

Workshop on Hospital Approval of Clinical Trials

26 Jun 2015



香港中文大學醫學院
Faculty of Medicine
The Chinese University of Hong Kong



Before study starts.....

CREC approval

What?

What? A screenshot of a Clinical Research Ethics Committee (CREC) approval form. The form is titled "Application for Conducting Clinical Trial (Research Involving Patients in N/TEC)". It includes fields for:

- Title:** To: Prof. [Name], Dept. of Clinical Oncology, [Hospital Name]
- Study Title:** A phase III clinical trial of [Drug Name] in combination with [Drug Name] and [Drug Name] in the treatment of [Cancer Type] with [Biomarker] positive, [Biomarker] negative locally advanced or metastatic breast cancer.
- Investigators:** [Name], [Name], [Name], [Name], [Name], [Name], [Name], [Name]
- Co-investigator:** A copy of Clinical Trial Certificate is required to submit to CREC before the start of clinical trial.
- Remarks:**
 - 1) Safety Form to be signed by N/TEC, CRMB and HA.
 - 2) Researcher's name shall printed from 10 August 2017 until the end of the official email signature. 31 August 2015.
 - 3) Competence Form as required is attached.

Why?

How?

Hospital approval

How? A screenshot of a hospital approval form titled "Application for Conducting Clinical Trial (Research Involving Patients in N/TEC)". The form includes:

- Section I: Information to be completed by applicant.**
 - A. Project Title or Short Title of Project
 - B. Study Protocol No.
 - C. CREC No.
 - D. Name of Principal Investigator (PI)
 - E. PI's Name
 - F. Department/Hospital
 - G. Anticipated Start Date
 - H. Planned End Date
 - I. Researcher's Expertise (Please tick all that apply):
 - Clinical Research Ethics Committee Approval (Mandatory)
 - Clinical Trial Certificate
 - Inpatient Industry Form for Sponsored Trials (only for submitted separately documents)
 - Mean Body Faculty & Students Office (TPO) conducting the research of clinical trial research, or Clinical Trial Institute Certificate (or research-conducting permit)
 - Undergoing main Clinical Research Pharmacy (CRP) for PRM only - when available and applicable
- Section J: Working Hours Involved in Conducting the Clinical Trial (Mandatory - please adhere strict if required)**

Name of PI's staff involved (NAME AND GRADE - ONLY English)	Rank	Expected number of hours spent per week on conducting the research/ trial	Time working hours	Outside working hours
- Section K: Declaration by PI.**
 - Name of PI: _____ Date: _____
 - Contract No: _____ Date: _____
 - Signature of PI: _____ Date: _____
- Section L: Declaration by N/TEC.**
 - Name: _____ Signature: _____
 - LOS as: _____ Hospital: _____ Date: _____
- Section M: Declaration by HCR (Mandatory)**
 - Applicable as approved / not approved
 - Signature: _____ Remarks: _____
 - Date: _____

Before study starts.....




Clinical Research Management and Compliance at Study Sites - HAHO 2010 (http://www.ha.org.hk/ho/research_ethics/ha_handbook.pdf)

- 5.2.1HA has established a **two-tier** structure for governance of clinical research, including:
 - (a) Management governance by cluster/institution management; and
 - (b) Research ethics governance by RECs.
- 5.2.3 Any clinical study undertaken by any HA institution and/or its employees, officers and appointees under the HA's employment/appointment is subject to **initial management approval** and **continuous** review and supervision by the management of the institution at where the study site is located.
- 5.4.1 **Departmental management** is responsible for overseeing the clinical management, resources management and risk management aspects of clinical studies on departmental level.

NTEC Policy and CRMO SOP for Hospital approval

Policy on Clinical Research (Mar 2011)



**Hospital Authority New Territories East Cluster
Cluster Management Committee (CMC)**

Policy on Clinical Research

Document Number NTEC-CMC-A-001-V1	Date 24 March 2011
Prepared by Dr. Li Chi Kong, PWTC(CS)/PWHPAED COS(PAED)	Approved by Cluster Management Committee

1. Objective
To ensure safe conduct of clinical research in according to laws and regulation.

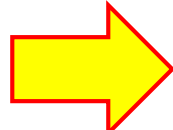
2. Scope
All clinical research involving patients of NTEC hospitals.

