The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee

Clinical Study Categorization Form

Risk Group	Risk Factors *(See notes overleaf)*		Yes	No
Human Subjects	1	Recruitment of human subjects [***see notes of completion***]	☐ →2	☐ →B
Medical Products	2	Use of any medical product that is not needed or used for the Subjects' normal clinical care [***see notes of completion***]	☐ →3	☐ →8
	3	Each medical product used is registered or permitted to be marketed in Hong Kong	☐ →4	☐ →5
	4	Use of each medical product is within the labeled use in Hong Kong [***see notes of completion***]	☐ →8	☐ →5
	5	Any medical product used is a chemical or biological drug that is to be tested in humans for the first time	☐ →C	☐ →6
Study Designs	6	The study is a phase 1 clinical trial on a chemical or biological drug as designated on its study protocol	☐ →C	☐ →7
	7	The study only has human pharmacology, tolerability and/or safety (but not efficacy) of the chemical or biological drug as its primary objective(s) as specified on its study protocol	☐ →C	☐ →8
	8	Involvement of placebo, impeding access to available treatment, or withdrawal of ongoing treatment driven by the study protocol	☐ →A	☐ →9
Clinical Procedures	9	Involvement of any clinical procedure that is not needed or applied for the subjects' normal clinical care [***see notes of completion***]	☐ →10	☐ →11
	10	Each clinical procedure applied presents no more than minimal clinical risk to the subjects [***see notes of completion***]	☐ →11	☐ →A
Subject Assignment Methods	11	Subjects are assigned to different clinical methods/strategies (i.e. therapies, prophylaxes or diagnoses) by randomization or other research specific methods (other than by the professional judgment of qualified medical professionals)	☐ →A	☐ →12
Subject Vulnerability	12	Involvement of vulnerable subjects [***see notes of completion***]	☐ →A	☐ →B

Channel A	**Full review by Standard Panel** (unless otherwise determined by the IRB/REC according to the IRB/REC's SOP)
Channel B	**Expedited review by Expedited Panel** (unless otherwise determined by the IRB/REC according to the IRB/REC's SOP or requested by the principal investigator for a full review)
Channel C	**Full review by Phase 1 Panel** (unless otherwise determined by the IRB/REC according to the IRB/REC's SOP) / Recommend the principal investigator to collaborate with a study site under the jurisdiction of a research ethics committee with a specific review panel for phase 1 clinical trials

Official Use Only

Categorization by IRB/REC: ☐ **Channel A** ☐ **Channel B** ☐ **Channel C**

Reason (if IRB/REC applies a different categorization):

Notes for Completion of the Clinical Study Categorization Form

Risk Factors	Remarks
1	Recruitment of human subjects means prospective recruitment of subjects into a clinical study, irrespective of the nature of the study. Retrospective research on human materials or human data that have already been collected may not require recruitment of human subject unless separate informed consent is required for some or all of the subjects in the circumstances.
2	Medical products may include (but not limited to): (a) drugs (e.g. chemical drugs, biological drugs and vaccines); (b) medical devices (e.g. implants, diagnostic kits and imaging machines) (c) Chinese/herbal medicines (e.g. proprietary/traditional Chinese medicines); (d) health/nutritional supplements; (e) cell therapies (e.g. stem cells); and (f) gene therapies (e.g. viral vectors).
4	Labeled use refers to the use a medical product in accordance with the conditions of registration in Hong Kong (e.g. indications, patient groups, formulations and dosages).
9	Clinical procedures include (but not limited to): (a) clinical examination/assessments (e.g. venipuncture) (b) surgical procedures (e.g. tumor resection); (c) nursing procedures; (d) physiotherapies; (e) occupational therapies; (f) psychotherapies; (g) behavioral therapies; (h) alternative therapies (e.g. acupuncture); and (i) imaging methods (e.g. X-ray examination).
10	Minimal clinical risk means the probability and magnitude of harm or discomfort anticipated to be caused to the human subjects are not greater than those ordinarily encountered in their daily life or normal clinical care (e.g. the clinical risk associated with a buccal swab, taking of a small quantity of blood by venipuncture, and a chest x-ray examination).
12	Vulnerable subjects are individuals whose willingness to participate in clinical studies may relatively easily be unduly influenced by biases or coercive factors, or who are incapable of giving free informed consent through a normal informed consent process, such as: (a) children or adolescent (of less than 18-year-old); (b) illiterates; (c) mentally incapacitated persons; (d) impoverished persons; (e) ethnic minority groups; (f) patients in emergency conditions; (g) prisoners; and (h) subordinates or students of investigators.