Clinical Research Site Facility & Personnel Requirements

Hong Kong Science and Technology Parks Corporation ("HKSTP")

Clinical Research Ethics Committee

Version History

Version	Effective Date
1	23/03/2023

---

1. Overall Clinical Research Site Requirements

A Clinical Research Site (CRS) facility should be clean, secure, designed to ensure proper conduct of the clinical research, as well as to protect participants' safety, privacy, and confidentiality. Proper space for instrument placement, lighting, ventilation, temperature control, and operation must be available. Working environments should include adequate water taps, sinks, drains, electrical outlets, gas, and suction, when applicable. Specimen movement and workflow through the laboratory should be such that opportunities for specimen loss, specimen mix-up, and exposure of laboratory personnel to biohazards are minimized.

According to NIH's standards and guidelines on good clinical laboratory practice and site clinical operations and research essentials manual, CRS should offer the followings, as applicable:

- Hazard free entrance area and, if possible, handicap accessible
- Rest area where a participant can register and wait comfortably during waiting periods
- Private setting(s) for conducting informed consent discussions and counselling
- Appropriate examination/treatment rooms for conducting study visits and procedures must comply with the Private Healthcare Facilities Ordinance (Cap. 633)
- Post- examination/ treatment area to perform close observation on participants' physical conditions/ status
- Temperature and humidity control
- Adequate infection-control equipment and procedures
- Access to a sink and safety equipment in the laboratory
- Power back-up system to ensure continuity of electricity, internet connection, etc.
- Adequate space for monitoring visits
- Data management and storage area
- Office/workspace
- Emergency facilities

For more information on NIH's standards and guidelines on good clinical laboratory practice, refer to https://www.niaid.nih.gov/sites/default/files/gclpstandards.pdf

For more information on NIH's site clinical operations and research essentials manual on clinical research site facility requirements, refer to https://www.niaid.nih.gov/sites/default/files/clinical-research-site-personnel-qualifications.pdf

2. Venue Restrictions in HKSTP

According to Cap. 633, the following medical procedures that may only be carried out in a hospital.

- Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ
- Image-guided core biopsy of deep-seated organ
- Transarterial catheterisation or deep venous catheterisation
- Continuous veno-venous haemofiltration or continuous veno-venous haemodiafiltration
- Organ transplant [except corneal transplant] or complicated transplant procedures
- Bronchoscopy or pleuroscopy
- Therapeutic gastrointestinal endoscopy for children aged under 12 years old
- Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region;
- Blood transfusion
- Radiotherapy for children aged under 18 years old
- Frame-based stereotactic radiosurgery
- Intra-operative radiotherapy
- Total body irradiation
- Half body irradiation
- Total skin electron beam treatment
- Brachytherapy
- Radionuclide therapy except iodine-131 therapy for thyrotoxicosis up to 400MBq, radium-223 therapy for advanced prostate cancer and radiosynoviorthesis therapy

3. Private Healthcare Facilities Ordinance (Cap. 633)

Clinic research project involving any provision of day procedures, clinics and health services, is required to comply with Cap. 633. Under Cap. 633, the Director of Health is empowered to issue a code of practice ("CoP") and the licensee of a private healthcare facility ("PHF") shall ensure the PHF comply with the licence conditions and the CoP. The CoP sets out the licensing standards in respect of the governance, staffing, facilities and equipment, service delivery, quality and safety of care, infection control, and other matters related to the operation of the PHF.

Day procedure centres refer to any premises that do not form part of the premises of a hospital, and are used, or intended to be used, by registered medical practitioners or dentists for carrying out scheduled medical procedures on patients, without lodging. Scheduled medical procedures covers a wide range of procedures of different risk levels. Risk of any procedure is defined by any one of the following three factors; Risk of procedures, risk of anaesthesia involved and patient's condition.

All day procedure centres must obtain a valid license, issued by the Hong Kong Department of Health, before performing any procedures.

All clinics and health services establishments must obtain a valid license or letter of exemption, issued by the Hong Kong Department of Health, before performing any procedures.

Regulatory actions are considered when there is a breach of conditions of licence or CoPs. "Non-compliance" refers to unsatisfactory fulfilment or failure to meet the conditions of licence or requirements under the CoPs. PHFs are expected to take immediate actions to rectify non-compliances to mitigate risks to patient safety. If a PHF does not rectify the non-compliance within

the timeframe imposed or the rectification is unsatisfactory, regulatory actions may be escalated in accordance with the risk level.

For more information on regulations of PHF, refer to https://www.orphf.gov.hk/en/regulatory_regime/new_licensing_scheme_standards_for_private_healthcare_facilities

For more information on regulations of Cap. 633, refer to https://www.elegislation.gov.hk/hk/cap633

4. Chinese Medicine Ordinance (Cap. 549)

Activities or matters relating to Chinese medicines must comply to the standards and requirements of Cap. 549. Any activities involving the practise of Chinese medicine, storing, preparing, or dispensing of Chinese medicine must be licensed.

Chinese medicine practitioners should ensure that the environment and equipment used for the respective activity meet the required safety and hygiene standards. Based on the risk level of the proposed clinical intervention, the environmental requirements shall be reviewed on a case-by-case basis by HKSTP CREC.

