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# Guidance for Institutional Review Board/Independent Ethics Committee: Requirements, Responsibilities and Operations

Version June 2026

Pharmacy and Poisons Board of Hong Kong

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## Contents

|     |   |    |
|-----|---|----|
| 1.  | Introduction .....                      | 3  |
| 2.  | Scope .....                             | 4  |
| 3.  | Purpose.....                            | 4  |
| 4.  | Ethics Review Principles .....          | 4  |
| 5.  | Responsibilities .....                  | 8  |
| 6.  | Membership .....                        | 9  |
| 6.1 | Composition .....                       | 9  |
| 6.2 | Appointment .....                       | 10 |
| 6.3 | Term of Office.....                     | 10 |
| 6.4 | Conflicts of Interest .....             | 10 |
| 7.  | Standard Operating Procedures .....     | 11 |
| 8.  | Operations .....                        | 12 |
| 8.1 | Initial Ethics Review Procedures .....  | 12 |
| 8.2 | Decision-making and Communication ..... | 13 |
| 8.3 | Continuing Review .....                 | 14 |
| 8.4 | Independence of Ethics Review .....     | 15 |
| 8.5 | Documentation and Record Keeping .....  | 15 |
| 9.  | IRB/IEC Listing and Requirements .....  | 16 |
| 10. | Management of Non-Compliance .....      | 17 |
| 11. | Glossary .....                          | 18 |
|     | Appendix 1 .....                        | 19 |
|     | Appendix 2 .....                        | 22 |

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## 1. Introduction

1.1 Under Regulation 36B of the Pharmacy and Poisons Regulations (Cap. 138A) (the Regulations), a Certificate for Clinical Trial (CCT)/Medicinal Test is required for the purpose of conducting a clinical trial on human beings or a medicinal test on animals. The Regulations only apply to pharmaceutical products.

1.2 The Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee (the Committee), established under the Pharmacy and Poisons Board (PPB) of Hong Kong, is the statutory body to issue clinical trial certificate. The Committee adopts the following definition of “clinical trial” as provided in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice E6(R3) (ICH Guideline for GCP):

“Any interventional investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s); and/or to identify any adverse reactions to an investigational product(s); and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.”

1.3 The ICH Guideline for GCP has been formally implemented in Hong Kong from 30 June 2026. Applicants of clinical trial certificate are required to submit the requisite documents as specified in the Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test. A key requirement is that prior approval must be obtained from the Institutional Review Board/Independent Ethics Committee (IRB/IEC) of the institution where the trial will be conducted before a certificate can be issued.

1.4 For the purpose of this guidance and in line with the ICH Guideline for GCP, the term “Institutional Review Board/Independent Ethics Committee” refers to *“an independent body constituted of medical professionals and non-medical members whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), the facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial participants”*.

1.5 The terms “IRBs/IECs” are synonymous with Research Ethics Committee (REC), and other equivalent designations. Any of these terms or other names may be adopted, provided

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the IRB/IEC fulfils the standards, responsibilities, and operational requirements set forth in this guidance.

1.6 For the procedures and details for application of CCT, "Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test" is available on the PPB's website at [https://www.ppbhk.org.hk/eng/doc/guidelines\\_forms/Guidance\\_Notes\\_en\\_Version.pdf](https://www.ppbhk.org.hk/eng/doc/guidelines_forms/Guidance_Notes_en_Version.pdf).

## **2. Scope**

2.1 This guidance applies to all IRBs/IECs established in Hong Kong that conduct independent ethics review and continuous oversight for clinical trials involving pharmaceutical products in human beings regulated under the Regulations.

## **3. Purpose**

3.1 This guidance defined a unified framework of standards and requirements for IRBs/IECs in Hong Kong with the following purposes:

- 3.1.1 Establish general standards for the composition, responsibilities, written procedures, and operations of IRBs/IECs.
- 3.1.2 Provide guidance on the fundamental principles underpinning ethics review.
- 3.1.3 Ensure the protection of the rights, safety and well-being of human participants involved in clinical trials.
- 3.1.4 Facilitate compliance with international standards, including the ICH Guideline for GCP and the Declaration of Helsinki.
- 3.1.5 Define the requirements and procedures for the Listing of IRBs/IECs by the PPB.

