Role of Investigator, Sponsor, Ethics Committee

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UPM Research Ethics Board

Overview

- Role of Investigators
- Role of Sponsors
- Role of Ethics Committee
  - *ICH Harmonized Tripartite Guideline For Good Clinical Practice (ICH-GCP) (1996)*
  - *Council for International Organizations of Medical Sciences (2009)*

1. Role of Investigator: GCP

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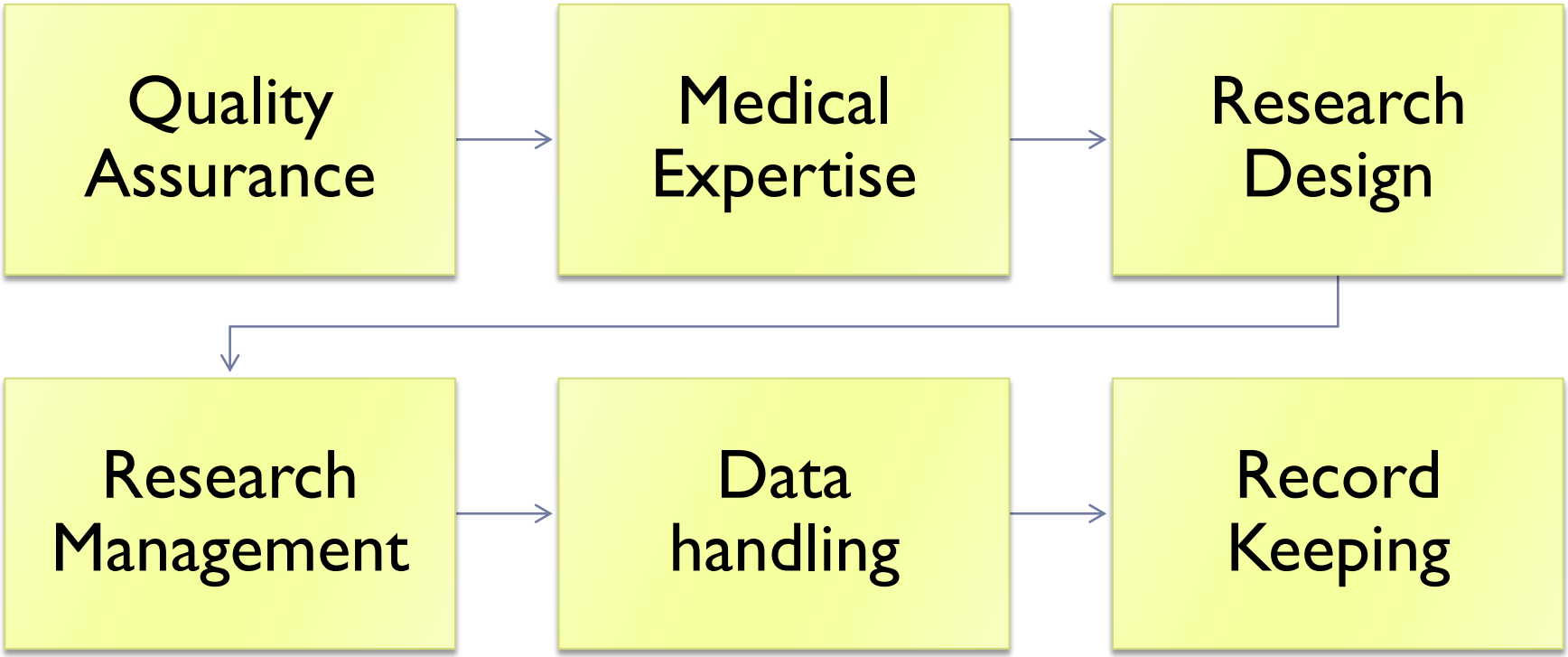
Safety Reporting

