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

醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Before study starts……

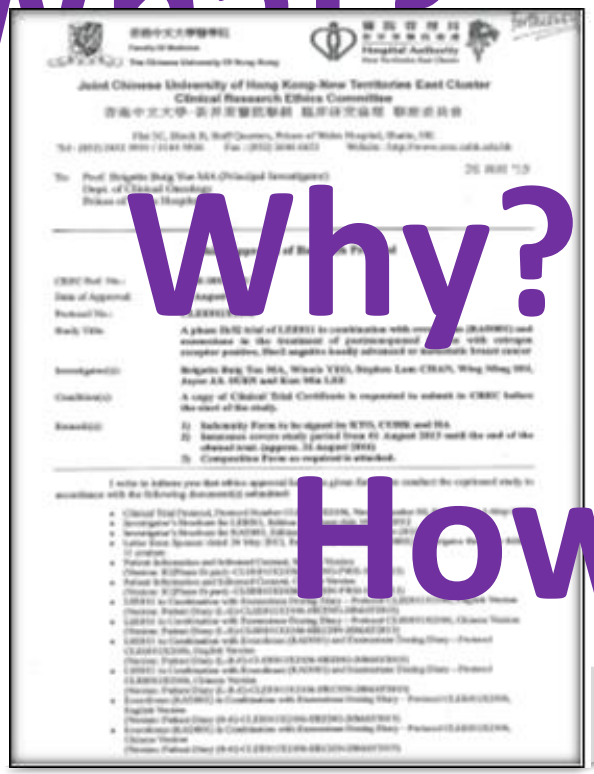
CREC approval

Hospital approval

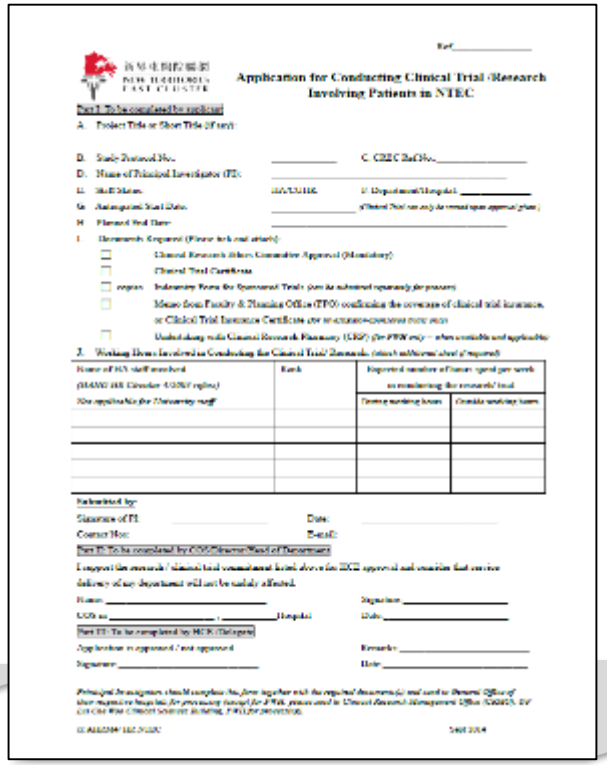
What?

Why?

How?



Joint Chinese University of Hong Kong-New Territories East Cluster
Clinical Research Ethics Committee