## **4. Ethics Review Principles**

4.1 IRBs/IECs should review clinical trials in accordance with the ethical principles that have their origin in the Declaration of Helsinki and consistent with good clinical practice as outlined in the ICH Guideline for GCP. All clinical trials should be designed and conducted in ways that respect participants and protect their rights, safety, and well-being.

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4.2 The ethics review of clinical trials should be guided by the following fundamental ethical principles:

4.2.1 Risk and benefit

- i. Clinical trials should be initiated and continued only when the anticipated benefits justify the known and anticipated risks, in particular, risks exceeding the standard of care that the participants would otherwise receive.
- ii. Measures to effectively minimize, mitigate, or manage the risks and burdens to trial participants should be implemented.
- iii. Risk-proportionate approach should be adopted in the design, conduct, and oversight of clinical trials.

4.2.2 Scientific validity

- i. Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches.
- ii. Clinical trials should be well-designed with a clear, concise, scientifically sound and operationally feasible protocol.
- iii. Clinical trial processes should be justified, fit for its intended purpose, and risk-proportionate, such that participants are not exposed to unnecessary burden or risk.

4.2.3 Participant recruitment and selection

- i. Recruitment materials and methods, including advertisements and information provided to potential participants, should be designed to be free from coercion or undue influence, protecting potential participants from pressure or inducements that might compromise the voluntary nature of their participation.
- ii. The selection of subjects should be equitable, fair, and non-discriminatory, and based on scientifically justified inclusion and exclusion criteria.

4.2.4 Informed consent

- i. Informed consent is a fundamental ethical requirement that reflects respect for the autonomy of trial participants. Informed consent for clinical

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trial participation shall be given freely and voluntarily by every participant or their legally acceptable representative and be properly documented prior to enrolment.

- ii. Informed consent should provide all necessary information for making an informed decision in language that is clear, concise, and understandable to potential trial participants or their legally acceptable representatives, enabling them to evaluate the anticipated benefits and potential risks and burdens of participation.
- iii. Potential participant should be informed of the right to refuse to participate or to withdraw consent to participate at any time without reprisal, penalty, or loss of benefits to which they are otherwise entitled.
- iv. No informed consent materials should contain any language that causes the participant to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor or their service providers from liability for negligence.
- v. Informed consent is a continuous process, and participants or their legally acceptable representatives should be kept informed of any new information that might affect their willingness to continue participating in a timely manner.

#### 4.2.5 Vulnerable population

- i. Vulnerable participants are individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students; subordinate hospital and laboratory personnel; employees of the pharmaceutical industry; members of the armed forces; and persons kept in detention. Other vulnerable participants may include persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent.
- ii. In vulnerable populations, additional safeguards may be necessary to ensure true understanding and voluntary participation. Vulnerable groups

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should not be exploited for research purposes, nor should they be inappropriately excluded from trial participation based solely on their circumstances. Instead, they should benefit from the advancements in medical knowledge that arise from clinical research.

- iii. Assent is a process of informing and seeking agreement from children or young people to participate in research. While children and young people typically lack the maturity to provide valid legal consent, they benefit from understanding the research process and having the opportunity to express their interests, questions, and concerns.
- iv. In case the participant does not have the capacity to provide consent (e.g. individuals with severe mental or neurological disorders), a valid consent should be obtained from a guardian appointed under the Mental Health Ordinance (Cap. 136) whose guardianship order confers the power to consent to treatment. Any risk or burden of the proposed research to the participant should be justified by the potential benefit to the participant.
- v. For emergency or intensive care research, investigators should obtain ethics approval for the model of consent that they will use or, alternatively, for a waiver of the requirement for informed consent. If it is not possible to obtain consent from the participant, then investigators should seek consent from the participant's guardian or authorised person, taking into account any relevant jurisdictional restrictions. After the participant regains the capacity to make decisions about participation, the investigators should explain what ongoing participation involves and confirm if the participant is willing to continue the participation and explain the right to withdraw from the research without affecting the quality of care that the participant is receiving.

