Defining the Role of the Institution in Responsible Conduct of Research

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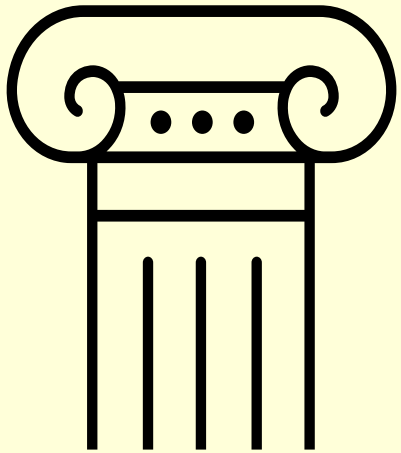
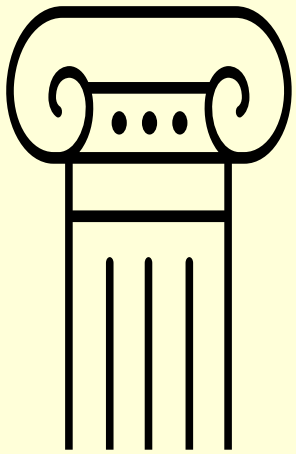
GCP Definitions

- **Institution -** Any public or private entity or agency or medical or dental organisation in whose remit clinical trials are conducted. (ICH-GCP E6 Glossary)



- **Investigator** - Where an investigator/ institution is referenced in the GCP guideline, it describes expectations that may be applicable to the investigator and/or the institution… Where required by the applicable regulatory requirements, the “investigator” should be read as “investigator and/or the institution.” (ICH-GCP E6 Glossary)

GCP Definitions



Institutional Review Board (IRB)

ICH-GCP E6 Glossary

An independent body (a review board or an institution committee…) constituted of medical professionals and non-medical members whose responsibility it is to ensure the protection of the rights, safety and well-being of human participants

- Functions:
  - Review and approve/provide favourable opinion on the trial protocol,
  - the suitability of the investigator(s),
  - the facilities,
  - the methods and material to be used in obtaining and documenting informed consent of the trial participants.

The legal status, composition, function, operations and regulatory requirements pertaining to IRBs/IECs may differ among countries but should allow the IRB/IEC to act in agreement with GCP as described in this guideline.

– (ICH-GCP E6 Glossary)

