedical research financial partners (WHO, governments, foundations, NGOs) in the area of influenza research relevant for humans.

The candidate will have:

- Extensive combined national or international experience at a senior managerial, scientific or technical level in major programs or activities related to clinical science, basic science (virology, immunology) or public health research.
- Considerable management experience in the identification and development of research projects, programs, and policies.
- Excellent communication and interpersonal skills, with the ability to lead projects involving a diverse range of organisations, and ideally the ability to present at board level.

The project will be guided by a consortium of research funders and research organisations (including the Bill and Melinda Gates Foundation, Institut Pasteur, National Institutes of Health, WHO, Chinese Center for Disease Control and Prevention and the Wellcome Trust).

To apply, please send a full CV with a covering letter detailing how you feel you meet the requirements of the post (including a daytime telephone number and details of your current salary) to HR Department, Wellcome Trust, 215 Euston Road, London NW1 2BE. Alternatively, email hr@wellcome.ac.uk. Applications must be received by Friday 13 July 2007. Informal enquiries about the position can be addressed to j.whitworth@wellcome.ac.uk or HaydenF@who.int

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WHO Influenza Research Coordinator

- **Develop central inventory of research activities related to human influenza**
 - **Focus on vaccines, drug therapies, and population science**
- **Coordinate series of road-mapping exercises to identify key gaps in knowledge**
 - **Liaise with partners to develop cohesive research agenda**
- **Facilitate interactions between major non-commercial biomedical research partners (government, foundations, NGOs, WHO)**
 - **Assist funding agencies in their activities**

www.seaclinicalresearch.org