#### 4.2.6 Suitability of investigators and study sites

- i. The investigators and study team shall be qualified by education, training and experience to perform their respective tasks and duties for the proper conduct of the trial.
- ii. Clinical trials shall be conducted at suitably equipped sites with adequate facilities and resources.

#### 4.2.7 Compensation

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- i. Compensation for trial participants shall serve to reasonably reimburse expenses related to participation and acknowledge the time and inconvenience involved, without constituting coercion or undue influence.
  - ii. Payments shall be prorated and not wholly contingent on completion, to avoid compromising participants' right to withdraw.
  - iii. Appropriate compensation and treatment shall be made available to participants in the event of trial-related injury.
  - iv. Information concerning payment to participants shall be set forth in the informed consent materials.

#### 4.2.8 Privacy and confidentiality

- i. Appropriate measures shall be implemented to protect the privacy of trial participants and the confidentiality of their personal information.
- ii. All personal data collected, held, processed or used shall be handled in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).
- iii. Participants shall be informed of the purposes for which their personal data will be collected, methods of collection, intended use, and any potential disclosures. Informed consent shall be obtained prior to data collection and processing.

## **5. Responsibilities**

5.1 The purpose of an IRB/IEC is to safeguard the rights, safety and well-being of all trial participants.

5.2 An IRB/IEC should:

- 5.2.1 Conduct initial ethical review of human clinical trials;
- 5.2.2 Conduct continuing review of ongoing trials at intervals appropriate to the degree of risk to participants;
- 5.2.3 Assess the qualifications and suitability of investigators and study sites;

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- 5.2.4 Review informed consent procedures and documents to ensure they are appropriate, understandable, and contain all necessary information for potential participants;
  - 5.2.5 Review assent information for minor participants, considering their age, maturity and psychological state, if minors are to be included in a trial;
  - 5.2.6 Determine whether the participation of individuals who lack capacity to give informed consent is scientifically necessary and ethically appropriate;
  - 5.2.7 Assess the adequacy of participant safety monitoring, adverse event reporting, and data confidentiality measures;
  - 5.2.8 Review the amount and method of compensation to participants (if any) to ensure that neither presents problems of coercion or undue influence.
- 5.3 Based on its review, the IRB/IEC may:
- 5.3.1 Grant approval for the conduct or continuation of clinical trial;
  - 5.3.2 Request modifications prior to granting approval or permitting the continuation of clinical trial;
  - 5.3.3 Disapprove the conduct or continuation of clinical trial with written justifications;
  - 5.3.4 Withdraw or suspend any prior approval.

## **6. Membership**

### **6.1 Composition**

- 6.1.1 Each IRB/IEC should be constituted of at least FIVE members who collectively have the qualifications and experience to adequately review and evaluate the science, medical aspects and ethics of clinical trials commonly conducted at the institution. The composition should include:
  - i. At least one non-scientific member (whose primary area of interest is not in medical sciences);
  - ii. At least one member who is independent of the institution/investigator site.

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- 6.1.2 An IRB/IEC should demonstrate diversity in expertise, gender, age, and representation of communities.
  - 6.1.3 Each IRB/IEC should maintain a current list of members and their qualifications.
  - 6.1.4 An IRB/IEC may invite individuals with specialised expertise to assist in reviewing applications that require expertise beyond that available within the IRB/IEC. Such consultants should have no conflicts of interest and should not participate in the voting on IRB/IEC decisions.

## **6.2 Appointment**

- 6.2.1 Members should be provided with a formal notice of appointment that specifies:
  - i. The responsibilities, including participation, training, confidentiality and disclosure of interests;
  - ii. The membership category;
  - iii. The term of appointment;
  - iv. Remuneration or other benefits they may receive (if applicable);
  - v. That they are assured legal protection for liabilities arising from bona fide performance of their duties.