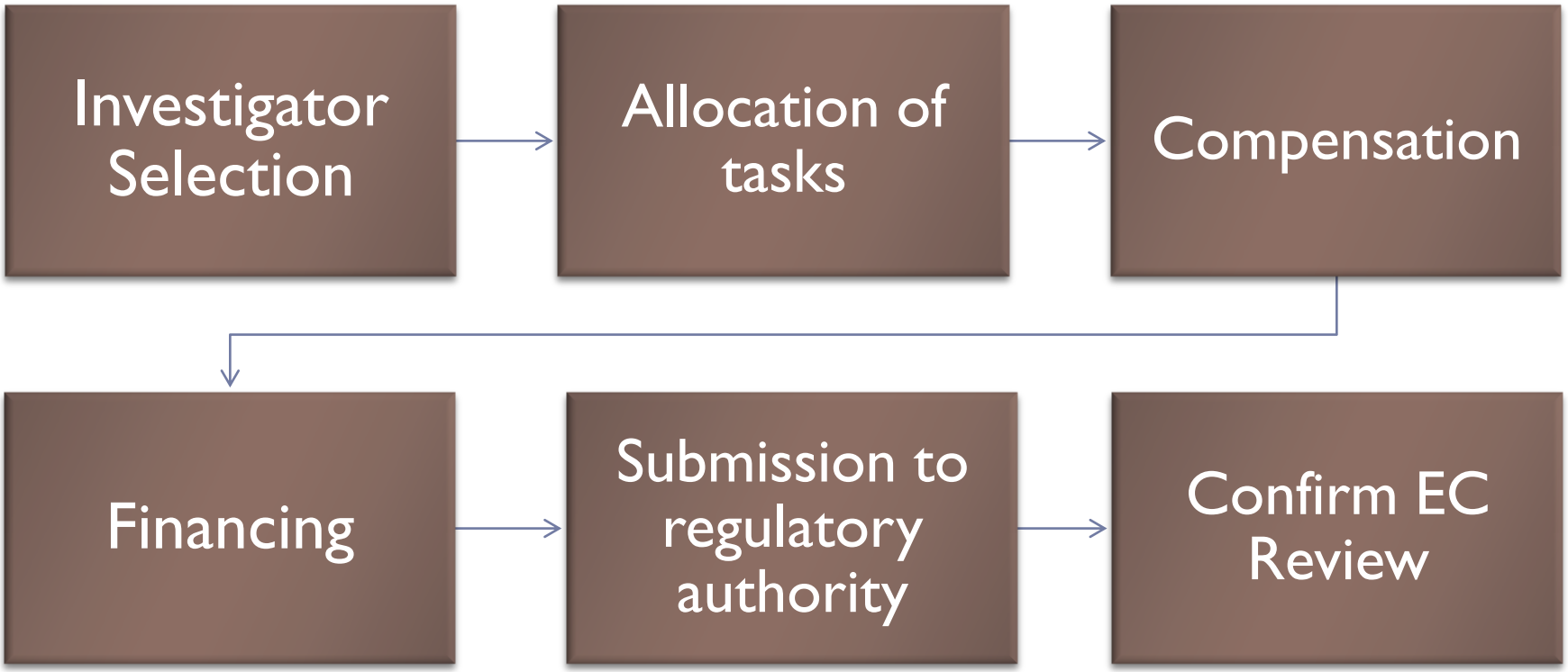
Premature Termination or Suspension

Final Report

Role of Sponsor: GCP



3. Role of Sponsor: GCP



