Clinical Research Ethical Approval Application Form

Joint CUHK- NTEC Clinical Research Ethical Review Application Form

Instructions to applicant:

1. Download the electronic form template from the (http://www.crec.cuhk.edu.hk or http://ntec.home/Research%20Ethics/main.asp)
2. Complete all sections of the application form. Nil entry is required unless otherwise indicated.
3. No of copies of documents required:
   Full review of Clinical Trials / Clinical Research
   12 hardcopies (included original) of application form and research proposal, information on consent, information material, relevant documents as listed below.
   The copies should be submitted to the Joint CUHK-NTEC CREC office at
   [Secretary of the Clinical Research Ethical Committee c/o
   Flat 3C, Block B, Staff Quarter,
   Prince of Wales Hospital].
4. Indicate version/revision number for research protocol, investigator brochure, consent form and questionnaire (if a research instrument).
5. Selected information (about logistics and not study design) will be passed to the HA Central Register of Clinical Research to facilitate risk management and procurement of insurance.

Nature of Document	**Requirement**
Completed 'Application Form'	Mandatory
Research Protocol	
Principal Investigator's short Curriculum Vitae (CV) Co-investigators' short Curriculum Vitae (CV)	
Subject Consent Form$^{\Delta}$	Mandatory$^{\Omega}$
Investigator's Brochure	Submit if part of the research design
Written information to be given to subject, such as recruitment advertisement, information sheet, etc.$^{\Delta}$	
Questionnaires$^{\Delta}$	
Completed 'Investigator's Conflict of Interest Declaration Form'	Pre-licensing trial of drug/medical device, study of unlicensed use*
Indemnity Agreement	
Insurance policy statement/certificate [Required if the Committee has doubt about the sponsor's financial capacity.]	

$^{\Delta}$ *These documents must be in languages suitable for the target subjects.*
$^{\Omega}$ *Unless qualified to be waived (refer HA Guide for Cluster REC, section 7.6, 7.7).*
* *Follow the latest HA policy and requirements on external indemnity / insurance.*

For Joint CUHK-NTEC Office Use:

Date Received: _____ *(dd/mm/yy)* Application Reference Number: _____

Check documents received: Yes/No

- Completed 'Application Form' ☐
- Research Protocol ☐
- Subject Consent Form ☐
- Principal Investigator's short Curriculum Vitae (CV) ☐
- Co-investigators' short Curriculum Vitae (CV) ☐
- Investigator's Brochure ☐
- Written information to be given to subject ☐
  - Specify: ☐
- Questionnaires ☐
- Completed 'Investigator's Conflict of Interest Declaration Form' ☐
- Indemnity Agreement ☐
- Insurance policy statement/certificate ☐
- Clinical research ethics approval from other REC (for multi-centre trial) ☐

Important Note: This form is to be completed by Principal Investigator. Please read the Guidelines on Research Involving Human Subject (**http://www.crec.cuhk.edu.hk**) carefully before completing this Form. The Committee approval, with or without conditions attached, or disapproval of the application will normally be communicated in writing to the principal investigator within 8 weeks, depending on the complexity of the study. Nil entry is required. Enter 'NA' if not applicable.

For office use
Date received: _____
CRE Number: _____
(Cluster/YY/no.)

PART I: OUTLINE OF APPLICATION

1. Full study title

2. Principal Investigator

2.1 Name :

☐ University Staff Position :

☐ HA Staff Position :

☐ Student - Programme :
University :
Supervisor :

2.2 Department/Unit :

2.3 Institution/Hospital :

2.4 Telephone number :

2.5 Fax number :

2.6 E-mail :

2.7 Qualifications & relevant experience in the past 5 years

3. Co-investigators (Short CV for Co-investigators should be submitted.)

	Name	Relevant qualification	Affiliating centre
A			
B			
C			

D			
E			
F			

4. Study site(s):

4.1 Is this a multi-centre trial in HK ? ☐ Yes ☐ No

4.1.1 If yes, number of local study sites: ☐

4.1.2 Main clinical specialty involved: ☐

5. Multicentre study

5.1	Local study site(s)		Department	Institute/Hospital
5.1.1	Primary study site			
5.1.2	Other study sites	Site 1		
		Site 2		
		Site 3		
		Site 4		
		Site 5		

