

Hospital Approval of Clinical Trials



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

What?

Why?

How?

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. Name of Principal Investigator (PI): _____

E. Staff's status: HA/CUHK F. Department/Hospital: _____

G. Anticipated Start Date: _____ (Clinical Trial only to be started upon approval given)

H. Planned End Date: _____

I. Documents Required (Please tick and attach):

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

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

Name of HA staff involved (HA/HC HR Circular #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 No: _____ 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: _____

Principal Investigators should complete this form together with the required documents (a) and send to General Office of their respective hospitals for processing (except for PWH: please send to Clinical Research Management Office (CRMO), 8/F, Lee Chee Mooi Clinical Sciences Building, PWH for processing).

cc: AHRM/ HR NTEC Jun 2016

Hospital approval

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): _____

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D. Name of Principal Investigator (PI): _____

E. Staff's status: HA/CUHK F. Department/Hospital: _____

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Submitted by:
Signature of PI: _____ Date: _____
Contact No: _____ E-mail: _____

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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.
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COS in _____ Hospital Date: _____

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

Principal Investigators should complete this form together with the required documents (a) and send to General Office of their respective hospitals for processing (except for PWH: please send to Clinical Research Management Office (CRMO), 8/F, Lee Chee Mooi Clinical Sciences Building, PWH for processing).

cc: AHRM/ HR NTEC Jun 2016

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)

CRMO-SOP-018



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

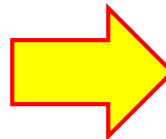
To ensure safe conduct of clinical research in according to laws and regulation.

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.



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
Version No.	02 (Addendum 01, effective on 01 Jun 2016)
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).
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

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 RefNo.: _____

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

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: _____

Principal Investigators should complete this form together with the required documents (6) and send to General Office of their respective hospitals for processing (except for FWH, please send to Clinical Research Management Office (CRMO), 8/F, Li She Woo Clinical Sciences Building, FWH for processing).

cc AHRM/HR/NTEC Jun 2016

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 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*)

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

醫院管理局
Hospital Authority
New Territories East Cluster

聯合中文大學及新界東醫院聯網臨床研究倫理委員會
Joint Chinese University of Hong Kong-New Territories East Cluster
Clinical Research Ethics Committee
聯合中文大學-新界東醫院聯網臨床研究倫理委員會

The HC, Block B, Staff Quarters, Area of Wilks Hospital, Shatin, ND
Tel: (852) 2632 8000 / 2194 1930 Fax: (852) 2638 4652 Website: <http://www.crc.hk/ethics>

To: Prof. Brigitte Day Yau MEd (Principal Investigator) 20. 08. 2017

Dept. of Clinical Oncology
Wilks of Wilks Hospital

Ethics Approval of Research Protocol

CREC Ref No.: 4388-0014-000-0
Date of Approval: 23 August 2017
Protocol No.: CR201701004
Study Title: A phase II/III trial of LBB251 in combination with everolimus (RAMBO) and exemestane in the treatment of postmenopausal women with estrogen receptor positive, HER2 negative locally advanced or metastatic breast cancer

Investigators: Brigitte Day Yau MEd, Wilson YF Li, Stephen Lee CHAN, Wing Wah Wai, Joyce K.S. SEW and Sam Wai LAM
Condition(s): A copy of Clinical Trial Certificate is requested to submit to CREC before the start of the study.
Remarks: 1) Indemnity Form to be signed by WHO, CRMO and HA.
2) Sponsor's cover study period from 23 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:

