HOSPITAL AUTHORITY (HA) GUIDE ON RESEARCH ETHICS

(for Study Site & Research Ethics Committee)

Version	Effective Date
4	01/08/2024
3	01/10/2018
2	01/02/2015
1	15/08/2007

Document Number	HAHO-COM-GL-REC-001-v04
Author	HAHO Steering Committee on Research Ethics (HA REC)
Custodian	HA REC
Approved / Endorsed By	HA REC
Approval Date	26/07/2024
Distribution List	Central Institutional Review Board (Central IRB), Institutional Review Board of the University of Hong Kong / HA Hong Kong West Cluster (HKU/HA HKW IRB), The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (Joint CUHK-NTEC CREC)

Version and Review Highlights

Version No.	Issue Date (DD/MM/YY)	Effective Date (DD/MM/YY)	Review Date (DD/MM/YY)	Highlights for the Issue
4	31/07/2024	01/08/2024	01/08/2027	1. Correction of typo errors and standardization of the term “clinical study” 2. Governance structure updated for the Centralisation of Research Ethics in HA [section 4] 3. Delineated the roles of COS(s) and Head(s) of department(s) under “Administrative Approval” [section 5.2 (i) & (ii)] and specified the process of CTA negotiation [section 5.2 (iii)] 4. Application dossier rearranged for easy understanding [Annex] 5. All references to “subject(s)" are replaced by “participants” in line with the latest research ethics practice.

Table of Content

1. Introduction

1.1 Clinical trial and clinical research (collectively referred to as "clinical study") are necessary if medicine is to progress. They contribute to the generation of knowledge and development of technology for healthcare advancement. Such objectives, however, do not take precedence over the interests of the research participants.

1.2 Clinical study is premised on trust. At times, it places research participants at risk for the good of the community. The community and the research participants therefore have legitimate expectations that a system of protection should be in place. This guideline sets out the system of protection within HA. The requirements have been developed with reference to overseas practice and local experience. HA expects that the requirements set out in this document should apply to all clinical trials conducted in HA to safeguard the safety of trial participants.

1.3 For research oversight on Phase 1 clinical trials, please refer to the latest online versions of the following documents for the additional requirements:

(i) Guideline of Ethics Oversight and Scientific Evaluation of Phase 1 Clinical Trials

(ii) Standard Operating Procedure of the Joint Scientific Committee for Phase 1 Clinical Trials

2. Ethical Requirements in Clinical Study

2.1 In clinical study, the mandatory ethical requirements are the principles of the Declaration of Helsinki, and whenever applicable, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice ("ICH-GCP Guideline"). Legal requirements and local institution policies must also be complied with. Some of the important requirements are:

(i) Clinical study methodology must be scientifically valid and adequate in addressing the questions posed;

(ii) Clinical study designed must minimize the potential risks to the research participants, and its anticipated benefits must justify the potential risks;

(iii) Equipoise must exist between different arms of a therapeutic trial comprising different interventions or different dosages;

(iv) To ensure voluntary participation in clinical study, research participants must be

adequately informed of the experimental nature of the clinical study, its risks, burdens and benefits, and their rights to withdraw at any time, which will not affect the care that they are entitled to;

(v) As each person weighs risks and benefits differently, we must respect other's freedom to decide, based on his/her own value and belief, without coercion and undue influence;

(vi) Selection precautions should be taken to protect vulnerable research participants; and

(vii) Throughout a trial, research participants should be provided with updated information about the clinical study (including adverse events) so that they are free to decide whether or not to continue.

3. HA's Obligations as a Research Institution

3.1 As a public healthcare service provider, HA has to ensure that:

(i) Services are accorded priority;

(ii) Research participants' rights, safety and welfare are protected;

(iii) Clinical study is conducted ethically and lawfully amongst its staff;

(iv) Public confidence is sustained by an environment that upholds scientific and ethical integrity; and

(v) Liabilities to HA be minimized.

3.2 HA established an ethics review and oversight mechanism through the Institutional Review Board ("IRB") / Research Ethics Committee ("REC") structure as an added layer of protection for research participants.

4. Governance Structures of Research Ethics Oversight in HA

4.1 Upon completion of Centralisation of Research Ethics Review in HA in 1Q 2024, governance structure of research ethics oversight in HA is organized into two levels:

(i) Policy administration in HA Head Office ("HAHO"); and

(ii) Ethics review by Central IRB for studies conducted by HA staff and within HA premises or by the IRB/REC(s) having affiliation with teaching hospital for research conducted in respective teaching hospital and cluster.

