

Guidelines for research proposals submitted to the CIRB that qualifies for review by exempt procedure

(Adapted from Bioethics Advisory Committee Report, Research Involving Human Subjects: Guidelines for IRBs; Part B: Human Biomedical Research, Section 3.15)

(<http://www.bioethics-singapore.org/uploadfile/30129%20PMIRB%20II%20-%20Human%20Biomedical%20Research.pdf>)

Research activities, in which the only involvement of human subjects fits into one or more of the following categories, can be considered for exemption from review by the Chairperson of the CIRB.

- a. Writing up or reporting of individual patient's clinical results by the patient's doctors, provided that the patient's consent for procedures and interventions in clinical management have been obtained and the patient's privacy protected, for example, the review of a clinical programme that includes demographic, clinical and outcome parameters, which are useful in the audit of the programme; or the review of a procedure or treatment (a surgical technique or drug treatment outcome) by a physician or surgeon, where the choice of the drug or technique is based on the clinical judgment of the physician or surgeon and on best practices and not on any randomisation procedure. Researchers who are not the attending physicians in the programme but wish to have access to such information should send their proposals to the CIRB in the usual way.
- b. Research using appropriately designed data escrow or other arrangements in which personal or other identity information is securely withheld from researchers by a third party provider of information, there being no possibility of the researchers by themselves being able to trace or reconstruct significant information on the identity of subject donor.
- c. Research using established commercially available cell lines or commercially available anonymous DNAs, RNAs and fixed tissues.
- d. The development of diagnostic tests using existing samples for test validation purposes provided that the necessary consent has been obtained.
- e. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or observation of public behaviour, unless:
 - i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
 - ii. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.