PHARMACY AND POISONS ORDINANCE (CHAPTER 138)

APPLICATION FOR CERTIFICATE FOR CLINICAL TRIAL/MEDICINAL TEST

(This form is used for application for a clinical trial submitted under the Listed Scheme)

<table>
<tr><td colspan="6">PART A: STUDY INFORMATION</td></tr>
<tr><td rowspan="2">A1.</td><td rowspan="2">Protocol title</td><td rowspan="2"></td><td>Protocol no.</td><td></td></tr>
<tr><td>Protocol date</td><td></td></tr>
<tr><td>A2.</td><td>Name of applicant</td><td colspan="3"></td></tr>
<tr><td rowspan="2">A3.</td><td rowspan="2">Business address of applicant</td><td rowspan="2"></td><td>Tel. no.</td><td></td></tr>
<tr><td>Fax no.</td><td></td></tr>
<tr><td>A4.</td><td>Name of principal investigator</td><td colspan="3"></td></tr>
<tr><td>A5.</td><td>Name and address of institution conducting the study</td><td colspan="3"></td></tr>
<tr><td>A6.</td><td colspan="4">Is this a study in which a certificate was issued previously and will soon expire?
☐ Yes (CTC no._____ and valid until_____)
☐ No</td></tr>
</table>

PART B: STUDY DESCRIPTION		
B1.	The study is	☐ single centre ☐ multi-centre
B2.	No. of study centres in Hong Kong	Total no. of centres_____ Centre name(s)_____
B3.	Study centres outside Hong Kong (if any)	No. of centres in each country (e.g. Mainland China – 2 centres, Singapore – 2 centres) _____
B4.	Sponsor of the study	Name of sponsor: _____ Address of sponsor: _____ *(Remarks: As this study is initiated and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)*
B5.	Recruitment size	Planned no. of subjects in Hong Kong_____ Total planned no. of subjects world-wide_____
B6.	Study period	Planned start date_____ and planned end date_____
B7.	The study is	☐ phase I (first-in-man? ☐Yes ☐No) ☐ phase II ☐ phase III ☐ phase IV Describe if necessary:_____
B8.	The study is	☐ open label ☐ single blind ☐ double blind ☐ other (please specify)_____)
B9.	The study is	☐ non-randomized ☐ randomized
B10.	Therapeutic area	(e.g. Oncology, Endocrinology)
B11.	Disease/Disease type	(e.g. Nasopharyngeal cancer, Diabetes mellitus)

PART C: STUDY DRUG		
C1.	Study drug to be investigated	
C2.	The study involves concurrent use of	☐ placebo ☐ comparator drug ☐ concomitant drug ☐ none of the above
C3.	Comparator drug used (if any)	
C4.	Concomitant drug used (if any)	

PART D: DECLARATION OF THE APPLICANT	
I/We* hereby declare that, if the application is approved and the study proceeds:	
D1.	Agree to submit local drug related safety reports, yearly progress reports and final study report of the study as stated in "Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial" (Appendix 3).
D2.	This study will be conducted in accordance with the principles established in Good Clinical Practice.
D3.	The information given in this application is true and correct.

* Delete as appropriate

Signature	Company stamp (if the applicant is a company)
Signatory's name in block letters	Date (DD/MM/YY)

PART E: FOR OFFICE USE ONLY	
Date Received	Fee Paid

Appendix 1

Checklist for Clinical Trial Application Submitted under the Listed Scheme

	For all studies, the following documents:	Yes	No
1.	A completed application form and this checklist.	☐	☐
2.	A cover letter listing all the submitted documents.	☐	☐
3.	A completed clinical trial risk assessment form.	☐	☐
4.	Documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted (this may be submitted when available at a later date).	☐	☐
5.	The proposed patient information and patient consent form, in both English and Chinese, or in Chinese only.	☐	☐
6.	A copy of the proposed protocol.	☐	☐

For studies in which a certificate was issued previously and will expire, the following additional documents:

7.	A copy of the previous certificate.	☐	☐
8.	Clinical trial progress report(s) (if not available, please provide justification; if the trial has not been started, please also provide justification).	☐	☐

Appendix 2

Risk Assessment Form for Clinical Trial Submitted under the Listed Scheme			
PART A: DRUG INFORMATION			
		Trial drug 1	Trial drug 2 (this column is used only when >1 trial drug; additional columns may be used if applicable)
A1.	Name of trial drug		
A2.	Is the trial drug registered in Hong Kong?	☐ Yes (registration no: HK-_____) ☐ No	☐ Yes (registration no: HK-_____) ☐ No
A3.	Approved indication, dosage and route of administration	Indication:	Indication:
		Dosage:	Dosage:
		Route of administration:	Route of administration:
PART B: TRIAL INFORMATION			
B1.	Protocol title and no.:		
B2.	Is the trial initiated and conducted by a sponsor-investigator?	☐ Yes ☐ No (the Listed Scheme is <u>not applicable</u>; please submit under the Standard Scheme)	
B3.	Targeted disease or condition:		
B4.	Trial regimen, including dosage and route of administration:		

PART C: RATIONALE FOR SUBMITTING THE TRIAL UNDER THE LISTED SCHEME

Please tick one of the following rationales and provide explanation of the risk assessment:

C1. ☐ The trial is a Type A* because the trial drug is registered in Hong Kong and used in accordance with the approved indication, dosage and form (see 4.1.1 of the guidance notes).
Local package insert or other reputable drug references, e.g. Martindale, should be provided as supporting evidence.