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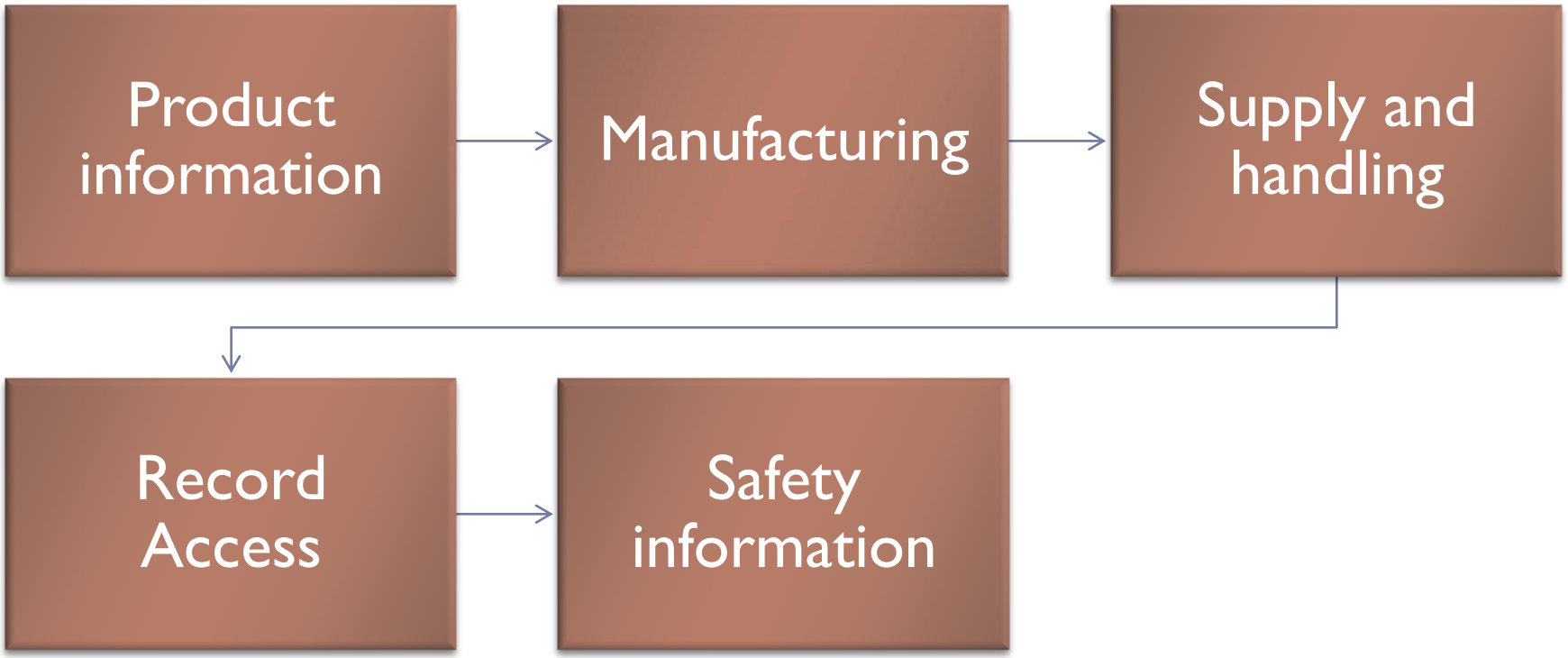

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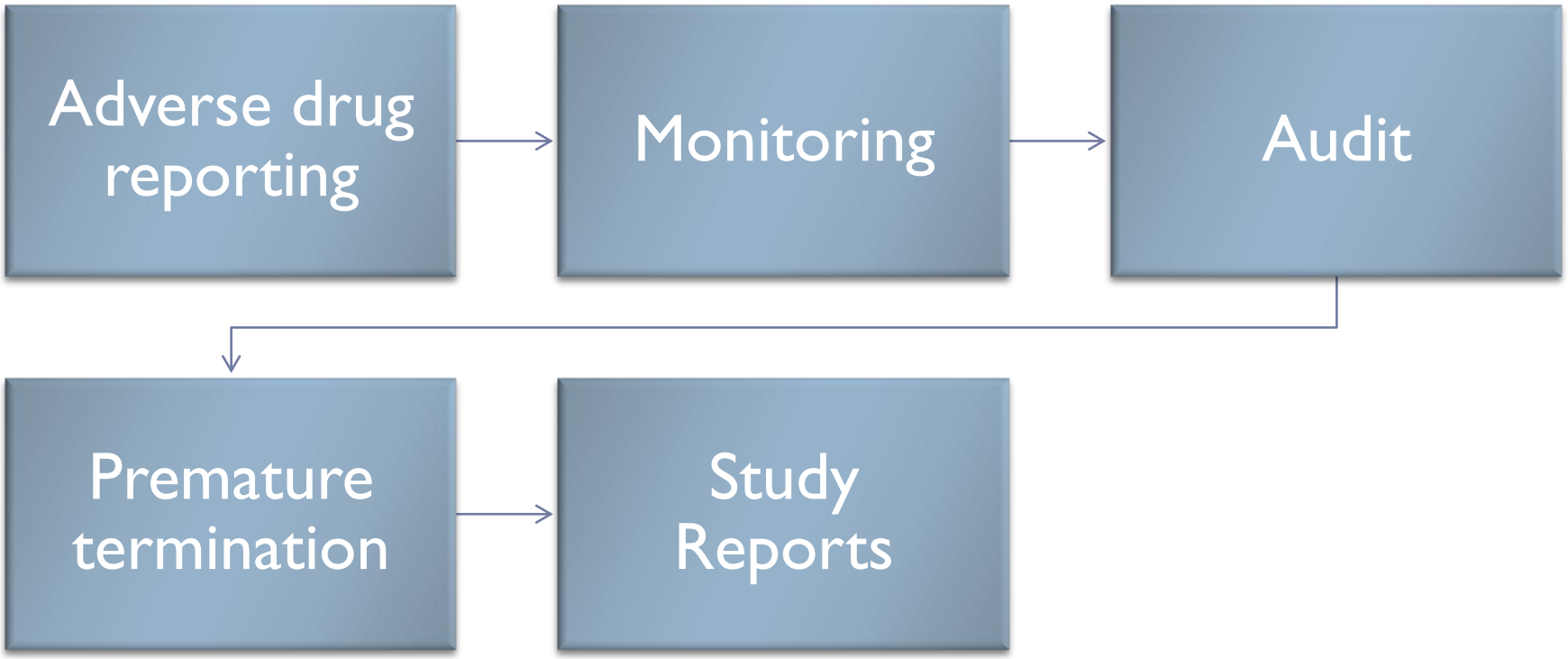