Application for Conducting Clinical Trial /Research Involving Patients in NTEC

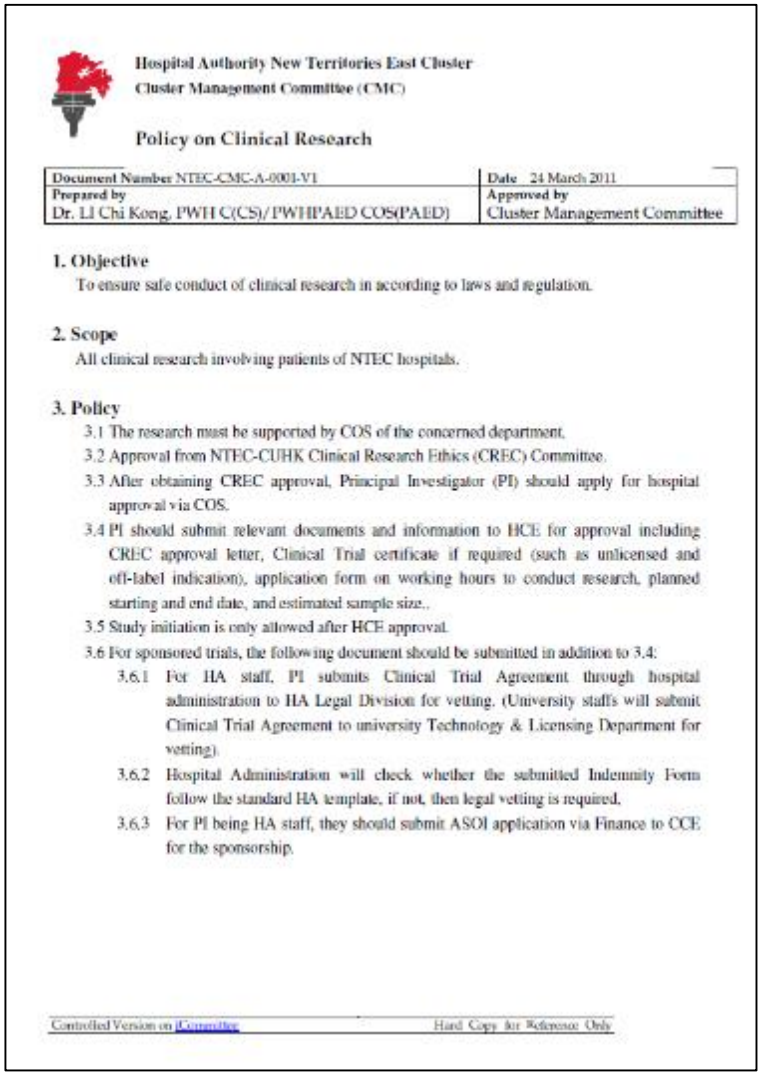
Before study starts……

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

- 5.2.1 ……HA 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-0001-V1	Date: 24 March 2011
Prepared by: Dr. LI Chi Kong, PWH C(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:

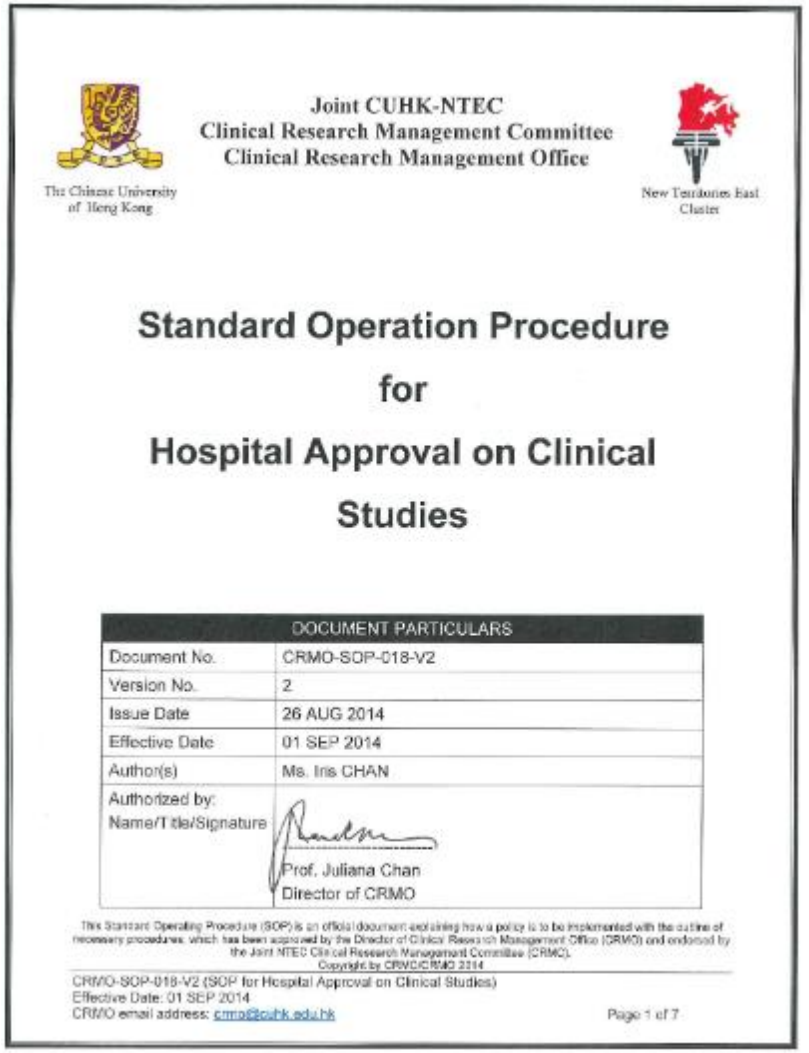
3.6.1 For HA staff, PI submits Clinical Trial Agreement through hospital administration to HA Legal Division for vetting. (University staffs will submit Clinical Trial Agreement to university Technology & Licensing Department for vetting).