3. Policy


- 3.1 The research must be supported by COS of the concerned department.
- 3.2 Approval from NTEC-CUHK Clinical Research Ethics (CREC) Committee.
- 3.3 After obtaining CREC approval, Principal Investigator (PI) should apply for hospital approval via COS.
- 3.4 PI should submit relevant documents and information to HCE for approval including CREC approval letter, Clinical Trial certificate if required (such as unlicensed and off-label indication), application form on working hours to conduct research, planned starting and end date, and estimated sample size.
- 3.5 Study initiation is only allowed after HCE approval.
- 3.6 For sponsored trials, the following document should be submitted in addition to 3.4:
 - 3.6.1 For HA staff, PI submits Clinical Trial Agreement through hospital administration to HA Legal Division for vetting. (University staffs will submit Clinical Trial Agreement to university Technology & Licensing Department for vetting).
 - 3.6.2 Hospital Administration will check whether the submitted Indemnity Form follow the standard HA template, if not, then legal vetting is required.
 - 3.6.3 For PI being HA staff, they should submit ASOI application via Finance to CCE for the sponsorship.

Controlled Version on [iCompliance](#)

Hard Copy for Reference Only



CRMO-SOP-018



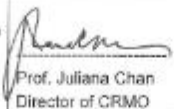
The Chinese University
of Hong Kong

**Joint CUHK-NTEC
Clinical Research Management Committee
Clinical Research Management Office**



New Territories East
Cluster

Standard Operation Procedure for Hospital Approval on Clinical Studies

DOCUMENT PARTICULARS	
Document No.	CRMO-SOP-018-V2
Version No.	2
Issue Date	26 AUG 2014
Effective Date	01 SEP 2014
Author(s)	Ms. Iris CHAN
Authorized by: Name/Title/Signature	 Prof. Juliana Chan Director of CRMO


This Standard Operating Procedure (SOP) is an official document outlining how a policy is to be implemented with the outline of necessary procedures, which has been approved by the Director of Clinical Research Management Office (CRMO) and endorsed by the Joint NTEC Clinical Research Management Committee (CRMC).
Copyright by CRMC/CRMO 2014

CRMO-SOP-018-V2 (SOP for Hospital Approval on Clinical Studies)
Effective Date: 01 SEP 2014
CRMO email address: crmo@cuhk.edu.hk

Page 1 of 7

Application Form for Hospital Approval

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. CTEC Ref No.: _____

A proof to show your good practice in complying with regulation!

Part II: To be completed by COS/Instructor/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 /Delegated

Application is approved / not approved _____ Remarks: _____
Signature: _____ Date: _____

Principal Investigators should complete this form together with the required document(s) and send to General Office of their respective hospital for processing (except for PWH, please send to Clinical Research Management Office (CRMO), 8/F Tai Che Wan Clinical Science Building, PWH for processing).

© AHRM/HR NTEC Sept 2014

Documents for Hospital Approval- CREC approval letters

I. 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 Faculty & Planning Office (FPO) 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 available and applicable*)

**Joint Chinese University of Hong Kong-New Territories East Cluster
Clinical Research Ethics Committee**
香港中文大學-新界區醫務院 臨床研究倫理 聯合委員會

The HC, Block B, Staff Quarters, Wilson Hospital, Sha Tin, NT
Tel: (852) 2632 8931 / 2194 1936 Fax: (852) 2632 4623 Website: <http://www.crc.edu.hk>

To: Prof. Brigitte Day, MEd (Principal Investigator) 20 August 2017
Dept. of Clinical Oncology
Wilson Hospital

Ethics Approval of Research Protocol

CREC Ref No.: CR08-001390-0
Date of Approval: 20 August 2017
Protocol No.: CR20170109
Study Title: A phase II/III trial of LBB931 in combination with everolimus (RAD001) and exemestane in the treatment of postmenopausal women with estrogen receptor positive, HER2 negative locally advanced or metastatic breast cancer
Investigator(s): Brigitte Day, MEd, Wilson YEI, Stephen Lee, CHAN, Wing Wah, MD, Joyce K.S. SEW and Sun Wai LAM
Condition(s): A copy of Clinical Trial Certificate is requested to submit to CREC before the start of the study.
Remark(s): 1) Indemnity Form to be signed by WHO, CREC and HSA.
2) Sponsor's source study period from 20 August 2017 until the end of the relevant trial (approx. 28 August 2019)
3) Compliance Form as required is attached.