5.2 Is this committee the primary research ethics committee (REC)? ☐ Yes ☐ No

If **no**, state the primary REC ☐

5.3 Study protocol has been approved by other REC (name the RECs & provide proof if available) ☐

5.4 If yes, specify reference number of protocol approved other REC: ☐

5.5 Has the proposal ever been rejected by a REC? ☐ Yes ☐ No

5.6 Study involves the following overseas countries ☐

6. Brief summary of study in lay language (limit to 300 words)

☐

7. State whether the study involve the following:

7.1 Incur an additional clinical intervention to participants	☐ Yes	☐ No
7.2 Raise sensitive / important privacy concerns	☐ Yes	☐ No
7.3 Impose additional risk to participants	☐ Yes	☐ No

8.

Proposed start date	Proposed finish date	Expected final report date
(dd/mm/yy)	*(dd/mm/yy)*	*(mm/yy)*

PART II: STUDY DETAILS

9. Scientific Basis

9.1 Aim of study / research question

9.2 Current scientific knowledge & evidence (Limit to 300 words)

10. Expected outcome and impacts of study

10.1 Potential in improving health care or advancing knowledge

10.2 What steps will be taken to disseminate the study results?

11. Independent Scientific assessment

Proposal has been scientifically assessed by an independent review [ ] Yes [ ] No

If **yes**, by whom? (and provide report)

12. Participants

12.1 Participant no.: total / per study arm /

12.2 Means to identify & recruit participants

12.3 Any unequal relationship between investigator & participant (other than doctor & patient)? e.g. supervisor & supervisee, teacher & student

12.4 Describe inclusion/exclusion criteria (or indicate source document & page number)

12.5 Explain how study intervention will be assigned

[ ] Randomisation (by [ ] computer program generated random code / [ ] list derived from random table / [ ] other means)
[ ] Some sort of planed / sequential assignment other than randomisation
[ ] Not controlled by investigator [ ] No control / comparison group
Please clarify:

13. Study Design & Method

13.1 Study design

[ ] Randomised controlled trial [ ] Quasi-experimental design (assignment planned but not randomised) [ ] Cohort study (concurrent controls) [ ] Cohort study (non-concurrent controls) [ ] Case-control study [ ] Correlational study [ ] Sequential clinical trial
[ ] Uncontrolled observational study [ ] Cross-sectional study [ ] Qualitative research
[ ] Others (please clarify):

13.2 Method(s) in obtaining the data required

13.3 Study termination criteria

13.4 Number of **extra** visits/ admissions compared to existing practice

13.5 Who will carry out the 'study intervention' apart from the investigators?

13.6 If study intervention involves a clinical procedure, where will it take place?

[ ] NA [ ] Operating room [ ] Designated study / treatment area
[ ] General ward [ ] Out-patient clinic [ ] Medical laboratory
[ ] Others:

13.7 If blood, tissue or body fluid samples are to be obtained, indicate

Nature & use of samples	
Total sample no. & volume	
Who has right of access to samples	
Duration of storage	

13.8 Will samples or data be stored for use in a future study? [ ] Yes [ ] No

If **yes**, explain how consent will be obtained

13.9 Will any samples go out of Hong Kong? [ ] Yes [ ] No

If **yes**, where & for what purpose?

14. Methods of Analysis

14.1 If method of analysis is **wholly or partly quantitative**, briefly describe

Statistical method(s)	
Statistical support *(Name & Institute)*	
Sample size justification, e.g. power of study	

14.2 If method of analysis is **wholly or partly qualitative**, briefly describe the analysis

15. Benefits, risks & inconvenience

15.1 Describe difference of study procedures from usual treatment provided at the study site

15.2 State possible benefits to participants

15.3 Will study procedures impose extra side effects to participants?

☐	Induce discomfort or distress	☐	Potential toxin, mutagen or teratogen
☐	Invasive/more invasive procedure	☐	Radiation or radioactive substance
☐	Increase physical or psychological risk	☐	Incur other hazards (please specify :)
☐	None of the above		