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 iCommittee — 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 explaining 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).

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. CREC Ref No.:

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: _____

Principal Investigator should complete this form together with the required document(s) and send to General Office of their respective hospitals for processing (except for PWH: please send to Clinical Research Management Office (CRMO), 3/F Lui Che Woo Clinical Sciences Building, PWH for processing).

cc AHRM/ HR NTEC Sept 2014

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

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

Ethics Approval of Research Protocol

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*
臨牀試驗/藥物測試* 證明書

It is hereby certified that [illegible]
現證明 (Name and address 姓名或名稱及地址)
Fl [illegible] 3, 14/F & [illegible] ,HK

is authorized, subject to the conditions endorsed hereon, to establish a clinical trial on human beings/XXXXXXXXXXXXXXXXX in respect of
已獲准以

[illegible] Inj. 100mg/4mL ; [illegible] Inj. 500mg/vial ; [illegible] Inj. 100mg/16.7mL ; [illegible] Inj. 600mg/60mL***
(Name of product or substance 製品或物質的名稱)

to be conducted by 1. Dr. [illegible]
對人類進行臨牀試驗/XXXXXXXXXXXX，並且由 (Name(s) of person(s) concerned 有關的人的姓名或名稱)
at 1. Prince of Wales Hospital, NT
於 (Name and address of institution where applicable 機構的名稱及地址如適用的話)
進行，但須受本證明書上所批註的條件規限。

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

Hong Kong.
香港

[illegible] 2016 (Date)
(日期)

(Y. F. YEUNG) (代行)
for *Pharmacy and Poisons Board*
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、進度報告及臨牀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、年度進度報告及臨牀試驗最後研究報告。

CTMT09 (Feb 2015)

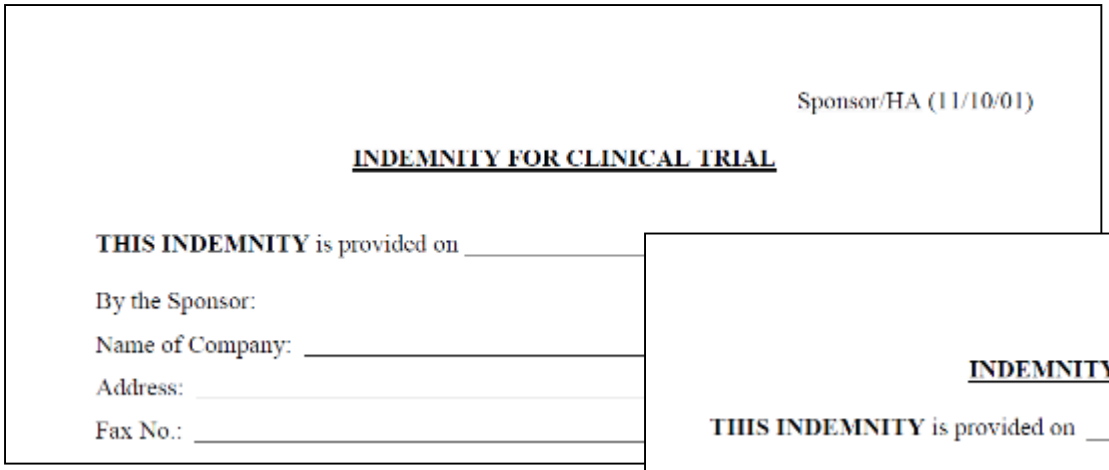
Documents for Hospital Approval- Clinical Trial Certificate (Updates)

