Informed Consent Form Checklist (Including Phase 1 Study)

This checklist is designed to assist researchers in drafting, and CREC members in reviewing Informed Consent Forms (including Phase 1 Study). The checklist contains essential elements that should be included in the Informed Consent Form. Carefully review the draft Informed Consent Form and check each element that is present:-

- the informed consent form clearly identifies :
  - ☐ the study title of the research
  - ☐ the full name of Principle Investigator (PI), and if the PI is a student, the supervisor(s) full name; and
  - ☐ the sponsor(s) of the research (if applicable);

- the purposes and arrangements, including:
  - ☐ the research nature of the trial;
  - ☐ the purposes of the trial;
  - ☐ the details of the trial treatments and any randomization arrangement;
  - ☐ the experimental aspects of the trial;
  - ☐ the detailed trial procedures;
  - ☐ the expected duration of participation in the trial by each subject;
  - ☐ the circumstances where a subject's participation in the trial will be terminated; and
  - ☐ the approximate number of subjects involved or to be involved in the trial;

- the potential risks and benefits, including:
  - ☐ the potential benefits of the study; and
  - ☐ the foreseeable risks of the study;

- subjects' rights and responsibilities, including:
  - ☐ the right of voluntary participation in and free withdrawal from the trial;
  - ☐ the availability and details of any alternative treatment;
  - ☐ the right to be promptly informed of any new information that may affect

subjects' willingness of continuous participation in the trial;

- ☐ the right to contact a designated person for trial-related matters and his/her full name and contact details;
- ☐ the subjects' right to contact the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (香港中文大學－新界東醫院聯網 臨床研究倫理聯席委員會) Tel. no.: 3505 3935; and
- ☐ subjects' responsibilities in the trial;

- personal data protection, including:
  - ☐ the measures to be taken to protect subjects' privacy; and
  - ☐ each subject's permission to provide access to his/her personal data by certain designated parties and regulatory authorities;

- compensation and costs, including:
  - ☐ any payment to subjects;
  - ☐ the compensation and treatments available in the event of trial-related injury; and
  - ☐ any cost that may need to be borne by subjects;

- the informed consent form is written:
  - ☐ in the prospective subject's (or his/her substitute decision maker's) preferred language;
  - ☐ in layman terms (ordinary language) with simple explanations of all terms; and
  - ☐ at an appropriate level (taking into consideration the nature of the subject, e.g., child or adult);

- the informed consent form is signed:
  - ☐ by the subject (or Guardian/Parent where applicable);
  - ☐ by the person obtaining consent (e.g. Investigator/Researcher); and

☐ by the witness (if applicable).

The above elements are also applicable to Phase 1 Study. Aspects that are specific to or with higher importance in a Phase 1 Study, and need to be emphasized in the informed consent process may include:

☐ the early explorative nature of the trial;
☐ the foreseeable risks and uncertainties, considering the lack of or very limited human data on the IMP;
☐ the possible discomfort arising from trial procedures (e.g. intensive blood-taking);
☐ the lifestyle restrictions and inconvenience (especially if overnight stay at a study site is required);
☐ the privacy issues (especially if overnight stay at a study site is required);
☐ the stand-by subject arrangement (if applicable); and
☐ payment to subjects (if applicable, in particular how payments will be made in case of dropout or premature withdrawal/termination).