GCP Perspective

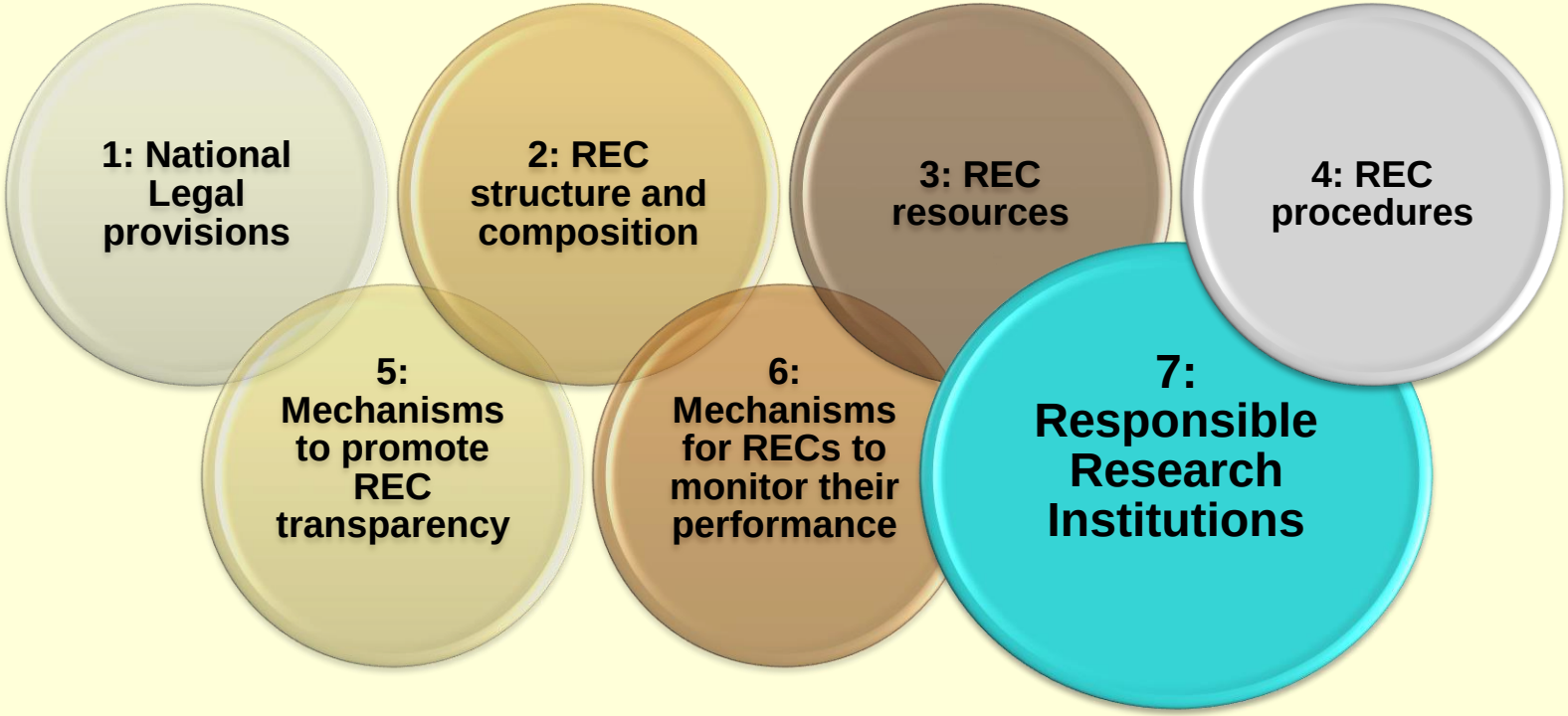
The role of the institution in GCP is also seen as part of site management to help investigators comply with their responsibilities such as:

- 2.4.1 Communication with the IRB
  - Submission to the IRB/IEC may be made by the investigator/institution or sponsor in accordance with applicable regulatory requirements
- 2.7.1 Medical Care of Trial Participants
  - During and following participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a participant for any adverse events…
  - The investigator/institution should inform a participant when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.

Overview of Asian Countries: FERCAP Recognized/ Certified RECs in 15 countries	**WHO GBT Level of Performance**		
WHO GBT Indicators 1: Not implemented 2: Partially implemented 3: Fully implemented	Low Income Country	Middle Income Country	High Income Country
1. Legal & Regulatory Framework	2	2-3	2-3
2. REC Structure & Composition	**3**	**3**	**3**
3. REC Procedures	**3**	**3**	**3**
4. REC Resources	**3**	**3**	**3**
5. REC Transparency & Accountability	2	2	2
6. REC Monitoring of REC Performance	2	2	2
7. Responsible Research Institutions	2	2	2-3