- 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

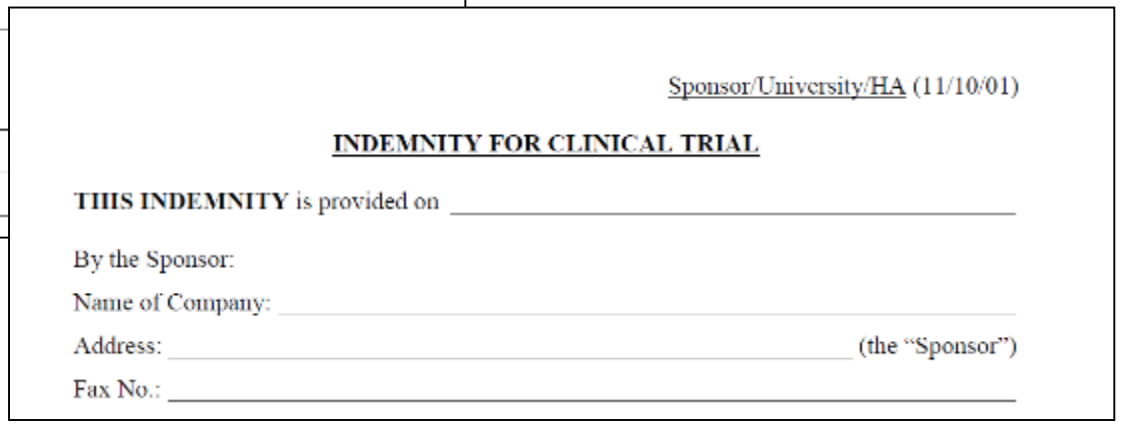
THIS INDEMNITY is provided on _____

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")

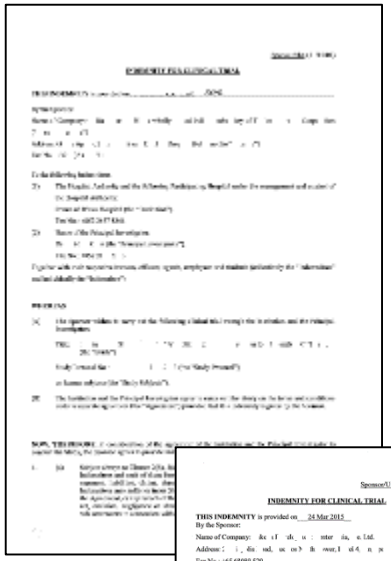
Fax No.: _____

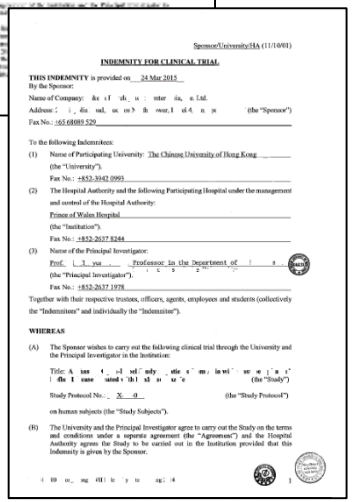
Documents for Hospital Approval- Indemnity Form (for sponsored trials)

Can the clause of indemnity form be changed?

