Gleneagles Hospital
HONG KONG
港怡醫院

HKU-GHK Institutional Review Board

Terms of Reference

1. University of Hong Kong – Gleneagles Hospital Hong Kong Institutional Review Board (HKU-GHK IRB) was established by The University of Hong Kong (HKU) and Gleneagles Hospital Hong Kong (GHK) for overseeing clinical studies involving human subjects undertaken by and/or conducted in the premises owned, managed and/or controlled by HKU and/or GHK, and/or involving patients and/or staff thereof as human subjects in such clinical studies. The mission of HKU-GHK 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.

2. HKU-GHK 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:

    a. 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;

    b. Performing continuous ethics and scientific oversight during the period of each approved clinical study and giving its decision(s)/opinion(s);

    c. Creating and maintaining necessary records with respect to ethics and scientific review and oversight of clinical studies;

    d. Reporting to its Education, Training & Research Committee (ETRC) the status of operation of HKU-GHK IRB and any significant issue with respect to the clinical studies under HKU-GHK IRB's oversight;

    e. Allowing and facilitating audits by the ETRC and inspections by competent regulatory authorities;

    f. Promoting the concepts of clinical research ethics; and

    g. Performing other duties related to ethics and scientific review and oversight of clinical studies as delegated by the ETRC or jointly by HKU and GHK.

3. HKU-GHK IRB has the powers to:

    a. Request for, collect and review information, documents and materials necessary for performance of ethics and scientific review and oversight;

    b. Recommend modifications to study designs and arrangements on sound ethical or scientific basis and in line with HKU-GHK IRB's mission;

    c. Approve or disapprove clinical studies and give other opinions with respect to the ethical and scientific aspects of such clinical studies;

    d. Suspend or terminate any approved clinical study if unacceptable risk to subjects arises;

    e. Audit clinical studies to assess compliance with study protocols, HKU-GHK IRB's requirements and other applicable standards and requirements;

    f. Disclose information of clinical studies to the ETRC, HKU, GHK and competent regulatory authorities; and

    g. Exercise other authorities related to ethics and scientific review and oversight of clinical studies as delegated by the ETRC or jointly by HKU and GHK.