C2. ☐ The trial is a Type A* because the trial drug is registered in Hong Kong. Although it is not used in accordance with the approved indication, dosage and form, the use in the trial is an established practice (see 4.1.1 of the guidance notes).
Published evidence such as reputable clinical guidelines or institutional guidelines should be provided as supporting evidence.

C3. ☐ The trial is a Type B**. However, there is extensive clinical experience with the trial drug and no reason to suspect a different safety profile in the trial population, Therefore, a grading of Type A is justified (see 4.2.1 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

If the trial is submitted under the Listed Scheme with the following rationales, i.e. C4 and C5, it needs to be considered by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee of the Pharmacy and Poisons Board of Hong Kong. The final decision on whether the trial can be proceeded under the Listed Scheme will be made by the committee.

C4. ☐ The trial is a Type B**. There is no extensive clinical experience with the trial drug. However, the sponsor-investigator is of the view that submission under the Listed Scheme is felt to be justified (see 4.2.2 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

C5. ☐ The trial is a Type B**. Although the trial drug is not registered in Hong Kong, there is extensive class data or pre-clinical and clinical evidence of the drug (see 4.2.3 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

Explanation of the risk assessment:

Remarks: * Type A trial has risk no higher than the risk of standard medical care.
** Type B trial has risk somewhat higher than the risk of standard medical care.

Appendix 3

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION

Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial

All certificate holders of clinical trial/medicinal test are required to report to this office the following:

1. All local drug-related safety reports i.e. reports on adverse drug reactions (ADRs).

(a) For adverse drug reactions that are both serious* and unexpected** as soon as possible. (The attached CIOMS form [Appendix 4] may be used for reporting.)

(i) Fatal or life-threatening unexpected ADRs should be reported as soon as possible but no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar medicinal products.

(ii) Other serious, unexpected ADRs that are not fatal or life-threatening, it should be reported as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

(b) For non-serious adverse reactions and serious adverse reactions that are expected, it should be reported in a brief summary at the conclusion of the trial.

* Serious Adverse Drug Reaction or Adverse Event :

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

** Unexpected Adverse Drug Reaction:

An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational medicinal product).

2. Progress report on yearly basis and a final study report at the end of the study. The attached forms (Appendix 5 & 6 respectively) may be used for reporting.

3. Please forward all reports to the following address:

Drug Registration and Import/Export Control Division
Drug Office
Department of Health
3/F, Public Health Laboratory Centre
382 Nam Cheong Street
Shek Kip Mei, Kowloon
Hong Kong

Fax no.: 2803 4962
Email: ct@dh.gov.hk

Appendix 4

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first. last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab date)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING ☐ CONGENITAL ANOMALY

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRO-DUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period. etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOWUP	

Appendix 5

DEPARTMENT OF HEALTH

DRUG OFFICE

DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION

Clinical Trial Yearly Progress Report

Report period _____ to _____ Date of this report_____

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____ Anticipated end date: _____

Target no. of patient (as stated in protocol) _____

No. of patient intend to recruit (per centre) _____

No. of patient recruited (per centre) _____

No. of patient completed the trial (per centre) _____

No. of patient drop-out from study (per centre) _____

Reasons for drop-out:

Any changes for principal investigator? (If yes please give details)

Summary of amendments during report period (if any)

Summary of Serious Adverse Events (if any)

Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)

Summary of recent findings (especially information about risks associated with the research)

Progress of study:

☐ According to plan

☐ Extend study period (reason_____)

☐ Premature termination (reason_____)

Name:_____ Signature:_____

Posting:_____ Date:_____

Appendix 6

DEPARTMENT OF HEALTH

DRUG OFFICE

DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION

Clinical Trial Final Report

Report period _____ to _____ Date of this report_____

CT cert no.:	
Protocol no.:	
Protocol title:	

Start date: _____ End date: _____

Target no. of patient (as stated in protocol) _____

No. of patient intend to recruit (per centre) _____

No. of patient recruited (per centre) _____

No. of patient completed the trial (per centre) _____

No. of patient drop-out from study (per centre) _____

Reasons for drop-out:

Summary of Serious Adverse Events (if any)

Does SAE affect the study? How and what action has been taken?

Summary of complaints about the study (if any)

Study duration:

☐ According to plan

☐ Extend study period (reason_____)

☐ Premature termination (reason_____)

Summary of study outcome

Name:_____ Signature:_____

Posting:_____ Date:_____