- 1. Clinical Trial Protocol, Protocol Number: CR201701004, Protocol Number: 00, Submission 1 (May 2017)
- 2. Investigator's Brochure for LBB251, Volume 1, Submission 1 (May 2017)
- 3. Investigator's Brochure for RAMBO, Volume 1, Submission 4 (14 Nov 2016)
- 4. Letter from Sponsor dated 28 May 2017, Re: Approval/Refusal (CR201701004) Investigator's Brochure Volume 1 of 1 (copy)
- 5. Patient Information and Informed Consent, English Version
- 6. Chinese 2 (Phase II study): CR201701004-000-0 (CR201701004-000-0)
- 7. Patient Information and Informed Consent, Chinese Version
- 8. Chinese 2 (Phase II study): CR201701004-000-0 (Phase II study)
- 9. LBB251 in Combination with Everolimus (RAMBO) and Exemestane (RAMBO-EE) Study - Protocol (CR201701004, English Version)
- 10. LBB251 in Combination with Everolimus (RAMBO) and Exemestane (RAMBO-EE) Study - Protocol (CR201701004, Chinese Version)
- 11. LBB251 in Combination with Everolimus (RAMBO) and Exemestane (RAMBO-EE) Study - Protocol (CR201701004, English Version)
- 12. LBB251 in Combination with Everolimus (RAMBO) and Exemestane (RAMBO-EE) Study - Protocol (CR201701004, Chinese Version)
- 13. LBB251 in Combination with Everolimus (RAMBO) and Exemestane (RAMBO-EE) Study - Protocol (CR201701004, English Version)

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 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*)

No. _____
編號 _____


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
(Name and address of sponsor or sponsor's agent)
T. O. 2. S. S. D. C. (HK)
is authorized, subject to the conditions endorsed hereon, to establish a clinical trial on human beings ~~medicinal product~~
in respect of
已獲准以
.....
100mg/4ml; Inj. 500mg/vial; i. 100mg/1.6.7ml; Inj.
600mg/60ml*** (Name of product or substance) (中文名稱或物質名稱)

to be conducted by J. Dr.
對人類進行臨床試驗 / 藥物測試 * 並且由
(Name of person(s) concerned) (姓名或姓名名稱)
at J. Prince of Wales Hospital, ST.
於
(Name and address of institution where applicable) (名稱及地址或地址名稱)
進行, 但須受本證明書上所註的條件規限。
2. This certificate will be valid until 2021
本證明書的有效期至 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 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*)

Sponsor/HA (Jan 2016)

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

Name of Company: _____

Address: _____

Fax No.: _____

Sponsor/University/HA (Jan 2016)

INDEMNITY FOR CLINICAL TRIAL

THIS INDEMNITY is provided on _____

By the Sponsor:

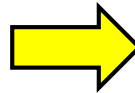
Name of Company: _____

Address: _____ (the "Sponsor")

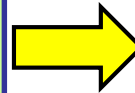
Fax No.: _____

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

A document titled "INDemnITY FOR CLINICAL TRIALS" with a header "ABC COMPANY/ HA". The form contains several sections: "1. THE SPONSOR", "2. THE HOSPITAL AUTHORITY", "3. THE PARTICIPATING UNIVERSITY", and "4. THE PRINCIPAL INVESTIGATOR". It includes fields for names, addresses, and phone numbers, and a section for the date of the indemnity agreement.A document titled "INDemnITY FOR CLINICAL TRIALS" with a header "ABC COMPANY/ UNIVERSITY/ HA". It contains sections for "1. THE SPONSOR", "2. THE HOSPITAL AUTHORITY", "3. THE PARTICIPATING UNIVERSITY", and "4. THE PRINCIPAL INVESTIGATOR". It includes fields for names, addresses, and phone numbers, and a section for the date of the indemnity agreement. There are also logos at the bottom right.

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 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*)



- Investigators should assess the risk level of their trials and decide whether or not to join the scheme.

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

Ref No.: _____

I. Applicant's Section

Name of Principal Investigator: Prof./Dr. _____
 CU History Title (if any): _____
 Department: _____
 Address: _____
 Contact: Tel. _____ Email: _____
 Project Title: _____

II. Documents Required

Copy of Updated Clinical Research Ethics Committee Approval
 Study Protocol

III. Payment Arrangement
 (*HK\$200 for first 100 subjects, HK\$100 for 101-200 subjects, and no extra cost for more than 200 subjects)

No. of subjects stated in the protocol: _____
 Total Premium payable: (_____ x HK\$200 + _____ x HK\$100) = HK\$ _____
 • If less than the no. of subjects stated in the protocol, please provide justification: _____

Premium settled by:

<input type="checkbox"/> Cheque	<input type="checkbox"/> CHEQUE/DEBIT CARD BY DEBITMENT/FAST APPROVED BY HMO
<input type="checkbox"/> Bank	<input type="checkbox"/> CREDIT/DEBIT CARD BUSINESS/AMERICAN EXPRESS
<input type="checkbox"/> Interdepartmental Transfer	<input type="checkbox"/> CHEQUE/DEBIT CARD BY DEBITMENT/FAST APPROVED BY HMO

Please complete the account details. * Payment will only be effected upon receipt from insurer.

