WHO BioHub System
Summary of biosafety and biosecurity: criteria and operational modalities

What is the WHO BioHub System?
The aim of the World Health Organization (WHO) BioHub System is to implement the timely sharing of biological materials between laboratories and partners globally. This international exchange system will enable rapid assessment of risk and subsequent mitigation measures for epidemic- and pandemic-prone diseases, and thus make global preparedness and response against these diseases more effective.

How to join the WHO BioHub System
Laboratories wishing to receive biological materials as part of this international exchange system will need to be accepted by WHO as a Qualified Entity (QE). To acquire QE status, laboratories must meet pre-agreed conditions, including biosafety and biosecurity measures, and various regulations.

Laboratories applying for QE status sign the standard material transfer agreement (SMTA) 2 (non-commercial use) or 3 (all uses including commercial ones), which means that when receiving biological materials with epidemic or pandemic potential (BMEPP), they are deemed to have confirmed proper conformance to the biosafety and biosecurity criteria. This is in addition to compliance with other relevant WHO guidance documents and applicable national and international regulations. WHO reserves the right to ask laboratories for more details for the purpose of processing applications for QE status and to review the biosafety and biosecurity conformance and performance of QEs.

How to achieve QE status
A checklist for QEs is given below, for indication purposes; full details can be found in the document available from the WHO BioHub webpage. 1

1 See https://www.who.int/initiatives/who-biohub/
Criteria for QEs

The following checklist outlines the criteria that are used to ensure that biosafety and biosecurity measures are in place in laboratories applying for QE status:

- **Biosafety, biosecurity and risk assessment**
  - Facility biosafety and biosecurity capacities, capabilities and risk assessments in place and documented.

- **Core requirements**
  - Compliance with “core requirements”, as defined in the WHO Laboratory biosafety manual 4th edition (LBM4), including observance of good microbiological practice and procedure (GMPP) and standard operating procedures (SOPs).

- **Heightened control measures**
  - Compliance with “heightened control measures”, as defined in the LBM4 and as determined by the risk assessment for the planned experiments.

- **Maximum containment measures**
  - Where applicable, compliance with “maximum containment measures”, as defined in the LBM4 and as determined by the risk assessment for the planned experiments.

- **Biosafety manual**
  - A complete biosafety manual in place, containing institutional policies, programmes and plans as well as responsibilities of biosafety personnel and other staff.

- **Biosecurity plan**
  - A biosecurity plan in place, outlining the security measures, including physical security of the facility, access restrictions, information control and personnel reliability.

- **Dual-use research of concern**
  - Commitment and a transparent regime in place to address dual-use research of concern (DURC) and report such research to WHO.

- **Training and competency**
  - Training programme, competency assessments and associated records in place.

- **Medical surveillance programme (occupational health)**
  - Medical surveillance programme (occupational health) in place.

- **Emergency and incident response plan**
  - Emergency and incident response plan in place.

- **Incident reporting system**
  - Incident reporting system and records in place.

- **Inventory control system**
  - Inventory control system and records in place.

- **Audits and inspections**
  - Records of audits and inspections (internal and external) in place.

- **Maintenance and servicing**
  - Maintenance and servicing programme for facility, equipment and technical installations in place.

- **Transportation systems**
  - Transportation systems in place, including export and import permits.