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SOP No: P12

INSTITUTIONAL REVIEW BOARD APPLICATION AND COMMUNICATIONS**CLINICAL TRIALS CENTRE DEVELOPMENT TEAM:**

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 Signature/Date
REVISIONS:

No.	Section No.	Page No.	Initials/Date

DATES OF NEXT REVISION OF THIS SOP:

Date	Signed	Date	Signed

SOP No: P12**INSTITUTIONAL REVIEW BOARD APPLICATION AND COMMUNICATIONS****I. Purpose**

To outline the procedures involved in applying to an Institutional Review Board (IRB) to conduct a clinical trial.

II. Other Related Procedures

SOP P3: Review of Protocol Amendments

SOP T5: Obtaining Written Informed Consent

SOP T6: Adverse Event and Serious Adverse Event Reporting

III. Procedures

The IRB is an independent body, a review board or a committee, institutional, regional, national or supra-national, constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-beings of humans subjects involved in a clinical trial.

The IRB should provide public assurance of protection by reviewing and approving or providing favourable opinion on the trial protocol, the suitability of the Investigator's facilities and the method and materials to be used in obtaining and documenting informed consent should always be reviewed by the IRB.

- 1) Obtain the necessary documents and forms from the IRB
- 2) Check when the IRB holds its meetings, because if it does not meet very often, this may delay the start of the trial. At the same time, check the response time for processing IRB applications.
- 3) When submitting an application, the Investigator may designate a member of staff to prepare the submission. However he/she must take full responsibility for reading it and signing it off.
- 4) If more than one centre is using the same IRB, the Investigator should identify whether each centre should independently obtain IRB approval, or whether one central IRB will approve the trial for all centres.
- 5) For applications to the University of Hong Kong/Hospital Authority Hong Kong West Cluster Institutional Review Board, refer to the website at: <http://www.hku.hk/facmed/research/ec.html>