WHO-GBT Components

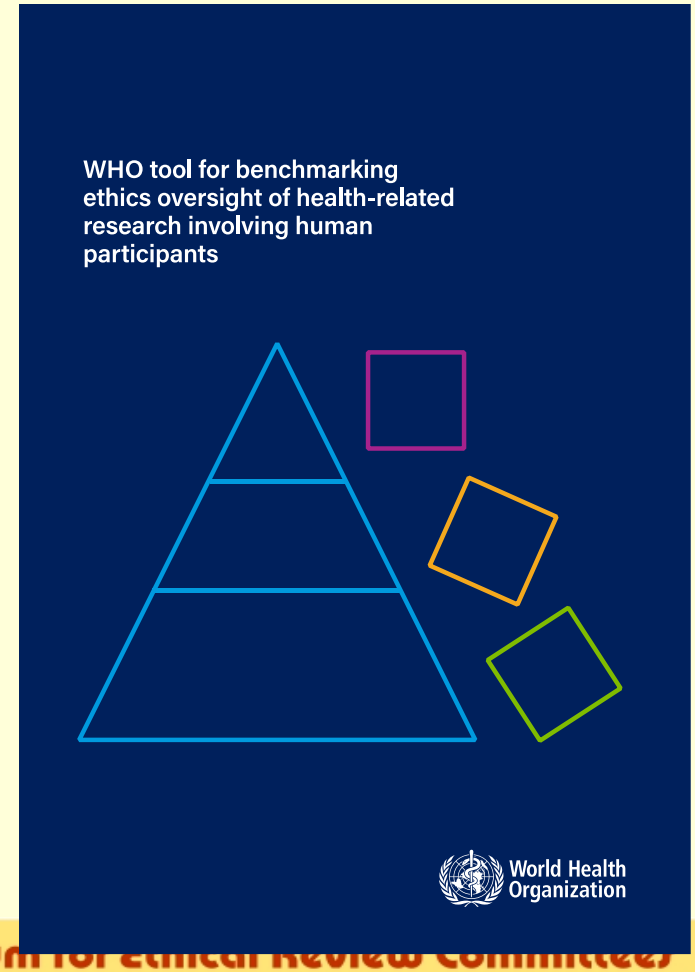
for EC review of human research



Institutional Responsibilities
WHO-GBT for ethics oversight of human research (2023)

- 07.01: The institution verifies that all proposals for health-related research involving humans are **submitted to a registered REC** if any part of the research is to be conducted by **a researcher affiliated with the institution**

- 07.05: The institution has **its own REC**, it ensures that the REC has the **resources to support its operations.**



7.01 Evidence to check compliance

a. **Institutional policies** that require that all health-related research involving humans be submitted to an REC if any part of the research is to be conducted by **a researcher affiliated with the institution;**

b. Institutional policies specifying the REC(s) on which the institution relies for reviewing research conducted by researchers affiliated with it

c. Evidence that the institution ensures that researchers affiliated with it comply with these policies

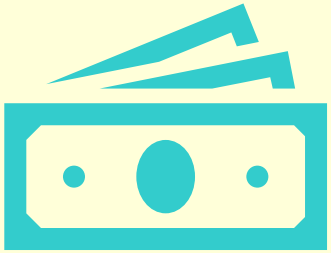
7.01 Evidence to check compliance

d. Information about any actions taken against researchers who failed to comply with these policies;

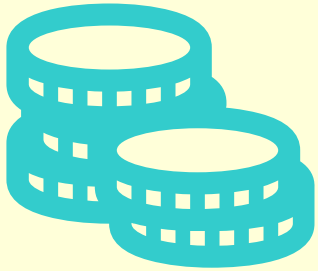
e. Information about all health-related research involving humans conducted by researchers affiliated with the institution in the current and previous years, with evidence that the studies were submitted to RECs;

f. Evidence of the institution's express commitment to comply with international and national ethical standards in health-related research involving humans

7.05 Evidence to check compliance



Provisions in the institutional budget to support the REC



Any other information about the sources of funding and other resources provided to the REC

Institutional Responsibilities: Conflicts of Interests

- 07.02: The institution has policies and procedures for **declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself**

- 07.03: Institutions with their own **RECs have policies and procedures for declaration and management of conflicts of interest** of REC members and non-member participants in REC meetings.

7.02 Relevant evidence to check compliance

- Institutional policies and procedures for declaration and management of conflicts of interest of researchers affiliated with the institution and of the institution itself;
- Evidence that those policies and procedures are consistently followed;
- Declarations of conflict of interest submitted to the institution in the current and previous years;
- Information about actions taken by the institution when conflicts of interest have been declared;
- Information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution’s policy.

