

Scientific Title of Study

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PART V: DECLARATION & ENDORSEMENT

Note: Certain trial information will be passed to a Central Database for risk management purpose and to assist HA's finance controller in sourcing insurance coverage for clinical trial activities

26.1: Declaration by Investigator(s)

1. I / We declare that the information supplied is to the best of our knowledge and accurate.
2. I / We declare that the protocol comply with Declaration of Helsinki.
3. I / We agree to uphold the protection of research subjects' right and safety through adherence to local laws, Declaration of Helsinki, institutional policies* and whenever applicable, the ICH-GCP.
4. I / We understand that approval by the Cluster REC is subject to regular renewal according to local policy.
5. I / We agree to report to the

Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee
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 - any planned change(s) to the study, and further agree not to implement any change(s) without receiving prior approval, except to eliminate immediate hazard to research subjects or when the change(s) involve only logistical or administrative issues.
 - any fatal events in applying site within the specific time according to the Standard Operating Procedures of the Cluster REC while pending investigation, and any serious adverse events in applying site (with an extended report) preferably within seven days but not later than 15 days (from the day it was made known to me / us).
 - any new information on the project that adversely influences the risk/benefit ratio.
 - progress report(s) (as requested by the Cluster REC) and a final report (after completion of study).
6. I / We agree to keep all study documents for a period of at least three years after study closure.
7. I / We agree to maintain adequate records and to make them available for audit / inspection.
8. 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.

** HA Guide on Research Ethics (for Study Site & Research Ethics Committee) and Investigator's Code of Practice; HA Clinical Data Policy Manual; and other prevailing HA policies.*

26.2: Signature(s) from Principal Investigator (and Other Investigator(s))

Role	Title (e.g. Prof., Dr.)	First Name	Surname	Position	Responsibility for Clinical Oversight (Y/N)	Signature	Date (DD/MM/YYYY)
Principal investigator							
Other investigator							

26.3 (For Student Project): Signature(s) from Academic Supervisor(s) and Site Supervisor(s)

Role	Name	Position	Responsibility for Clinical Oversight (Y/N)	Signature	Date (DD/MM/YYYY)

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26.4: Endorsement by COS of Department# Contributing to the Research

1. I endorse the application and authorise the captioned study to be undertaken in my department upon approval by the Cluster REC/IRB.
2. I am of 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 support for the research to be conducted in a safe manner.

Signature	Name	Email	Position	Department	Hospital	Date (DD/MM/YYYY)

It should be another suitable senior staff (e.g. HCE or Acting COS) if the COS is the Applicant for the study or on leave.

26.5: Endorsement by Head of Department^ Contributing to the Research

1. I endorse the application and authorise the captioned study to be undertaken in my department upon approval by the Cluster REC/IRB.
2. I am of 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 support for the research to be conducted in a safe manner.

Signature	Name	Email	Position	Dept/School/Faculty	Institution	Date (DD/MM/YYYY)

^ It should be another suitable senior staff (e.g. Acting Head / Senior Member in the Department) if the Head of Department is the Applicant for the study or on leave.

26.6: Endorsement by COS(s) or Head(s) of Other Department(s)+ Contributing to the Research

I support the captioned study and verify that the workload to be incurred will not interfere with the department's service priority.

Signature	Name	Email	Position	Dept/School/Faculty	Hospital/ Institution	Date (DD/MM/YYYY)

+ If the study involves other departments, it is the Applicant's obligation to inform and obtain endorsement by the COS(s) or Head(s) of the Department(s).