



**TERMS OF REFERENCE FOR SEASONAL INFLUENZA FOR ESSENTIAL REGULATORY  
LABORATORIES  
OF THE WHO GLOBAL INFLUENZA SURVEILLANCE AND RESPONSE SYSTEM**

The Essential Regulatory Laboratories (ERLs) together with the the World Health Organization (WHO) Collaborating Centres for Influenza (WHO CCS), H5 Reference laboratories and National Influenza Centres (NICs) form the WHO Global Influenza Surveillance and Response System (GISRS) coordinated by the WHO Global Influenza Program (GIP).

The GISRS, previously known as the Global Influenza Surveillance Network (GISN) until 2011, was established in 1952. It has been, and is, the primary global mechanism and resource for surveillance and control of influenza. The GISRS continuously monitors the evolution of influenza viruses around the world in the interest of public health, conducts risk assessment and recommends risk management measures. GISRS functions through efficient sharing of influenza viruses and surveillance information, provision of technical support and updated reagents by and to GISRS members. The function of GISRS is coordinated by the GIP across the three levels of WHO: headquarters, regional offices and country offices.

**General conditions and WHO recognition**

ERLs are institutions that are formally associated with national regulatory agencies, fulfilling critical functions connecting surveillance and risk assessment activities with influenza vaccine response, in particular in relation to the development, standardization and regulation of influenza vaccines.

The identification and recognition of new ERLs is decided by WHO, based on the overall assessment of global public health needs, the ability of candidate laboratories to fulfil the Terms of Reference listed below, and, in particular, the added value that inclusion of candidate laboratories would bring to the GISRS.

Membership in the GISRS is done *on a case-by-case basis* and is reviewed periodically to ensure the optimum effectiveness of GISRS in meeting emerging public health risks.

ERLs are supported by government funding and any supplemental funding from public bodies, charities and other financial resources must not result in a conflict of interest or impact on the impartiality of the ERL in carrying out its essential activities.

**Activities related to influenza viruses that are “PIP biological materials”:**

Terms of Reference for ERLs on the work related to Pandemic Influenza Preparedness biological materials are described in Annex 5 of the PIP Framework <sup>1</sup>.

<sup>1</sup> [http://www.who.int/influenza/resources/pip\\_framework/en/](http://www.who.int/influenza/resources/pip_framework/en/)

**Activities related to Human seasonal influenza viruses and other non-PIP BM influenza viruses:**

In coordination with GIP, ERLs:

- Collaborate and exchange information and influenza viruses with WHO Collaborating Centres for Reference and Research on Influenza and other institutions under the scope of activities defined in the TORs; and
- Are a primary information resource for WHO on issues related to influenza vaccines

In particular, ERLs:

- Standardize and update the generic protocol for the calibration of influenza antigen content in vaccines;
- Produce, calibrate and make available, as timely as possible, reagents needed for use in the influenza vaccine potency assay;
- Facilitate and/or perform serological studies using sera from human influenza vaccinees and share results to support influenza vaccine virus selection;
- Participate in the WHO vaccine composition consultations to review data generated by GISRS and make recommendations on influenza vaccine composition for the next northern or southern hemisphere influenza seasons;
- Facilitate, build and/or maintain capacity for influenza vaccine virus development using classical reassortment and/or reverse genetic technologies; and
- Serve as the interface of GISRS with national/regional regulatory agencies and influenza vaccine manufacturers on issues related to vaccine response: seasonal, zoonotic and pandemic influenza