3. Role of Investigator+Sponsor:CIOMS

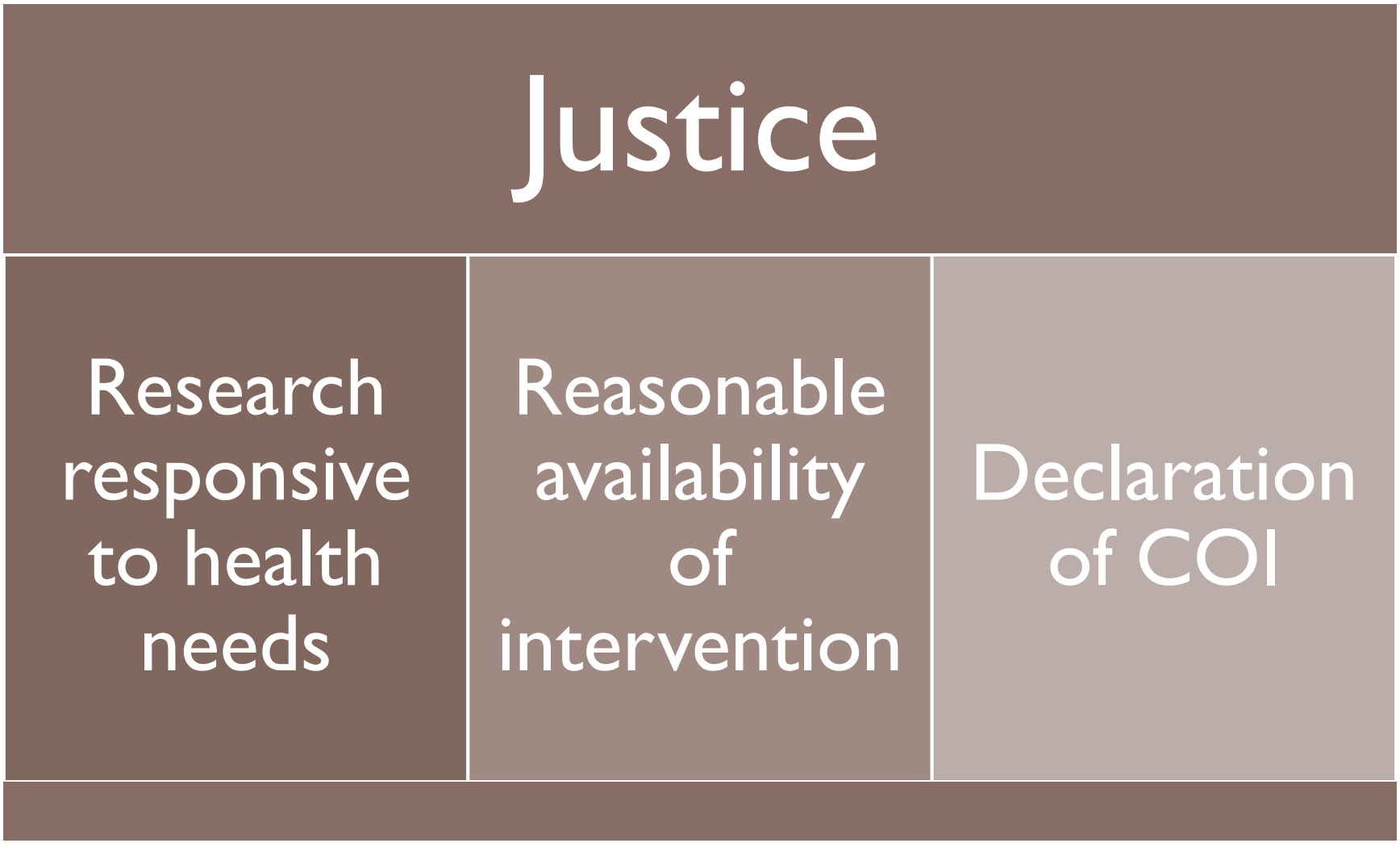
Informed Consent

Refrain from unjustified deception, undue influence, or intimidation	Seek consent only after adequate understanding of facts and consequences of participation with time to consider	Obtain individual signed IC from each prospective subject

3. Role of Investigator+Sponsor:CIOMS

Informed Consent		
Justify any exceptions to consent; obtain approval of the ethical review committee	Renew IC if there are changes or information updates that might affect willingness	Renew IC in long-term studies even if there are no changes or updates

3. Role of Investigator+Sponsor:CIOMS



3. Role of Investigator+Sponsor:CIOMS

Capacity building

Independent competent ethical review	Research capacity	Public health and healthcare technology	Educating the community

4. Role of EC: GCP

Safeguard the rights, safety, and well-being of all trial subjects

4. Role of EC: GCP

PRE-APPROVAL: *Obtain trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfill its responsibilities.*

4. Role of EC: GCP

PRE-APPROVAL:

- Review within a reasonable time and document its views in writing (minutes and other documents)
- Set decision points: Approval, modification, disapproval
- Review investigator qualifications
- If needed, request more information for meaningful IC
- Assess regulatory compliance especially in ability of participant to consent
- Review compensation

4. Role of EC: GCP

POST APPROVAL

- Conduct continuing review at intervals appropriate to the degree of risk
- Review SAEs
- Review compliance/deviation
- Review completion of studies
- Review grievances

4. Role of EC: GCP

COMPOSITION, FUNCTION, OPERATIONS