Approach HA's nominated lawyers to vet and approve the proposed amendment

ABC company/ HA



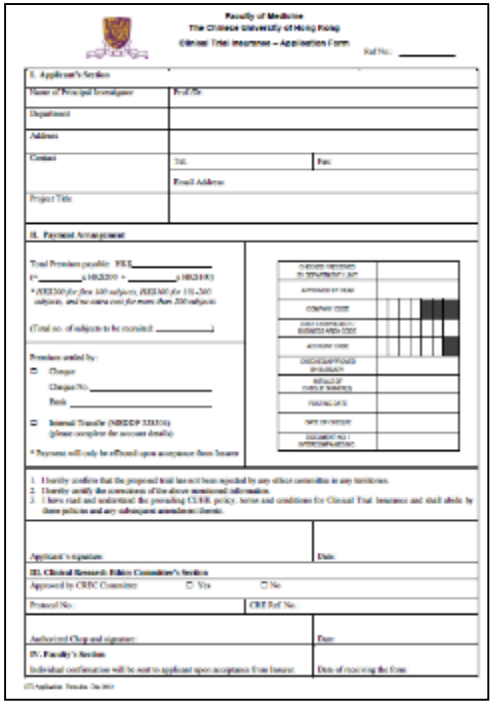


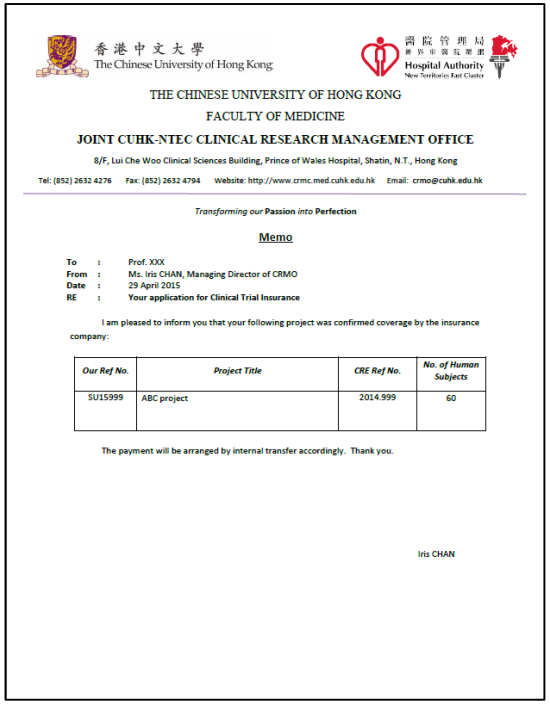
ABC company/ University/ HA

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)*





香港中文大學
The Chinese University of Hong Kong

醫院管理局
Hospital Authority

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.

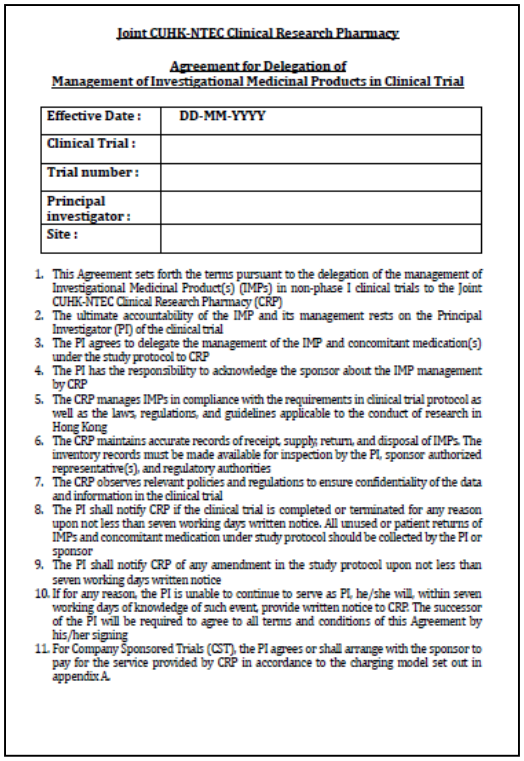
Iris CHAN

- 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)