4.2 HAHO Steering Committee on Research Ethics ("HA REC")

HA REC is to steer and oversee the development, execution and performance of research ethics governance in HA.

4.3 Central IRB and Teaching Hospital-affiliated IRB/REC(s)

4.3.1 The Central IRB is accountable to the governance represented by the Director (Quality & Safety) of HAHO and is responsible for conducting ethics review and function according to the Standard Operating Procedure.

4.3.2 The Teaching Hospital-affiliated IRB/REC is accountable to the governance represented by Cluster Chief Executive ("CCE"), and Dean of the Medical Faculty ("Dean"). They are responsible for conducting ethics review and function according to their Standard Operating Procedure.

4.3.3 Central IRB and Teaching Hospital-affiliated IRB/REC should have mechanism in place to monitor the compliance of the study duties conducted in the study sites.

4.3.4 Besides ethics approval, clinical study conducted on HA patients or within HA facilities must:

(i) Seek approval from study site management (i.e. hospital and/or affiliating academia who ever applicable) and;

(ii) Comply with regulatory requirements if applicable, (e.g. Certificate for Clinical Trial/Medicinal Test and Personal Data (Privacy) Ordinance (Cap.486)).

5. Responsibilities of the Study Sites Management

5.1 At the study site, all clinical studies must be approved by the Chiefs of Services (COS(s)) or Head(s) of the implicated Department(s), before submitting for ethics review. The Principal Investigator ("PI") has to submit the required documents (collectively "application dossier") to the COS(s) or Head(s) of the implicated department(s) for administrative approval (Please refer to Annex for the details of application dossier).

5.2 Administrative approval

(i) By signing the Clinical Research Ethics Review Application Form, the COS(s) or Head(s) of implicated department(s) endorsed that the clinical study is both

scientifically and ethically sound. S/he also confirmed that:

(a) Services priority of the department will not be affected;

(b) Research team is competent;

(c) The investigator(s) has sufficient resources to conduct the clinical study safely;

(d) Therapeutics intervention(s), if any, can be performed by appropriate personnel proficient in managing conditions that may arise;

(e) The study site has sufficient facilities to support the clinical study; and

(f) If the clinical study is sponsored[1], the Clinical Trial Agreement ("CTA") has been reviewed (or under process) by HAHO Legal Services Department ("LSD") or HA appointed institution;

(ii) The COS(s) or Head(s) of department(s) could seek advice from hospital management when necessary (e.g. in doubt of 5.2 (i) or clinical study involves testing of an article for unlicensed indications, which may expose the hospital to unknown risks).

(iii) In negotiating a CTA with the sponsor:

(a) The PI can approach the LSD for pre-approved HA CTA template and/or pre-approved drug company CTA templates through Central IRB or Teaching Hospital-affiliated IRB/REC.

(b) Other than where a pre-approved CTA is used, the PI should liaise with sponsors and LSD for amendments and the review of CTA through Central IRB or Teaching Hospital-affiliated IRB/REC.

(c) The site PI is responsible for ensuring the review of CTA is in place for his/her study site.

5.3 Handling of complaints on clinical study

(i) Complaints on clinical study, whether in respect of incompetence negligence, misconduct or otherwise, should be investigated promptly at the hospital level.

(ii) If there is a genuine concern on the safety of research participants, the hospital should suspend the clinical study while the complaint is being investigated.

(iii) The relevant IRB/REC(s) should be notified of the compliant and the investigation findings.

[1] ICH GCP Guideline defines sponsor as an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Annex: Application Dossier for Research Ethics Review Application

(i) A duly completed and signed Clinical Research Ethics Review Application Form;
(ii) A research protocol;
(iii) Conflict of interest declaration by all investigators;
(iv) Curriculum vitae of all investigators;
(v) Investigator's brochure (if applicable);
(vi) Informed consent form and/or participant information sheet (if applicable);
(vii) Information for research participants (e.g. recruitment notice, invitation letter and safety information) in suitable language(s) (if applicable);
(viii) Document/materials for use by research participants in the study (e.g. participant administered questionnaire) (if applicable);
(ix) Certificate of insurance for clinical study (if applicable);
(x) Certificate of Clinical Trial/Medicinal Test or other documents required by law (if applicable);
(xi) For sponsored clinical study or where commercial interest is involved (e.g. collecting data, evaluating a device, comparing different drugs, drug dosages or off-label use of a licensed drug), submission of Clinical Trial Agreement before study commencement is required.