I write to inform you that ethics approval has been given for you to conduct the registered study in accordance with the following document(s) reference:

- Clinical Trial Protocol, Protocol Number: CR20170109, Protocol Number 09, Sha Tin Site 1 (Sep 2017)
- Investigator's Brochure for LBB931, Volume 1, Sha Tin Site Wilson (2017)
- Investigator's Brochure for RAD001, Volume 1, Sha Tin Site 1 (14 Nov 2017)
- Letter from Sponsor dated 28 May 2017, Re: Approval/Refusal (CR20170109) Investigator's Brochure Volume 1 of protocol
- Patient Information and Informed Consent, English Version
(Sha Tin) 2 (Phase II/III study) CR20170109-001 (20170109) (20170109)
- Patient Information and Informed Consent, Chinese Version
(Sha Tin) 2 (Phase II/III study) CR20170109-001 (20170109) (20170109)
- LBB931 in Combination with Exemestane (Hong Kong) - Protocol CR20170109, English Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)
- LBB931 in Combination with Exemestane (Hong Kong) - Protocol CR20170109, Chinese Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)
- LBB931 in Combination with Everolimus (RAD001) and Exemestane (Hong Kong) - Protocol CR20170109, English Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)
- LBB931 in Combination with Everolimus (RAD001) and Exemestane (Hong Kong) - Protocol CR20170109, Chinese Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)
- Everolimus (RAD001) in Combination with Exemestane (Hong Kong) - Protocol CR20170109, English Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)
- Everolimus (RAD001) in Combination with Exemestane (Hong Kong) - Protocol CR20170109, Chinese Version
(Sha Tin) - Patient Study 2 - CR20170109-001 (20170109) (20170109)

Documents for Hospital Approval- Clinical Trial Certificate (for drug studies)

I. 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 Faculty & Planning Office (FPO) 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 available and applicable*)

No. _____
編號 _____

[Regulation 36B(3)]
[第36B(3)條]

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例
(Chapter 138)
(第138章)

PR/CT 0295/2016 (SC)
CERTIFICATE FOR CLINICAL TRIAL / MEDICINAL TEST*
臨床試驗 / 藥物測試 * 證明書

It is hereby certified that
茲證明
..... is authorized, subject to the conditions endorsed hereon, to establish a clinical trial on human beings
..... 獲准在 人體進行臨床試驗 / 藥物測試，且須受此處所訂列之條件所限制。


..... in respect of
..... 關於
.....
.....
.....

to be conducted by J. Dr.
由 醫生進行臨床試驗 / 藥物測試，且須受
.....
.....
.....

2. This certificate will be valid until 2021
本證明書的有效期至 2021 止。

Hong Kong.
香港

..... 2016 (Date)
..... (日期)


(V. F. YEUNG)
For Pharmacy and Poisons Board (代行)
藥劑業及毒藥管理局

CONDITIONS
條件

1. The holder of the Certificate is required to submit local drug related safety reports, yearly progress reports, final study report of the clinical trial in accordance with the "Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial" issued by the Drug Office.
證明書持有人須按照藥物辦公室發出的《關於本地藥物安全事故報告、進度報告及臨床試驗最後研究報告呈報規定的通知》，提交與本地藥物有關的安全事故報告、年度進度報告及臨床試驗最後研究報告。

CTMT09 (Feb 2015)

Documents for Hospital Approval- Clinical Trial Certificate (Updates)

- With effective from 6th February 2015
 - Extend the validity of clinical trial certificate from not exceeding **2 years** to not exceeding **5 years**
 - Provision of a **sample** of the product or substance is **no longer required** for the application
 - A person **must not conduct** a clinical trial on human beings/medicinal test on animals, or cause or permit such a trial/to be conducted, **except in accordance with a Clinical trial/Medicinal Test Certificate (CTC)** issued to the person. Any person who contravenes the above **commits an offense and is liable to a fine** at level 2 (currently HK\$ 5,000)