- **CREC approval** ✓ (Mandatory)
- **CTC** ✓ (If applicable)
- **Indemnity** ✓ (If applicable)
- **Clinical Trial Insurance** ✓ (If applicable)
- **CRP Undertaking** ✓ (If applicable)

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 *(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

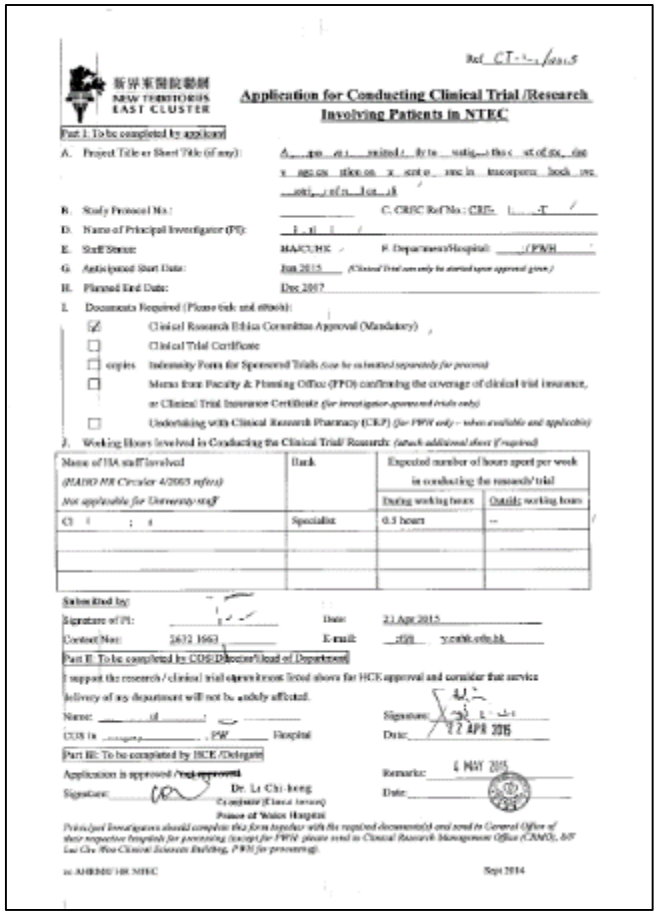
I support the research / clinical trial commitment listed above for HCE approval and consider that service delivery of my department will not be unduly affected.

Name: _____ Signature: _____

COS in _____ , _____Hospital Date: _____

SIGN HERE

Study Starts!



Ref CT-[illegible]/2015

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): [illegible]

B. Study Protocol No.:

C. CREC Ref No.: CRE- [illegible]

D. Name of Principal Investigator (PI): [illegible]

E. Staff Status: HA/CUHK / F. Department/Hospital: [illegible] /PWH

G. Anticipated Start Date: Jun 2015 *(Clinical Trial can only be started upon approval given.)*

H. Planned End Date: Dec 2017

I. Documents Required (Please tick and delete):

- ☑ 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)*

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

Name of HA staff involved *(HAHO HR Circular 4/2005 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
Cl [illegible]	Specialist	0.5 hours	--

Submitted by:

Signature of PI: [illegible] Date: 21 Apr 2015

Contact No.: 2632 1663 E-mail: [illegible]@ha.org.hk

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

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

Name: [illegible] of [illegible]

COS/Dir / [illegible] , PW Hospital

Signature: [illegible] Date: 22 APR 2015

Part III: To be completed by HCE /Delegate

Application is approved / ~~not approved~~

Signature: [illegible] Dr. Li Chi-keng Co-opted (Clinical Services) Prince of Wales Hospital

Remarks: [illegible] Date: 6 MAY 2015

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 PWH, please send to Clinical Research Management Office (CRMO), 6/F Lui Che Woo Clinical Sciences Building, PWH for processing).

