香港中文大學醫院
CUHK
Medical Centre

Pioneering Solutions in Healthcare
開拓醫護新領域

CUHK Medical Centre (CUHKMC)
Clinical Research Ethics Committee (CREC)

Terms of Reference

CREC 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 the HMC the status of operation of the CREC and any significant issue with respect to the clinical studies under the CREC's oversight;
e. allowing and facilitating audits by the HMC and inspections by competent regulatory authorities;
f. promoting the concepts of clinical research ethics; and
g. perform other duties related to ethics and scientific review and oversight of clinical studies as delegated by the HMC or the BoD.

CREC 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 the CREC'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, the CREC's requirements and other applicable standards and requirements;
f. disclose information of clinical studies to the HMC, the BoD and competent regulatory authorities; and
g. exercise other authorities related to ethics and scientific review and oversight of clinical studies as delegated by the HMC or the BoD.