1. I hereby confirm that the proposed trial has not been endorsed by any ethics committee in any jurisdiction.
 2. I hereby certify the correctness of the above mentioned information.
 3. I have read and understood the prevailing CRMO policy, terms and conditions for Clinical Trial Insurance and shall abide by these policies and any subsequent amendments thereto.

Applicant's signature: _____ Date: _____

IV. Clinical Research Ethics Committee's Section

Approved by CRMO Committee: Yes No
 Protocol No.: _____ CRMO Ref. No.: _____
 Authorized Chair and signature: _____ Date: _____

CUHKS/CRMO/01/Rev. 01/17

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) 3505 4276 Fax: (852) 3505 4794 Website: <http://www.crm.med.cuhk.edu.hk> Email: crm@cuhk.edu.hk

Transforming our Passion into Perfection

Memo

To : Prof. XXX
 From : Ms. LOUISS TSANG, Managing Director of CRMO
 Date : 26 July 2017
 RE : Your application for Clinical Trial Insurance

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

Project Title	CRMO Ref No.	No. of Hospital Subjects
ABC	CR-2017-999	20

The payment will be arranged by internal transfer accordingly.

If there is any change about the study that may impact the insurance coverage, please kindly inform us as soon as possible so we can notify the insurance company. Thank you.

Louise TSANG

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
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- 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*)

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 :	

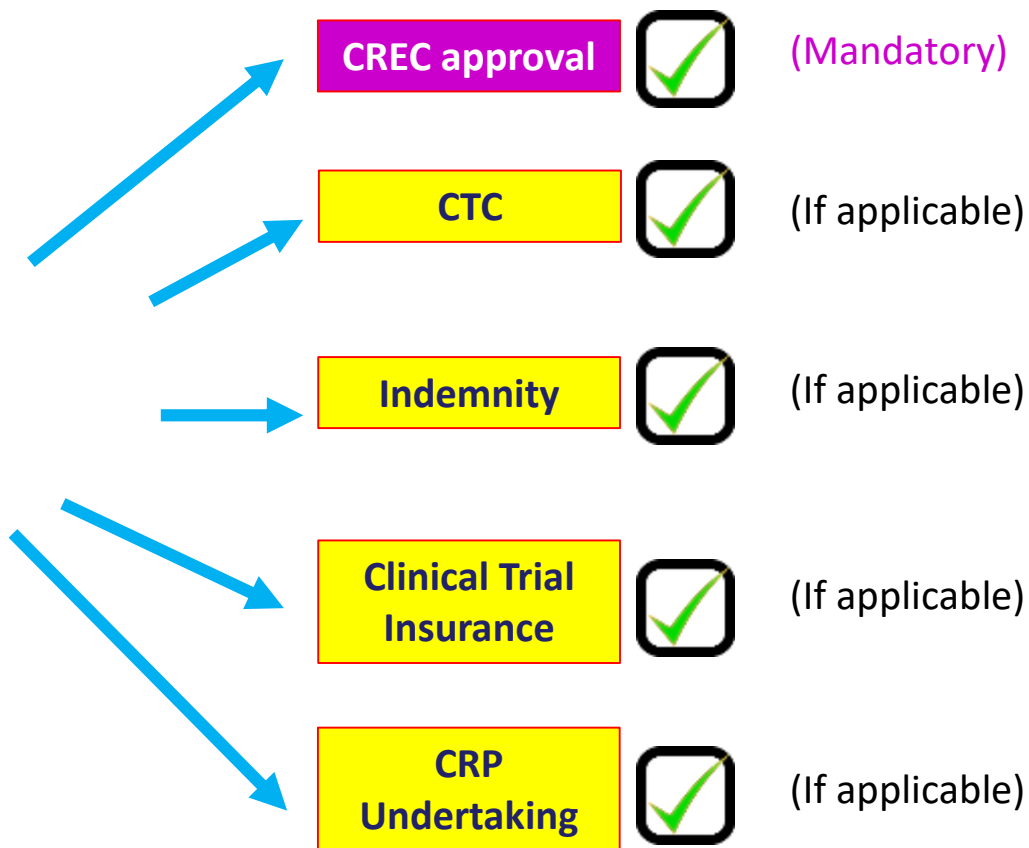
1. This Agreement sets forth the terms pursuant to the delegation of the management of Investigational Medicinal Product(s) (IMPs) in non-phase I clinical trials to the Joint CUHK-NTEC Clinical Research Pharmacy (CRP)
2. The ultimate accountability of the IMP and its management rests on the Principal 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:
 - Email: cmc261@ha.org.hk
 - Tel: 3505-4285