cc AHHKH/HK NTEC Sept 2014

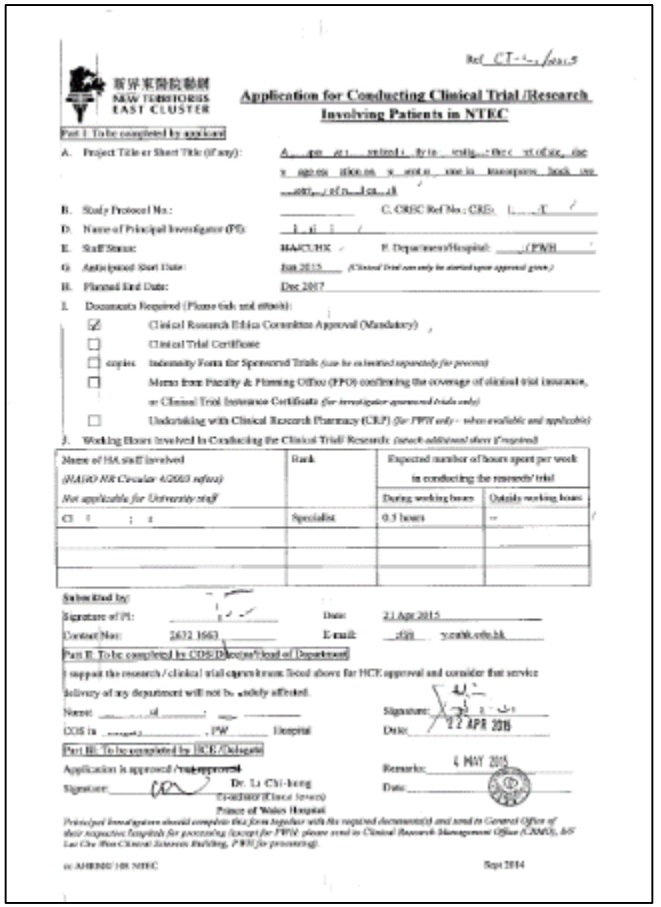
Endorsement:

- **COS/ Director/ Depart. Head** ☑
- **HCE** ☑

During Study

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

Re-apply !



Application for Conducting Clinical Trial /Research Involving Patients in NTEC

New Territories East Cluster

Part I: To be completed by applicant

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

B. Study Protocol No.:

C. CREC Ref No.:

D. Name of Principal Investigator (PI):

E. Staff Status: HA/CUHK

F. Department/Hospital: PWH

G. Anticipated Start Date: Jun 2015

H. Planned End Date: Dec 2017

I. Documents Required (Please tick and attach):

- ☑ Clinical Research Ethics Committee Approval (Mandatory)
- ☐ Clinical Trial Certificate
- ☐ copies Indemnity Form for Sponsored Trials
- ☐ Memo from Faculty & Planning Office (FPO) confirming the coverage of clinical trial insurance, or Clinical Trial Insurance Certificate
- ☐ Undertaking with Clinical Research Pharmacy (CRP)

J. Working Hours Involved in Conducting the Clinical Trial/ Research

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
CI	Specialist	0.5 hours	--

Submitted by:

Signature of PI: Date: 21 Apr 2015

Contact No.: 2632 1663 E-mail: ...@ha.org.hk

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

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

Name: ... Signature: ...

COS in ..., PW ... Hospital Date: 22 APR 2015

Part III: To be completed by HCE/Delegate

Application is approved / ~~not approved~~ Remarks:

Signature: Dr. Li Chi-hong Date: 4 MAY 2015

Chief Executive (Acting)

New Territories East Cluster

Prince of Wales Hospital

Principal Investigator should complete this form together with the required documents and send to General Office of their respective hospitals for processing (except for PWH, please send to Clinical Research Management Office (CRMO), 6/F Lui Che Woo Clinical Sciences Building, PWH for processing).

cc AHHOC/HR 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 ✗ HA patient ✓	
2. An exercise habit survey in HK healthy primary school children.	HA staff ✓ HA patient ✗	
3. An apps program development for healthy diet plan	HA staff ✗ HA patient ✗