Joint CUHK-NTEC Clinical Research Pharmacy

The Joint CUHK-NTEC Clinical Research Pharmacy (CRP) has been established under the Joint CUHK-NTEC Clinical Research Management Committee (CRMC) in April 2015 to ensure safe and quality management of Investigational Medicinal Product (IMP) for non-phase 1 clinical trials conducted in Prince of Wales Hospital.

Governance Structure of CRP

CUHK Faculty of Medicine

HA-NTE Cluster Management Committee

CUHK Research Committee

↓

CUHK-NTEC Clinical Research Management Committee

↓

CUHK-NTEC Clinical Research Pharmacy

CRP is located at the G/F of the Day Treatment Block and Children Wards. The premises is secured with burglar alarm system and restricted access control. The environment is air-conditioned with continuous temperature and humidity monitoring and alert system. It is equipped with pharmaceutical refrigerators and freezer; and a biological safety cabinet for aseptic reconstitution of parenteral preparations. A tailored computer system has been developed for efficient IMP inventory management, dispensing and finance reporting. The operation of CRP is supervised by pharmacists with appropriate certification on Good Clinical Practice (GCP).

CRP offers coordinated IMP management in compliance with GCP and requirements from regulatory authorities. Scope of service includes professional advice on regulatory and contractual requirements on IMP management; coordination on study monitoring visits/audits or inspections by accreditation or regulatory authorities; and effective IMP inventory management and dispensing with accurate and confidential keeping of all documents and records.

CRP –Scope of Service

IMP involved in all new trials and on-going trials with remaining patient recruitment period longer than 1 year should be managed by the CRP. Charging on cost recovery basis for the IMP management will be applied to maintain the efficient operation of the pharmacy. The standardized charging model in HA hospitals comprises of three major components – start-up fee, annual management fee, and dispensing/ reconstitution fee. An agreement for the delegation of IMP management in clinical trial to CRP is arranged and signed by the Principal Investigator (PI) and the Pharmacist In-charge of CRP before initiation of the study. Principal investigators are recommended to approach CRP in the early stage of planning of a clinical trial for assessing the feasibility of IMP management by CRP especially for the products requiring special storage condition or reconstitution. For further information, please visit CRMO website at www.crmo.med.cuhk.edu.hk or contact Dr. Grace Chan, senior pharmacist of CRP at cmc261@ha.org.hk.

Standardized Charging Model in HA Hospitals