Documents for Hospital Approval- Indemnity Form (for sponsored trials)

I. 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 Faculty & Planning Office (FPO) 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 available and applicable*)

Sponsor/HA (11/10/01)

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

Name of Company: _____

Address: _____

Fax No.: _____

Sponsor/University/HA (11/10/01)

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

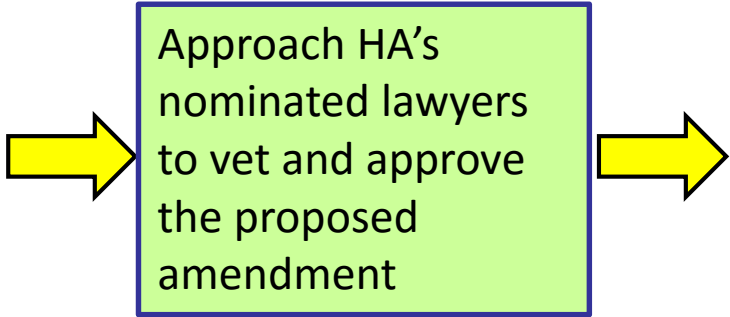
Name of Company: _____

Address: _____ (the "Sponsor")

Fax No.: _____

Documents for Hospital Approval- Indemnity Form (for sponsored trials)

Can the clause of indemnity form be changed?



ABC company/ HA

ABC company/ University/ HA

Documents for Hospital Approval- Clinical Trial Insurance

I. 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 Faculty & Planning Office (FPO) 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 available and applicable*)

Faculty of Medicine
The Chinese University of Hong Kong
Clinical Trial Insurance - Application Form

I. Applicant's Section

Name of Principal Investigator: Dr. Z. Ho

Department: _____

Address: _____

Contact: _____ Tel: _____ Fax: _____

Email Address: _____

Project Title: _____

II. Payment Arrangement

Total Premium payable: HK\$ _____

By: _____ (HK\$1000)

* HK\$200 per day (for 100 subjects) / HK\$300 for 100-500 subjects, and no extra cost for more than 500 subjects.

(Total no. of subjects to be covered: _____)

Payment method by:

Cheque

Cheque No: _____

Bank: _____

Internal Transfer (NIBCEP 222514)

(Please complete the account details)

* Payment will only be effected upon acceptance from Insurer.

1. I hereby confirm that the proposed trial has not been accepted by any other committee in any territory.

2. I hereby certify the correctness of the above mentioned information.

3. I have read and understood the prevailing CUHK policy, terms and conditions for Clinical Trial Insurance and shall abide by these policies and any subsequent amendments thereto.

Applicant's signature: _____ Date: _____

III. Clinical Research Ethics Committee's Section

Approved by CREC Committee: Yes No

Protocol No: _____ CREC Ref No: _____

Authorized Chair and signature: _____ Date: _____

IV. Faculty's Section

Individual confirmation will be sent to applicant upon acceptance from Insurer.

Date of receiving the form: _____

(17) Update: Form 10a (01)

香港中文大學
The Chinese University of Hong Kong

醫院管理局
Hospital Authority
New Territories East Cluster

THE CHINESE UNIVERSITY OF HONG KONG
FACULTY OF MEDICINE
JOINT CUHK-NTEC CLINICAL RESEARCH MANAGEMENT OFFICE

8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, N.T., Hong Kong

Tel: (852) 2632 4276 Fax: (852) 2632 4794 Website: <http://www.crmc.med.cuhk.edu.hk> Email: crmo@cuhk.edu.hk

Transforming our Passion into Perfection

Memo

To : Prof. XXX

From : Ms. Iris CHAN, Managing Director of CRMO

Date : 29 April 2015

RE : Your application for Clinical Trial Insurance

I am pleased to inform you that your following project was confirmed coverage by the insurance company:

Our Ref No.	Project Title	CRE Ref No.	No. of Human Subjects
SU15999	ABC project	2014.999	60

The payment will be arranged by internal transfer accordingly. Thank you.