## **6.3 Term of Office**

- 6.3.1 Every member of an IRB/IEC should hold office for a term—not exceeding five years—as determined by the institution, and may be eligible for re-appointment.

## **6.4 Conflicts of Interest**

- 6.4.1 IRB/IEC members taking part in a review should declare any real, potential, or perceived conflicts of interest prior to reviewing any applications and IRB/IEC meetings.
- 6.4.2 Members who have conflicts of interest or potential conflicts of interest that may affect their impartial evaluation of an application under consideration by the IRB/IEC:

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- i. Should not participate in the review of the application;
  - ii. Should refrain from discussion or decision-making regarding that application, except to provide factual information when requested by the IRB/IEC;
  - iii. Should not be counted towards quorum for that review.

## **7. Standard Operating Procedures**

7.1 An IRB/IEC should establish standard operating procedures (SOPs) that promote good ethics review. The SOPs should address:

7.1.1 IRB/IEC composition and the governing authority;

7.1.2 Procedures for initial and continuing review, including review timelines;

7.1.3 Meeting conduct and decision-making procedures, which should specify:

- i. Frequency of meetings;
- ii. Quorum requirements for meetings and decisions;
- iii. Preparation and timely distribution of agendas and materials;
- iv. Documentation of meeting minutes;
- v. Methods of deliberation and decision-making; and
- vi. Attendance of non-members at meetings.

7.1.4 Procedures for reporting and review of proposed amendments or changes to the protocol, informed consent form, investigator's brochure, and other trial-related documents before implementation, except when necessary to eliminate immediate hazards to the participants.

7.1.5 Procedures for receipt and review of progress report and final report.

7.1.6 Reporting requirements and procedures, which should ensure prompt reporting of:

- i. Protocol deviations;

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- ii. Changes that increase risk to participants or significantly affect trial conduct;
  - iii. All suspected unexpected serious adverse reactions (SUSARs) in accordance with applicable regulatory requirements; and
  - iv. New information that may affect participant safety or trial conduct.

7.1.7 Procedures for reconsideration and appeals, if any;

7.1.8 Records management;

7.1.9 Conflicts of interest management;

7.1.10 Measures to ensure confidentiality of applications, IRB/IEC deliberations, and study data.

## **8. Operations**

### **8.1 Initial Ethics Review Procedures**

8.1.1 An IRB/IEC should receive and review the following information for initial applications, where applicable:

- i. Clinical study protocol;
- ii. Investigator's brochure;
- iii. Investigator's qualifications;
- iv. Informed consent and/or participant information sheet;
- v. Participant recruitment materials (e.g. recruitment advertisement or poster);
- vi. Documents or materials for use by participants (e.g. questionnaires or diaries);
- vii. Investigator's declaration of conflicts of interest;
- viii. Certificate of insurance; and
- ix. Other documents as requested by the IRB/IEC to fulfil its responsibilities.

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- 8.1.2 Meeting papers should be provided sufficiently in advance of meetings to enable members to be fully informed.
  - 8.1.3 IRB/IEC may invite investigators to attend discussions regarding their submitted application at the discretion of the chairperson.
  - 8.1.4 IRB/IEC may seek advice from external experts or invite observers to attend meetings. They should be bound by confidentiality and conflicts of interest disclose requirements.
  - 8.1.5 IRB/IEC should render decisions on the ethical acceptability of clinical trial in an efficient and timely manner. An initial response should be provided within a reasonable timeframe upon successful application submission.
  - 8.1.6 During publicly declared emergencies, an IRB/IEC should establish an expedited review mechanism for research applications submitted in response to emergency situations.
  - 8.1.7 An IRB/IEC should ensure that the fundamental ethical principles (outlined in Section 4.2) are fulfilled in order to grant approval.

