

# **Guidelines for Ethical Review of Clinical Research or Research involving human subjects**

## **Medical Review & Ethics Committee (MREC) Ministry of Health Malaysia**

### **Guideline 1: Waiver of MREC review and approval for research not involving human subject**

1. A human subject (in the context of research) is a living individual about whom an investigator obtains either
  - Data through intervention (e.g. trial) with or without identifiable private information or
  - **interaction (e.g. physical examination, questionnaires) with the individual with collection of identifiable private information**

*Source: US Code of Federal Regulation Title 45 Part 46*

2. All research NOT involving human subject, as defined in (1) above, may be exempted from MREC review and approval. Such research is also automatically exempted from obtaining informed consent from study subject since by definition no human subject is involved.
3. The authority to exempt a proposed research from MREC review and approval may be delegated to an individual or body in the local institution. For MOH healthcare facilities, this would typically be the local Clinical Research Committee. Prior to authorizing exemption from MREC approval, the local authorizing body must verify that the proposed research is registered with the National Medical/Clinical Research Register to allow the MREC to track and review the appropriateness of exemption from MREC review. An investigator lacking access to a local body to authorize the waiver may apply instead to the MREC for the purpose.
4. The following types of research or data collection would be exempt from MREC review and approval:
  - a. Study or data collection based entirely on data abstraction from existing medical or laboratory record; with no interaction with the human subject concerned and with no collection of identifiable private information.
  - b. Study based entirely on existing biological specimen; with no interaction with the human subject concerned; with no collection of identifiable private information and with no further processing of and/or testing on the specimen.

- c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures (questionnaires), interview procedures or observation of public behaviour and with no collection of identifiable private information.

## **Guideline 2: Waiver of informed consent for research involving human subject**

1. The MREC may waive the requirement to obtain individual informed consent from the human subject participating in the research provided the MREC finds and documents that:
  - a. Subjects would be exposed to no more than minimal risk and the requirement of individual informed consent would make the conduct of the research impracticable

**OR**

  - b. Subjects would be exposed to no more than minimal risk and the study involves only publicly available data,

**OR**

  - c. The study involves private data but is carried out under legislative or public health authority.

*Source: CIOMS International Guideline for ethical review of Epidemiological studies*

2. For this purpose, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

*Source: US Code of Federal Regulation Title 45 Part 46*

3. The following types of research or data collection would be exempt from obtaining informed consent:
  - a. Research not involving human subject, as defined in Guideline 1
  - b. Clinical or disease registry or database, or large-scale non-interventional observational study, would also qualify provided the data collection is based on existing medical or laboratory records, the risk is minimal, it is impractical otherwise to conduct such study and the MOH is a sponsor of the registry or database or study.
4. Prior to waiving the requirement to obtain individual informed consent, the MREC must verify that the proposed research (*all types of research*) is registered with the National Medical/Clinical Research Register to allow the MREC to document and track the occurrences of such waiver.