Iris CHAN

- Investigators should assess the risk level of their trials and decide whether or not to join the scheme.
- Previously applied via FPO
- Currently apply via CRMO

Documents for Hospital Approval- Undertaking with CRP (for drug studies)

I. 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 Faculty & Planning Office (FPO) 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 available and applicable*)

Joint CUHK-NTEC Clinical Research Pharmacy

Agreement for Delegation of Management of Investigational Medicinal Products in Clinical Trial

Effective Date :	DD-MM-YYYY
Clinical Trial :	
Trial number :	
Principal investigator :	
Site :	

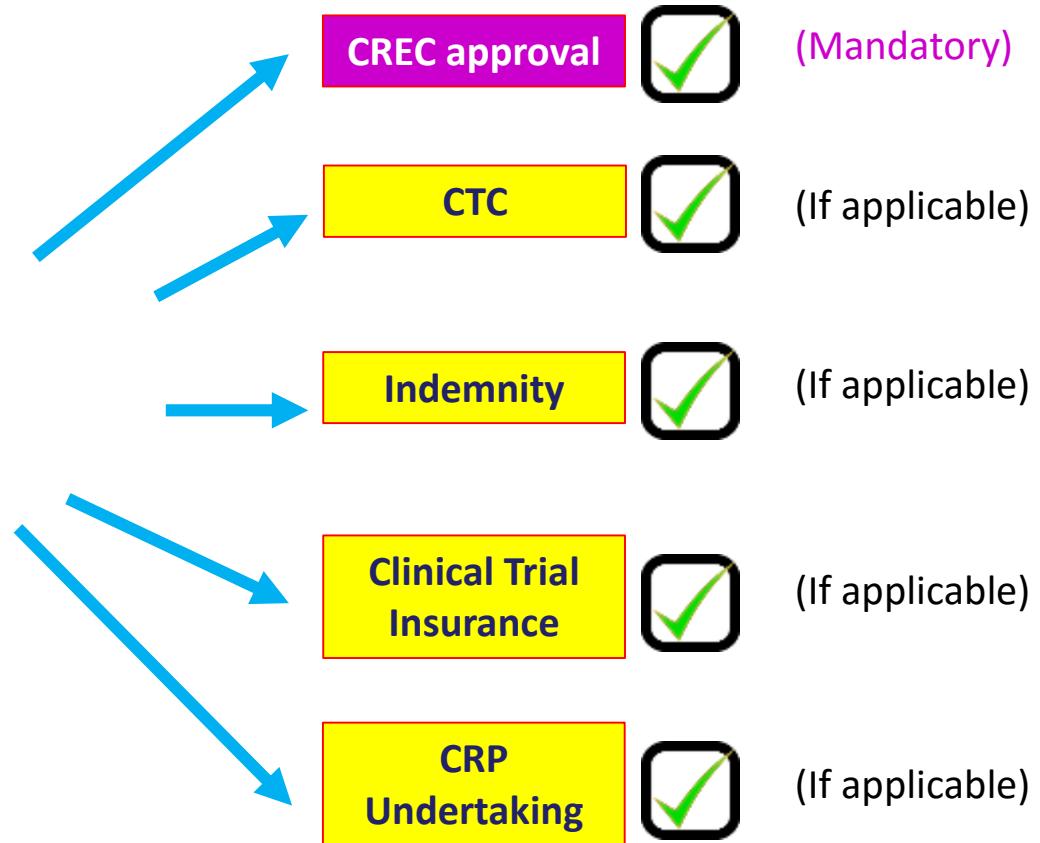
1. This Agreement sets forth the terms pursuant to the delegation of the management of Investigational Medicinal Product(s) (IMPs) in non-phase I clinical trials to the Joint CUHK-NTEC Clinical Research Pharmacy (CRP)
2. The ultimate accountability of the IMP and its management rests on the Principal Investigator (PI) of the clinical trial
3. The PI agrees to delegate the management of the IMP and concomitant medication(s) under the study protocol to CRP
4. The PI has the responsibility to acknowledge the sponsor about the IMP management by CRP
5. The CRP manages IMPs in compliance with the requirements in clinical trial protocol as well as the laws, regulations, and guidelines applicable to the conduct of research in Hong Kong
6. The CRP maintains accurate records of receipt, supply, return, and disposal of IMPs. The inventory records must be made available for inspection by the PI, sponsor authorized representative(s), and regulatory authorities
7. The CRP observes relevant policies and regulations to ensure confidentiality of the data and information in the clinical trial
8. The PI shall notify CRP if the clinical trial is completed or terminated for any reason upon not less than seven working days written notice. All unused or patient returns of IMPs and concomitant medication under study protocol should be collected by the PI or sponsor
9. The PI shall notify CRP of any amendment in the study protocol upon not less than seven working days written notice
10. If for any reason, the PI is unable to continue to serve as PI, he/she will, within seven working days of knowledge of such event, provide written notice to CRP. The successor of the PI will be required to agree to all terms and conditions of this Agreement by his/her signing
11. For Company Sponsored Trials (CST), the PI agrees or shall arrange with the sponsor to pay for the service provided by CRP in accordance to the charging model set out in appendix A.