## **8.2 Decision-making and Communication**

- 8.2.1 An IRB/IEC should establish effective communication channels with investigators to foster open communication and provide prompt written notification of IRB/IEC decisions.
- 8.2.2 An IRB/IEC may approve, request modifications to, reject or withdraw approval of a clinical trial application. If approval is rejected, withdrawn, or modifications are requested, the IRB/IEC should provide well-founded rationale for its decision, and reasoned and appropriately documented opinions.
- 8.2.3 The quorum for IRB/IEC meetings should consist of a minimum number of members sufficient to fulfill the composition requirements of an IRB/IEC (as specified in Section 6.1.1). No business shall be transacted at any meeting unless a quorum is present.
- 8.2.4 A decision by the IRB/IEC requires the agreement of a majority of members at a quorate meeting. IRB/IEC should attempt to reach decisions by general

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agreement or consensus. Members should thoroughly discuss the ethical issues before voting.

- 8.2.5 Where unanimous agreement cannot be reached, the voting record should include the number of members voting for, against, and abstaining, with dissenting opinions documented in detail in the meeting minutes.
- 8.2.6 Investigators should have the right to request reconsideration of IRB/IEC decisions, and the IRB/IEC is obligated to provide timely reconsideration of decisions affecting a clinical trial.
- 8.2.7 IRB/IEC should establish SOPs to handle appeals of its decisions or opinions.
- 8.2.8 IRB/IEC should promptly notify the institution and investigators of any decisions to suspend or withdraw ethics approval.

### **8.3 Continuing Review**

- 8.3.1 IRB/IEC should determine the nature and frequency of continuing ethics review based on a risk-proportionate approach. At minimum, continuing review should include an annual progress report and a final study report.
- 8.3.2 IRB/IEC may employ various mechanisms and strategies for continuous monitoring, including review or conduct of:
  - i. Reports from researchers, received at least annually;
  - ii. Reports from independent committees or groups, such as Data and Safety Monitoring Board;
  - iii. Adverse event and other safety reports;
  - iv. Study amendments;
  - v. Audit reports;
  - vi. Commissioned or inspection reports;
  - vii. Final study reports, published results, or dissemination of outcomes;
  - viii. Interviews or meetings with investigators; and
  - ix. Interviews with participants or other forms of participant feedback.

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- 8.3.3 To enable efficient and risk-proportionate review, IRB/IEC may employ a simplified review procedure for the following applications presenting minimal or lower risk:
- i. Minor modifications to an approved trial that do not affect the risk-benefit ratio; or
  - ii. Continuing review of approved trial.
- 8.3.4 IRB/IEC should establish SOPs for conducting simplified review.
- 8.3.5 Simplified review should be conducted by IRB/IEC member(s) designated by the chairperson, who should provide a review opinion. The opinion should be reported at the subsequent meeting.
- 8.3.6 If, during simplified review, a change in the risk-benefit ratio is identified, disagreement arises among reviewers, or a member request a meeting review, the matter should be escalated to a meeting review.

#### **8.4 Independence of Ethics Review**

- 8.4.1 An IRB/IEC should function impartially and maintain its independence. No institution or individual should interfere with the review process or decisions.
- 8.4.2 All ethics review processes and the criteria that are used for determining the appropriate process should be clear, transparent and should be available upon request by investigators, sponsors or regulatory authorities.

#### **8.5 Documentation and Record Keeping**

- 8.5.1 IRB/IEC should prepare and maintain adequate documentation of ethics review activities, including:
- i. Written SOPs;
  - ii. Membership list indicating each member's name, qualifications, representative capacity, and any employment or other affiliation with the institution;
  - iii. Copies of all reviewed clinical trial applications and submitted documents;

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- iv. Minutes of IRB/IEC meetings documenting attendance; actions taken; voting records, including the number of members voting for, against, and abstaining; rationale for requiring modifications or disapproving applications; and a written summary of the deliberations on discussed issues and their resolutions;
  - v. Records of continuing review activities;
  - vi. Copies of correspondence between the IRB/IEC and investigators.