For example, acupuncture should only be performed by a qualified acupuncture practitioner, a registered Chinese medicine practitioner by the Chinese Medicine Council of Hong Kong, in an environment where hygiene standards comply with the following requirements.

- The workplace for acupuncture should be clean, dry, well-ventilated and well-lit.
- There are sufficient facilities for hand hygiene in the workplace.
- All working surfaces should be smooth and impervious so that they could be cleaned and disinfected thoroughly.
- To keep the linen clean, soiled linen should be replaced immediately. Another option is to cover the treatment bed with single-use paper towel.
- Appropriate disinfectants should be chosen for environmental cleansing and disinfection.

For more details on the guidelines for performing acupuncture, refer to https://www.chp.gov.hk/files/pdf/proposed_guidelines_on_infection_control_related_to_acupuncture.pdf

For more details on the Chinese Medicine Ordinance (Cap. 549), refer to https://www.elegislation.gov.hk/hk/cap549

5. Pharmacy Requirements

A clinical research project that requires procurement, storage or prescribing of drugs (referring to substances and pharmaceutical products are regulated under the Pharmacy & Poisons Ordinance & Regulations (Cap. 138) and the Antibiotics Ordinance (Cap.137)) must be managed and performed by a licensed/registered Pharmacist. The licensed/ registered Pharmacist shall be responsible of activities including but not limited to receiving, storing, preparing, dispensing, and final disposition of study products for clinic research studies.

6. Equipment Requirements

All equipment used to conduct or provide assistance to support the research protocol must be in functional-state and can generate reliable data. A maintenance records shall be made readily accessible and retained through the entire project period.

6.1 Radiocommunications Medical Apparatus

Radiocommunications medical apparatus or any apparatus emitting radio frequency energy must comply with the Telecommunication Ordinance (Cap. 106). Possession and use of such radiocommunications apparatus must be covered by an appropriate licence issued by the Telecommunications Authority (TA) with the exception of those specifically exempted from licensing under the Cap. 106.

For more information on Cap. 106, refer to
https://www.elegislation.gov.hk/hk/cap106Z?xpid=ID_1438402553248_002

For more information on license registration for Industrial Scientific and Medical Electronic Machines (ISMEM), refer to
https://www.ofca.gov.hk/en/consumer_focus/guide/help_for_consumers/information_on_radio_applications/industrial_scientific_and_medical_electronic_mach/index.html

6.2 Irradiating Apparatus

All activities involving ionising radiation must comply with the Radiation Ordinance (Cap. 303). Possession and use of such irradiating apparatus must be covered by an appropriate licence issued by the Radiation Board of Hong Kong. Companies possessing any irradiating apparatus are responsible for provide a safe environment that is formally designed to maintain control over the source of exposure and to protect all workers who are occupationally exposed. Referring to the radiation health publications series issued by the Hong Kong Department of Health, the work area for the irradiating apparatus should comply with the following requirements.

- For fixed installations, the entire work area should be a controlled area (unless the irradiating apparatus is switched off from the electrical main supply).
- For mobile or portable installations, working procedures should be established to control access to the vicinity of the irradiating apparatus and the temporary controlled area. Assessment should be conducted to determine if additional temporary shielding is required to protect staffs in nearby areas.
- Entrance of the controlled area should be marked with appropriate warning notice and radiation warning sign.
- Information such as, why the area is controlled, under what circumstances is entry permitted, etc., should be available.
- A supervised area is required to be set up with the aim of ensuring that the doses (expected levels of exposure and of the likely variations in these exposures) to workers can confidently be predicted to be less than 3/10 of the occupational dose limit.

No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to the society to offset the radiation detriment caused. In relation to

any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposure where these are not certain to be received should all be kept as low as reasonable achievable, economic and social factors being taken into account.

For more information on the Radiation Health Publications Series from Hong Kong Department of Health, refer to https://www.rhd.gov.hk/en/infopub/infopub.html

For more information on license registration for Irradiating Apparatus License, refer to https://www.rbhk.org.hk/eng/la-IA.html

6.3 Possession of Dangerous Goods

Manufacture of dangerous goods ("DG") in any quantity or storage, conveyance or use of DG exceeding the Exempt Quantity ("EQ") must possess a valid dangerous good licence issued by the Hong Kong Fire Services Department ("FSD") and comply with the Dangerous Goods Ordinance (Cap. 295).

Table 1: Classification of Dangerous Goods

Category	Properties
1	Explosives and Blasting Agents
2	Compressed Gases
3	Corrosive Substances
4	Poisonous Substances
5	Substances giving off inflammable vapours
6	Substances which become dangerous by interaction with water
7	Strong supporters of combustion
8	Readily combustible substances
9	Substances liable to spontaneous combustion
10	Other dangerous substances

DG that are incompatible to each other should be stored separately. It is a requirement for storage locations of DG to be labelled "Hazardous Area", research teams are also required to submit details (such as layout plans, etc.) to FSD for assessing whether the proposed use area for DG is reasonable and safe.

For more details on the requirements for Dangerous Goods, refer to https://es.hkfsd.gov.hk/dg/en/

7. Environmental Monitoring

Proper environmental monitoring shall be conducted to ensure appropriate environment throughout the facility, especially on any biospecimens/ aliquots testing or storage unit or area, for the entire project duration.