- At least five members; at least one member whose primary area of interest is in a nonscientific area; at least one member who is independent of the institution/trial site.
- List should be maintained and available upon request
- Function according to SOP
- Decisions during meetings when there is quorum
- May invite experts during meeting
- Only members who are present can deliberate

4. Role of EC: GCP

PROCEDURES:

- Determining its composition
- Scheduling, notifying its members of, and conducting its meetings.
- Conducting initial and continuing review of trials.
- Determining the frequency of continuing review
- Providing, according to the applicable regulatory requirements, expedited review and approval/favorable opinion of minor change(s) in ongoing trials that have the approval/favorable opinion of the IRB/IEC.

4. Role of EC: GCP

PROCEDURES (continued) **:**

- Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favorable opinion of the trial.
- Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (change of monitor(s), telephone number)

4. Role of EC: GCP

PROCEDURES (continued)

- Require the PI to report:
  - Deviations
  - Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial
  - All adverse drug reactions (ADRs) that are both serious and unexpected
  - New information that may affect adversely the safety of the subjects or the conduct of the trial.
- Ensuring prompt notificatio in writing of:
  - Its trial-related decisions/opinions.
  - The reasons for its decisions/opinions.
  - Procedures for appeal of its decisions/opinions.

4. Role of EC: GCP

RECORD

- 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(ies).
- The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.

Contact Information

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