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 working hours</u>	<u>Outside working hours</u>



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: _____



Study Starts!

Ref: 17-2017-0259

新界東醫院聯網
NEW TERRITORIES
EAST CLUSTER

**Application for Conducting Clinical Trial /Research
Involving Patients in NTEC**

A. Project Title or Short Title (if any): RNA dig... bi... for es... ectio... n damage...
in a... blasti... mia

B. Study Protocol No.: _____ **C. CREC Ref No.:** 20

D. Name of Principal Investigator (PI): Prof. Chi Kong Li

E. Staff Status: HA/CUHK **F. Department/Hospital:** Paediatrics

G. Anticipated Start Date: 7 *(Clinical Trial can only be started upon approval given.)*

H. Planned End Date: 31

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 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)*

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>	Rank	Expected number of hours spent per week in conducting the research/ trial	
		During working hours	Outside working hours
<u>Prof. Chi Kong Li</u>	<u>Rt</u>	<u>0.2</u>	<u>0.2</u>

Submitted by:
Signature of PI: [Signature] Date: 2/7/17
Contact No: 3505 1019 E-mail: ckli@cuhk.edu.hk

Form 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: Dr. K.W. So Signature: [Signature]
COS in: C.O.S. in Paediatrics PWH Hospital Date: 31 JUL 2017

Form to be completed by HCE/ Delegate

Application is approved / not approved
Signature: [Signature] Remarks: _____
Date: 13 JUL 2017

Principal Investigator 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 Lai Che Woo Clinical Sciences Building, PWH) for processing.

cc: AHRM4/ HR NTEC Jun 2016

Endorsement:

**COS/
Director/
Depart.
Head**



HCE



During Study

Re-apply !

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



Ref: CT-2017-0289

新界東醫院聯網
NEW TERRITORIES
EAST CLUSTER

**Application for Conducting Clinical Trial/Research
Involving Patients in NTEC**

A. Project Title or Short Title (if any): rRNA diag. bi. for es. ectio. n damage. in a.

B. Study Protocol No.: _____ C. CREC Ref No.: 20

D. Name of Principal Investigator (PI): Prof. Chi Kong Li

E. Staff Status: HA/CUHK F. Department/Hospital: Paediatrics

G. Anticipated Start Date: 7 (Clinical Trial can only be started upon approval given.)

H. Planned End Date: 3

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 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)

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
<u>Prof. Chi Kong Li</u>	<u>Re</u>	<u>0.2</u>	<u>0.2</u>

Submitted by:
Signature of PI: _____ Date: 21/7/17
Contact Nos: 3505 1012 E-mail: ckli@cuhk.edu.hk

Part 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: Dr. K.W. So Signature: _____
COS in C.O.S. in Paediatrics PWH Hospital Date: 31 JUL 2017

Part to be completed by PI/Delegated

Application is approved / not approved
Signature: _____ Date: 04 AUG 2017

Remarks: _____

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), 8/F, Lai Che Woo Clinical Sciences Building, PWH for processing).

cc: AHRM/ HR NTEC Jun 2016

Contact Us!

PWH:

Email: crmo@cuhk.edu.hk

Tel: 3505 4276

Non-PWH:

Visit our CRMO website for details

<http://intranet.crmo.med.cuhk.edu.hk/crmoservices.aspx#ha>

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