15.4 Measures to minimise risk & assure early detection of adverse event

15.5 Will the study involve the following vulnerable subjects?

Fetuses in Uteri/ non-viable fetuses/ abortus	☐ Yes	☐ No
Infants (age 0 to <1)	☐ Yes	☐ No
Children (age 1 to <13)	☐ Yes	☐ No
Adolescents (age 13 to <18)	☐ Yes	☐ No
Pregnant/lactating women	☐ Yes	☐ No
Unequal relationship with investigators, e.g. students, employees	☐ Yes	☐ No
Special population, e.g. prisoner, mentally disabled	☐ Yes	☐ No
Other than the above	☐ Yes	☐ No

Specify if yes: _____

15.6 Are there any special precautions to protect the interest of vulnerable subjects?

15.7 Will participants be provided with contacts for emergency? ☐ Yes ☐ No

15.8 Will participants be provided with a reminder describing the study? ☐ Yes ☐ No

15.9 Product: Drug, Appliance, Device or Diagnostic Test

15.9.1 Will any product be administered to subjects for the purpose of this study? *i.e. in addition to treatment the subjects would receive even if not participating in research* ☐ Yes ☐ No

Go to Q 16 if "no", specify if "yes" ☐ Drug ☐ Traditional Chinese Medicine ☐ Medical device ☐ Others

15.9.2 If drug will be administered to subjects for the purpose of this study, the drug trial is Phase

15.9.3 Is this study sponsored by the industry/commercial agency? ☐ Yes ☐ No

15.9.4 If yes, specify nature of sponsorship:

15.9.5 Is the product licensed in Hong Kong? ☐ Yes ☐ No

If **no**, state its regulatory status overseas & whether a clinical trial certificate or exemption has been obtained?

15.9.6 Is the product being used for an off label indication? ☐ Yes ☐ No

If **yes**, justify off-label use & explain indemnity arrangement

16. Data & Safety Monitoring

16.1 Will an independent committee review data & safety of study? ☐ Yes ☐ No

If **yes**, who funds this committee?

Composition

16.2 Suggest a suitable time for 1st progress report to REC months after study began

PART III: BUDGET & USE OF RESOURCES

17. Budget

17.1 Source of funding

17.2 Will this study provide benefit to the investigators or host institution? Give details

18. Resource Implication

18.1 Does the study use public healthcare resources? Give details

18.2 How will service waiting time of patients not participating in study be affected?

19. Financial Costs & Payments to Participants

19.1 Will there be any financial cost to the participant? Give details.

19.2 If a study item is not commercially available, will it continue to be available to the participant after study if s/he benefits from it? ☐ Yes ☐ No ☐ NA

19.3 If the study article is registered in HK but not yet supplied by HA, will it continue to be available to the subjects after the study ends if the subjects benefited from the intervention? ☐ Yes ☐ No ☐ NA

19.4 If yes to either Q19.2/19.3, will there be a cost and how will this be met?

19.5 Does the consent form explain the above arrangement? ☐ Yes ☐ No ☐ NA

19.6 Will participant receive any payment or benefit from participating the study?

☐ No ☐ Reimbursement (travel expenses, absence from work, etc.)

☐ Honorarium (total amount:)

20. Indemnity & Compensation

20.1 Study is largely for the benefit of manufacturer/ distributor ☐ Yes ☐ No

If **yes.** Does the manufacturer/ distributor provide indemnity? ☐ Yes ☐ No

Is the indemnity supported by an insurance policy? ☐ Yes ☐ No

If **yes**, is an insurance certificate available for review? ☐ Yes ☐ No

Does indemnity arrangement comply with HA policy?$^{\Delta}$ ☐ Yes ☐ No

Is there any exclusion clause to limit liability of sponsor? ☐ Yes ☐ No

If **yes**, state exclusion clause

($^{\Delta}$ *Refer to HA standard indemnity form or HA Legal Section*)