8.5.2 Records should be retained for a minimum of 3 years from the date of submission of final report, and should be made available upon request by the Department of Health.

## **9. IRB/IEC Listing and Requirements**

9.1 For the purpose of issuing clinical trial certificates, approval from an IRB/IEC Listed by the PPB is a prerequisite.

9.2 To be eligible for Listing, IRBs/IECs should meet the standards and requirements specified in this guidance, declare compliance with the ICH Guideline for GCP and agree to allow and facilitate inspections conducted by personnel assigned by the PPB.

9.3 IRB/IEC applying for Listing should complete the application form at Appendix 1, and submit the following information:

- 9.3.1 Name, address, and contact details;
- 9.3.2 Terms of reference;
- 9.3.3 Membership and composition, including names, qualifications, and institutional affiliation status of members; and
- 9.3.4 Standard operating procedures; (as specified in Section 7)

9.4 IRBs/IECs should submit all the above information and documents to the Drug Office for the purpose of Listing. If submitted documents are found satisfactory, a letter of acceptance for Listing would be issued to the IRB/IEC by the Committee. The name of the Listed IRB/IEC would also be published on the website of the PPB and the Drug Office. Listed IRBs/IECs will be subject to inspections arranged by the PPB.

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9.5 IRBs/IECs should notify the Drug Office of any subsequent changes to the information submitted for listing as stipulated in this guidance within 30 calendar days of the change and submit relevant documents (please refer to Appendix 2 for the notification form). The Drug Office shall acknowledge the acceptable changes that comply with this guidance.

9.6 The completed application form (Appendix 1) or notification form (Appendix 2) should be submitted to the Drug Office by:

- email to ct@dh.gov.hk; or
- mail or delivery to the Clinical Trials and Pharmacovigilance Unit at Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong.

## **10. Management of Non-Compliance**

10.1 Where the PPB determines that any of the following circumstances exist in respect of a Listed IRB/IEC:

- 10.1.1 the prerequisites for Listing of the IRB/IEC no longer exist;
- 10.1.2 the composition and/or operation of the IRB/IEC is not in compliance with the requirements set out in this Guidance in a significant manner; or
- 10.1.3 the IRB/IEC is failing to perform its functions adequately,

the Listing of that IRB/IEC will be suspended.

10.2 Upon the decision to suspend the Listing of an IRB/IEC, the PPB will notify the IRB/IEC concerned in writing of the suspension and the non-compliance issues identified. The IRB/IEC will be required to provide a written response detailing the corrective and preventive actions that will be taken to address the issues identified within a prescribed period.

10.3 During the period in which the Listing of an IRB/IEC is suspended, application for CCT for studies that are under review of that IRB/IEC will not be approved.

10.4 Where the PPB confirms that adequate and appropriate corrective and/or preventive actions have been implemented to address the non-compliance issues, the suspension of listing of the IRB/IEC may be lifted.

10.5 If an IRB/IEC repeatedly fails to respond to or adequately address the issues raised in the written notification referred to in Section 10.2, the PPB may remove the IRB/IEC from the Listing (delisting). The PPB will inform the IRB/IEC of its decision in writing.

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10.6 Once the decision to delist an IRB/IEC has been made, no new subjects should be enrolled into any ongoing clinical trials that were approved by the delisted IRB/IEC. The Drug Office will notify the affected holders of the CCT, and the CCT holders will be required to promptly inform the affected Principal Investigators of the delisting and its implications.

10.7 A delisted IRB/IEC should not review or approve any new clinical trial applications or submissions for continuing review of ongoing trials. The affected CCT holders shall nominate another competent and Listed IRB/IEC and arrange for the transfer of oversight responsibilities for affected clinical trials within 30 working days. The CCT holders should notify the Drug Office in writing of the proposed transfer arrangements and timelines.

10.8 In the absence of competent IRB/IEC oversight of an ongoing clinical trial following the delisting of the originally approving IRB/IEC, the case may be put forward to the Committee for consideration of suspension or cancellation of the relevant CCT(s).