7.03 Evidence to check compliance

- Institutional policies and procedures for declaration and management of conflicts of interest of REC members and non-member participants;
- Evidence that these policies and procedures are consistently followed;
- information about actions taken by the institution when conflicts of interest have been declared;
- information about actions taken against individuals who fail to disclose conflicts of interest pursuant to the institution's policy;
- information about the institution's internal governance structure as it pertains to the conduct of health-related research involving human participants.

Institutional Responsibility: Training in Research Ethics

- 07.04: The institution has a policy that requires that all researchers affiliated with it be **trained in their responsibilities for ethical conduct of research.**

7.04 Evidence to check compliance

a. Institutional policies that require that all researchers affiliated with the institution be **trained** in their responsibilities for ethical conduct of research; *f*
b. Institutional policies that require researchers to provide proof **of compliance** with their training obligations;
c. Evidence or proof of training submitted by researchers affiliated with the institution in the previous year; and
d. Information about **actions taken against researchers** who fail to satisfy their training obligations.

Institutional Responsibility: Resolving unethical conduct

- 07.06: The institution facilitates lodging of complaints by research participants and prospective research participants about studies conducted by researchers affiliated with the institution… and the institution has a process for reviewing and responding to complaints.

- 07.07: The institution has a process for **investigating allegations** of unethical conduct by researchers and for imposing **consequences when unethical conduct** is determined to have occurred.

7.06 Evidence to check compliance

The institution provides research participants a **contact information** to respond to complaints about research, or how to submit complaints through that system;

Evidence of all complaints received in the current and previous years and the **institution's responses** to those complaints;

Evidence of any follow-up actions the institution has taken in response to complaints received, including remedial actions in ongoing studies and changes to the process of ethics review.

7.07 Evidence to check compliance

Institutional policies that specify a process for **investigating allegations** of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred;

Information about the **range of consequences** that might be imposed on researchers who are determined to have engaged in misconduct;

Information about the **due process protections** provided to researchers accused of misconduct;

Information about any investigations conducted of researchers accused of unethical conduct and the outcome of those investigations.

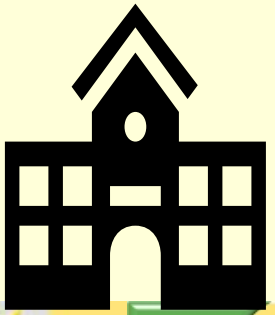
Defining Institutional Role in Responsible Conduct of Research

A. University of the Philippines Manila	National Graduate Office for Health Sciences
	Research Ethics Board
	Research Grants and Administration Office
	Research Integrity Office
B. National Institutes of Health	NIH Research Institutes and Study Groups
	NIH Research Ethics Training Program
	National Clinical Trial Translational Center
C. Philippine General Hospital	Site of clinical trials initiated by sponsors and researchers
	Residency and fellowship training in research

Current Directions

Addressing GAPS:

Need for better organizational coordination and integration among various offices



- Objective: UPM as center of excellence in site management of clinical trials and research
- UPM Code of Conduct for Researchers
- Institutional policies and organogram clearly defining mandate and oversight roles and functions of various committees
- Capacity building of research participants
- Grievance mechanism and resolution
- Institutional initiatives to train and capacitate communities/ patients for informed research participation
- Overall coordination of various offices for Human Protection

Further assistance to researchers

Provide overview of regulations and guidelines through GCP training
Assist in drafting the clinical protocol to comply with GCP and GRP guidelines
Provide templates for clinical monitoring activities, product disposition log, study protocol, and case report forms
Prepare written procedure for clinical trial monitoring (who, when, how, etc.)
Provide templates regarding protocol amendments, additional co-investigators, process changes, and adverse event reports
Provide updates related to in demand research topics, novel innovative design and technology


THANK
YOU!