Institutional Review Board (IRB) / Independent Ethics Committee (IEC)
IRB/IEC Defined

MGCP 1.37
Institutional Review Board (IRB) or Independent Ethics Committee (IEC)

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
What Are The Responsibilities Of The IRB/IEC?
What are the Responsibilities of the IRB/IEC?

MGCP 3.1.1

An IRB/IEC should safeguard the rights, safety and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.
How Does The IRB/IEC Carry Out Its Responsibilities?
How does the IRB/IEC Carry out its Responsibilities?

MGCP 3.1.2

The IRB/IEC reviews the following documents: trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, investigator’s brochure, safety information, information about payments and compensation, investigator’s curriculum vitae, and any other necessary documents.
How does the IRB/IEC carry out its Responsibilities?

MGCP 3.1.2 (Cont…)

The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for its decision on approval.
How Often Should An IRB/IEC Monitor An Approved Trial?
How often should an IRB/IEC Monitor an Approved Trial?

**MGCP 3.1.4**

The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the **degree of risk** to human subjects, but **at least once a year**.
Can The IRB/IEC Request Additional Information To Be Included In The Informed Consent Documents For A Trial?
Can the IRB/IEC request additional information to be included in the informed consent documents for a trial?

MGCP 3.1.5

The IRB/IEC may request more information to be given to subjects when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and well-being of the subjects.
What Is The Responsibility Of The IRB/IEC In Non-therapeutic Trials Where Consent Is From A Legally Acceptable Representative?
Responsibility Of The IRB/IEC In Non-therapeutic Trials Where Consent Is From A Legally Acceptable Representative.

MGCP 3.1.6

Where a non-therapeutic trial is to be carried out with the consent of the subject’s LAR, the IRB/IEC should determine that the proposed protocol and/or other documents adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
What Is The Responsibility Of The IRB/IEC In Situations Where Consent From A Subject Or The Subject’s Legally Acceptable Representative Is Not Possible?
What Is The Responsibility Of The IRB/IEC In Situations Where Consent From A Subject Or The Subject’s Legally Acceptable Representative Is Not Possible?

**MGCP 3.1.7**

The IRB/IEC should determine that the proposed protocol and/or other documents adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
How does the IRB/IEC review payments or compensation to subjects?
MGCP 3.1.8

The IRB/IEC should review the amount and method of payment to assure that neither presents problems of coercion or undue influence on the trial subjects. Payment should be prorated and not wholly contingent on completion of the trial by the subjects.
How does the IRB/IEC review payments or compensation to subjects? (cont.)

**MGCP 3.1.9**

The IRB/IEC should ensure that information regarding payments to subjects, including the methods, amounts, and the schedule of payment, is set forth in the written informed consent form. The way payment will be prorated should be specified.
What Is The Recommended Composition Of An IRB/IEC?
What is the recommended composition of an IRB/IEC?

MGCP 3.2.1

The IRB/IEC should consist of a reasonable number of members who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:

a) At least 5 members

b) At least one member whose primary area of interest is in a non-scientific area

c) At least one member who is independent of the institution/trial site.
What is the composition of an IRB/IEC?

MGCP 3.2.1 (cont.)

Only members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.

A list of IRB/IEC members and their qualifications should be maintained.
How Does An IRB/IEC Makes Its Decision On Approval Of A Trial?
How does an IRB/IEC makes its decision on approval of a trial?

**MGCP 3.2.3**

The IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written SOP, is present.

**MGCP 3.2.4**

Only members who participate in the review and discussion should vote/provide their opinion and/or advice.
How does an IRB/IEC make its decision on approval of a trial? (cont.)

**MGCP 3.2.5**

The investigator may provide information on any aspects of the trial, but should not participate in the deliberations or in the vote/opinion of the IRB/IEC.

**MGCP 3.2.6**

An IRB/IEC may invite non-members with expertise in special areas for assistance.
If An Institution Does Not Have An IRB/IEC, Can The Institution Use Another Institution’s IRB/IEC?
If an institution does not have an IRB/IEC, can the institution use another institution’s IRB/IEC?

MGCP 3.2.7

An institution without IRB/IEC may request IRB/IEC of Ministry of Health, Malaysia, to make decisions on behalf of the said institution.
What information should be in the SOPs of an IRB/IEC?
What information should be in the SOPs of an IRB/IEC?

MGCP 3.3

- The composition (names and qualifications of members), and the authority under which it is established.
- Scheduling, notifying its members of, and conducting their meetings.
- Conducting initial and continuing review of trials.
- Determining frequency of continuing review, as appropriate.
What information should be in the SOPs of an IRB/IEC? (cont.)

MGCP 3.3

- Providing expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.

- Specifying that no subject should be admitted to a trial before IRB/IEC issues its written approval/favourable opinion of the trial.
What information should be in the SOPs of an IRB/IEC? (cont.)

MGCP 3.3

- Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except:
  a) when necessary to eliminate immediate hazards to subjects, or
  a) When the changes involve only logistic or administrative aspects of trial.
What information should be in the SOPs of an IRB/IEC? (cont.)

MGCP 3.3

- Specifying that the investigator should promptly report to IRB/IEC:
  - Deviations from, or changes of, the protocol to eliminate immediate hazards to trial subjects.
  - Changes increasing risk to subjects and/or affecting significantly the conduct of the trial.
  - All adverse drug reactions that are both serious and unexpected.
  - New information that may adversely affect safety of subjects or conduct of trial.
What information should be in the SOPs of an IRB/IEC? (cont.)

MGCP 3.3

Ensure that IRB/IEC promptly notify in writing, in investigator concerning:

a) Its trial-related decisions/opinions.
b) The reasons for its decisions/opinions.
c) Procedures for appeal of its decisions/opinions.
How Long Should An IRB/IEC Retains Its Records?
How Long Should An IRB/IEC Retains Its Records?

MGCP 3.4

- IRB/IEC should retain all relevant records (e.g. written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority.

- The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.
Refer to website for specific MREC requirements for ethical approval.

www.nih.gov.my/mrec
Thank You