If **no.** Indemnity shall be covered by ☐ University ☐ HA ☐ Both

21. Information & Consent

21.1 In what form (written, oral) will consent be obtained? State reasons if not written.

[ ] Written [ ] Oral

21.2 Who is going to explain study to potential participants in obtaining consent?

21.3 Will an interpreter be available if required? ☐ Yes ☐ No

21.4 How much time will be allowed for a potential participant to decide?

21.5 To whom will consent be sought if a participant is incompetent to consent?

22. Confidentiality & Use of Results

22.1 How will data (including video tapes) be handled & stored to ensure confidentiality during & after study?

22.2 What will be done with the raw data after completion of study?

22.3 How long will the data be kept & who will be responsible for its safekeeping?

22.4 Who have right of access to the raw data or study records during & after the study?

22.5 Will any restriction be placed on publication of results? ☐ Yes ☐ No

If **yes**, give details

23. Declaration of Helsinki (http://www.wma.net/e/ethicsunit/helsinki.htm)

23.1 Have you read the current version of Declaration of Helsinki? ☐ Yes ☐ No

23.2 Does the study comply with the Declaration of Helsinki? ☐ Yes ☐ No

24. International Conference on Harmonisation - Good Clinical Practice (ICH-GCP)

24.1 Is this study a phase I, II, III or new indication drug trial? ☐ Yes ☐ No

24.2 If yes, does the protocol specify compliance to ICH-GCP? ☐ Yes ☐ No

and what is the phase of study? ☐

For Phase I Study, please complete the "Supplementary Information Sheet for Phase I Study".

(Download the electronic form template from the (http://www.crec.cuhk.edu.hk or http://ntec.home/Research%20Ethics/main.asp)

25. Any Other Issues

25.1 The study raises specific cultural, ethnic or gender issues:

25.2 Any important ethical issues not already dealt with:

PART IV: DECLARATIONS

(For study involving multiple study sites, applicants may submit more than one declaration form.)

Declaration by investigators

1. The information supplied is to the best of my knowledge and belief accurate.
2. I/We shall comply with the principles enunciated in the 1996 or a later version of the Declaration of Helsinki and HA Investigator's Code of Practice in Undertaking Clinical Research.
3. I/We understand that approval by the research ethics committee shall be renewed every 12 months.
4. I/We agree to report to the Joint CUHK-NTEC CREC any planned change in the study, and do not implement any change without receiving prior approval, except to eliminate immediate hazard to research subjects or when the change involves only logistical or administrative issues.
5. I/We agree to report to the Joint CUHK-NTEC CREC any unanticipated problems involving risks to subjects such as a severe adverse event within 24 hours of its identification.
6. I/We agree to report to the Joint CUHK-NTEC CREC any new information on the project that adversely influences the risk/benefit ratio.
7. I/We agree to report study progress to the Joint CUHK-NTEC CREC as requested, and to submit a final report at the end of the project.
8. I/We agree to keep all study documents for a period of at least three years after study closure.
9. I/We agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
10. I/We agree to maintain adequate accurate records and to make them available for audit/ inspection.

	Title and Name	Signature	Date
Principal investigator:			
Co-investigators:			

****Remarks: If the Project involves other departments, it is the Principal Investigator's obligation to inform and obtain agreement with the Chief of Service of that Department(s).**

2. Endorsement and Declaration by the Head of the Department and Chief of Service

1. I endorse this application and authorise the study to be undertaken in my department upon approval by the Clinical Research Ethics Committee.
2. I am in the opinion that the investigator(s) within my department/unit are appropriately qualified within the disease/therapeutic area involved, and are capable of undertaking this study in terms of their workload and time available, and that the study site(s) under my supervision have access to adequate facilities and supports for the research to be conducted in a safe manner.

Head of the Department	**Chief of Service**
Designation:	Designation:
Name:	Name:
Signature:	Signature:
Date:	Date:

**** If the COS is the Principal Investigator of the Study, s/he should seek senior management to endorse the research study, i.e. HCE or his/her designate.**

For office use
Date received: _____
CRE Number: _____
(Cluster/YY/no.)

Comments by members (please put a √ in the appropriate box and make comments as necessary)

1. Recommendation : ☐ Approved ☐ Not Approved

2. Comments, if any : _____

_____

Name of member _____ **Signed**_____