- Please contact Clinical Research Pharmacy (CRP):
 - Dr. Grace Chan, Senior Pharmacist: cmc261@ha.org.hk
 - Tel: 2632-4285

Documents for Hospital Approval



Principal Investigator (PI)



Application Form for Hospital Approval

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

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



During Study

Re-apply !

- Change PI
- Add Co-I (HA)
- Change Study Title
- Change Protocol No.



Ref: CT-1-10015

NEW TERRACES 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): Application for conducting research on the effect of the x-ray on the skin of the human back in the elderly population

B. Study Protocol No.: _____ C. CRIC Ref No.: CRIC-1-1-1

D. Name of Principal Investigator (PI): J. H. H.

E. Staff Status: HA/CLINIC F. Department/Hospital: PRH

G. Anticipated Start Date: Jan 2015 (Clinical trial can only be started upon approval given)

H. Planned End Date: Dec 2017

I. Documents Required (Please tick and attach):

- Clinical Research Ethics Committee Approval (Mandatory)
- Clinical Trial Certificate
- copies indemnity forms for Sponsored Trials (use for insured separately for present)
- Memo from Faculty & Planning Office (FPO) confirming the coverage of clinical trial insurance, or Clinical Trial Insurance Certificate (for investigator-sponsored trials only)
- Undertaking with Clinical Research Pharmacy (CRP) (for FPO only - when available and applicable)

J. Working Hours Involved in Conducting the Clinical Trial/ Research (check additional sheet if required)

Name of HA staff involved (MAYO NR Circular 4/2003 apply) Not applicable for University staff	Rank	Expected number of hours spent per week in conducting the research/trial	
		During working hours	Outside working hours
Dr. J. H. H.	Specialist	0.5 hours	--

Submitted by: _____ Date: 21 Apr 2015

Signature of PI: _____
Contact No: 2632 1663 E-mail: john.yee@hkechk

Part II. To be completed by CRIC/Department/Local of Department

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

Name: Dr. Li Chi-ting Signature: _____
COS in: PRH Hospital Date: 22 APR 2015

Part III. To be completed by HCE/Delegate

Application is approved / not approved

Signature: Dr. Li Chi-ting Remarks: 4 MAY 2015
Date: _____

Prince of Wales Hospital
Principal Investigators should complete this form together with the required document(s) and send to General Office of their respective hospitals for processing (except for FPO, please send to Clinical Research Management Office (CRMO), 607 Lee Chee Clinical Research Building, PRH for processing).

cc: AHEAD@hke.ntec

Sept 2014

Contact Us!

PWH:

Email: crmo@cuhk.edu.hk

Tel: 2632 4276

Non-PWH:

General Office of your hospital

Examples

Hospital Approval

- | | | |
|---|------------|---|
| 1. A retrospective study of the efficacy of Metformin on Type 2 diabetes mellitus patients. | HA staff | x |
| | HA patient | ✓ |
| 2. An exercise habit survey in HK healthy primary school children. | HA staff | ✓ |
| | HA patient | x |
| 3. An apps program development for healthy diet plan | HA staff | x |
| | HA patient | x |

