Ref_____

新界東醫院聯網
NEW TERRITORIES EAST CLUSTER

Application for Conducting Clinical Trial /Research Involving Patients in NTEC

Part I: To be completed by applicant

A. Project Title or Short Title (if any): _____

_____

B. Study Protocol No.: _____

C. CREC Ref. No. : _____

D. CFDA Study : Y☐ _____ N☐

(please provide CFDA Clinical Trial Permit no.)

E. Name of Principal Investigator (PI): _____

F. Staff Status: HA/CUHK G. Department/Hospital: _____

H. Anticipated Start Date: _____ *(Clinical Trial can only be started upon approval given.)*

I. Planned End Date: _____

J. Documents Required (Please tick and attach):

- ☐ Clinical Research Ethics Committee Approval (Mandatory)
- ☐ Clinical Trial Certificate
- ☐ copies Indemnity Form for Sponsored Trials *(can be submitted separately for process)*
- ☐ Memo from CRMO confirming the coverage of clinical trial insurance, or Clinical Trial Insurance Certificate *(for investigator-sponsored trials only)*
- ☐ Undertaking with Clinical Research Pharmacy (CRP) *(for PWH only -- when applicable)*

K. Working Hours Involved in Conducting the Clinical Trial/ Research: *(attach additional sheet if required)*

Name of HA staff involved *(HAHO HR Circular 4/2003 refers)* *Not applicable for University staff*	Rank	Expected number of hours spent per week in conducting the research/ trial	
		During working hours	Outside working hours

Submitted by:

Signature of PI: _____ Date: _____

Contact Nos: _____ E-mail: _____

Part II: To be completed by COS/Director/Head of Department

I support the research / clinical trial commitment listed above for HCE approval and consider that service delivery of my department will not be unduly affected.

Name: _____ Signature:_____

COS in _____ , _____Hospital Date:_____

Part III: To be completed by HCE /Delegate

Application is approved / not approved Remarks:_____

Signature:_____ Date:_____

Prinicipal Investigators should complete this form together with the required documents(s) and send to General Office of their respective hospitals for processing (except for PWH: please send to Clinical Research Management Office (CRMO), 8/F Lui Che Woo Clinical Sciences Building, PWH for processing).

cc AHRM4/ HR NTEC Apr 2019