10.9 Clinical trial data generated from trials for which the CCT has been suspended or cancelled by the Committee may not be accepted in support of an application for marketing authorisation.

## **11. Glossary**

11.1 Unless otherwise specified, the terms used in this Guidance have the same meaning as defined under the Glossary section of the current ICH Guideline for GCP.

**DEPARTMENT OF HEALTH**  
**DRUG OFFICE**  
**DRUG EVALUATION AND PHARMACOVIGILANCE DIVISION**  
**APPLICATION FOR LISTING AS IRB/IEC IN HONG KONG**

| <b>PART A: INFORMATION OF IRB/IEC</b> |  |  |               |
|---------------------------------------|--|--|---------------|
| A1.                                   | Name                                       |  |               |
| A2.                                   | Address                                    |  |               |
| A3.                                   | Name of contact person and contact details |  | Tel. no.      |
|                                       |  |  | Fax no.       |
|                                       |  |  | Email address |
| A4.                                   | Terms of Reference                         | (may add supplementary sheets or submit as appendix if required) |               |

| A5. Membership and Composition (may add supplementary sheets or submit as appendix if required) |   |   |                            |                       |
|---|---|---|----------------------------|-----------------------|
| Name  | Gender  | Membership Role<br>(Indicate Scientific or Non-Scientific (S/NS)) | Qualification / Profession | Affiliation and Title |
|   |   | ( S / NS *)   |                            |                       |
|   |   | ( S / NS *)   |                            |                       |
|   |   | ( S / NS *)   |                            |                       |
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|   |   | ( S / NS *)   |                            |                       |
|   |   | ( S / NS *)   |                            |                       |
| A6.   | Index of Standard Operating Procedures (SOPs) | (Please submit each set of SOPs separately)                       |                            |                       |

\* Delete as appropriate

**PART B: DECLARATION OF THE APPLICANT**

I/We\* hereby declare that:

|     |  |
|-----|--|
| B1. | IRB/IEC in this application would comply with the standards and requirements specified in the “Guidance for IRB/IEC: Requirements, Responsibilities and Operations” and the current ICH Guideline for GCP. |
| B2. | The information given in this application is true and correct.   |
| B3. | IRB/IEC in this application would allow and facilitate inspections conducted by personnel assigned by the Pharmacy and Poisons Board.  |

\* Delete as appropriate

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Company/Corporate stamp (if applicable)

\_\_\_\_\_  
Signatory’s name in block letters

\_\_\_\_\_  
Date (DD/MM/YYYY)

**PART C: FOR OFFICE USE ONLY**

Date Received

**Notification of Changes of Information of Listed IRBs/IECs in Hong Kong**

|                    |  |                                  |
|--------------------|--|----------------------------------|
| Date of submission |  | For office acknowledgement stamp |
| Name of IRB/IEC    |  |                                  |
| Address            |  |                                  |

  

Please choose the category of change and submit relevant documents (if applicable):

|   | Yes                      | No                       |
|---|--------------------------|--------------------------|
| i) Change of Standard Operating Procedures (please provide new SOPs and summary of change)  | <input type="checkbox"/> | <input type="checkbox"/> |
| ii) Change of Terms of Reference (please provide new TOR and summary of change)             | <input type="checkbox"/> | <input type="checkbox"/> |
| iii) Change of Membership and Composition (please provide clean and tracked-changes copies) | <input type="checkbox"/> | <input type="checkbox"/> |
| iv) Change of Name/ Address of IRB/IEC, and/ or Contact Details (please specify):<br>_____  | <input type="checkbox"/> | <input type="checkbox"/> |
| v) Others (please specify):<br>_____  | <input type="checkbox"/> | <input type="checkbox"/> |

Reported by    Signature: \_\_\_\_\_    Contact no.: \_\_\_\_\_

Signatory's name: \_\_\_\_\_    Date: \_\_\_\_\_

Company/Corporate stamp  
(if applicable): \_\_\_\_\_