



The University of Hong Kong



Hospital Authority Hong Kong West Cluster

Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB)

Terms of Reference

(Effective from 1st April, 2014)

ESTABLISHMENT & MISSION

HKU/HA HKW IRB was established by The University of Hong Kong (HKU) and Hospital Authority Hong Kong West Cluster (HA HKW) for overseeing clinical studies involving human subjects undertaken by and/or conducted in the premises owned, managed and/or controlled by HKU and/or HA HKW, and/or involving patients and/or staff thereof as human subjects in such clinical studies. The mission of HKU/HA HKW IRB is protecting the rights, safety and well-being of human subjects with respect to their participation in clinical studies through initial review and continuous oversight of such clinical studies from the ethical and scientific perspectives.

RESPONSIBILITIES

HKU/HA HKW IRB has the responsibilities to protect the rights, safety and well-being of human subjects with respect to their participation in clinical studies under its jurisdiction through:

- receiving applications for initial review of clinical studies from principal investigators, performing initial ethics and scientific review of such studies, and giving its decision(s)/opinion(s) on each application;
- performing continuous ethics and scientific oversight during the period of each approved clinical study and giving its decision(s)/opinion(s);
- creating and maintaining necessary records with respect to ethics and scientific review and oversight of clinical studies;
- reporting to its Governance Committee (GC) the status of operation of HKU/HA HKW IRB and any significant issue with respect to the clinical studies under HKU/HA HKW IRB's oversight;
- allowing and facilitating audits by the GC and inspections by competent regulatory authorities;
- promoting the concepts of clinical research ethics; and
- perform other duties related to ethics and scientific review and oversight of clinical studies as delegated by the GC or jointly by HKU and HA HKW.

POWERS

The IRB/REC has the powers to:

- request for, collect and review information, documents and materials necessary for performance of ethics and scientific review and oversight;
- recommend modifications to study designs and arrangements on sound ethical or scientific basis and in line with HKU/HA HKW IRB's mission;
- approve or disapprove clinical studies and give other opinions with respect to the ethical and scientific aspects of such clinical studies;
- suspend or terminate any approved clinical study if unacceptable risk to subjects arises;
- audit clinical studies to assess compliance with study protocols, HKU/HA HKW IRB's requirements and other applicable standards and requirements;
- disclose information of clinical studies to the GC, HKU, HA HKW and competent regulatory authorities; and
- exercise other authorities related to ethics and scientific review and oversight of clinical studies as delegated by the GC or jointly by HKU and HA HKW.

CHAIRMANSHIP AND MEMBERSHIP

The HKU/HA HKW IRB shall have a Chairman who shall be appointed jointly by HKU (represented by the Dean of Li Ka Shing Faculty of Medicine of HKU) and HA HKW (represented by the Cluster Chief Executive of HA HKW).

The HKU/HA HKW IRB shall consist of both genders and with a minimum of five (5) members, including:

- at least one (1) member whose primary expertise or area of interest is in medical, clinical or biological sciences or related disciplines (Scientific Member);
- at least one (1) member whose primary expertise or areas of interest is not in medical, clinical or biological sciences or related disciplines (Non-scientific Member); and
- at least one (1) member who is neither directly affiliated with HKU/HA HKW nor the direct family member of any person directly affiliated with HKU/HA HKW, irrespective of the member's primary expertise or area of interest (Independent Member).

The Chairman shall, on consultation with the GC, nominate a suitable number of candidates with a suitable mix of backgrounds and expertise as members for supporting the HKU/HA HKW IRB's responsibilities.

All nominations shall be submitted to the GC for consideration and recommendation to HKU and HA HKW for appointment.

The term of chairmanship and membership will be three (3) years. There is no restriction for reappointment as long as a Chairman/member continues to fulfill the relevant requirements.