Institutional Responsibilities in the Conduct of Schistosomiasis Research in the Community

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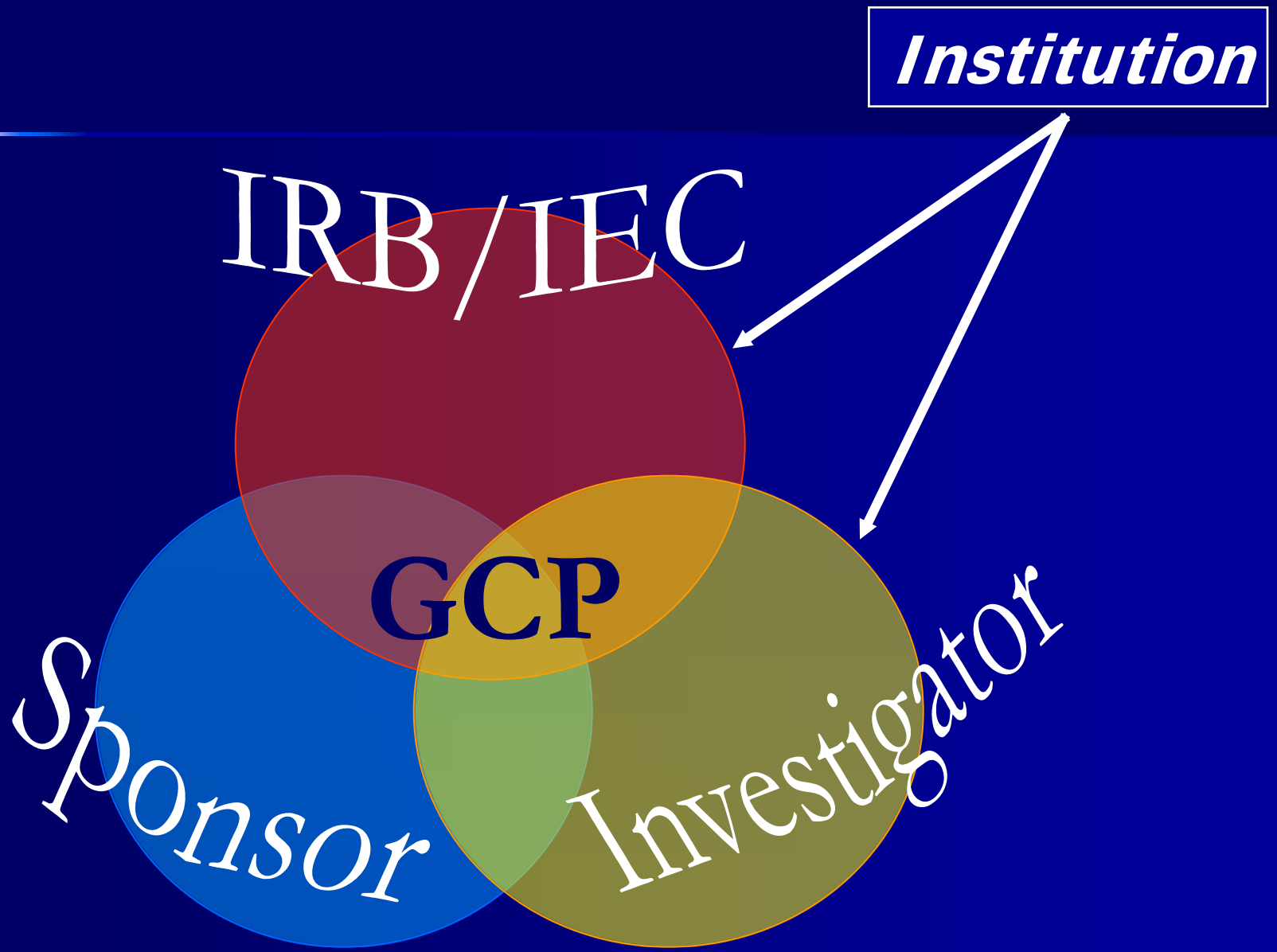
Stakeholder Responsibilities



Investigator and IRB need to apply the principles of Good Clinical Practice (GCP)

- To ensure the rights and safety of study participants in the community
- To ensure the integrity of research data

Context

- Country: The Philippines
- Research projects: Clinical and epidemiologic researches on schistosomiasis
- Study sites: Resource-poor communities in Visayas and Mindanao

Rationale of the Research Projects

- Schistosomiasis remains as a major public health problem in 28 poor provinces of the Philippines
- Highest prevalence in children 5-15 years of age
- Resurgence resulting from decentralization of health services
  - Lack of resources and capacity for control
- Researches crucial for policy and planning
  - Allocation of resources for drugs, IEC and their delivery
  - Method/s of delivery of mass treatment
  - Capacity building of local health units/staff

Context

- Institutions involved in schistosomiasis researches:
  1. Academic institution – IRB1
  2. Research institution – IRB2
  3. Department of Health Regional Office – IRB3
- **What is their extent of compliance with GCP standards?**

Institutional Responsibilities

- The Institutional Review Board (IRB)/Independent Ethics Committee (IEC) is the principal means to ensure ethical conduct in research.

  Ethical Conduct

  Research involving humans should be scientifically sound and conducted in accordance with basic ethical principles:
  - Respect for persons
  - Beneficence
  - Justice

IRB1 and IRB2 have duly constituted IRBs/IECs consistent with GCP guidelines.

IRB3 has a research coordinator.

Institutional Responsibilities - IRB

- Initial Review
- Continuing Review
- Continuing Responsibilities

Institutional Responsibilities- IRB Initial Review

- The IRB/IEC reviews the scientific merits of a protocol.

  Research Described in a Protocol

  Research involving humans should be scientifically justified and described in a clear, detailed protocol.

All IRBs request for submission of research protocol for review.

IRB1 and IRB2 have SOPs for review and approval of research protocols.

Scientific Review

- Rationale for the study
- Objectives
- Type and no. of subjects
- Recruitment procedures
- Inclusion and exclusion criteria
- Data analysis procedures including statistical measures
- Scientific oversight and data monitoring
- Confidentiality Issues

IRB1 and IRB2 conducts a systematic review of the research protocol.

Institutional Responsibilities- IRB Initial Review

- The IRB conducts benefit-risk assessment.

  Risk Identification and Benefit-Risk Assessment

  Foreseeable risks and discomforts and any anticipated benefits for the individual research subject and society should be identified.

IRB1 and IRB2 conduct benefit-risk assessment.

They are concerned about maximizing benefits and minimizing risks.

"How will study participants and communities benefit?"

IRB3 and studies on schistosomiasis eradication

- Foreign collaborators coordinate with health field office
- Old vehicle donated for health staff use in the field
- Case finding by stool examination and serology but with unacceptable delays in provision of results and treatment
- Weak capacity building aspect of project
- “Dumping” of molluscicide chemicals in study communities that kill other aquatic organisms and contaminate sources of water

Institutional Responsibilities- IRB Initial Review

- An independent institutional review board (IRB)/independent ethics committee (IEC) ensures a good system of check and balance in the review and implementation of research.

  Review by IEC/IRB

  Research involving humans should receive IEC/IRB approval/favorable opinion prior to initiation.

Independent reviews by IRB1 and IRB2 are known to occur.

Institutional Responsibilities- IRB Initial Review

- The IRB/IEC reviews and approves the consent form.

  Informed Consent

  Freely given informed consent should be obtained from every subject prior to research participation in accordance with national culture(s) and requirements.
- Review ethical concerns and apply regulatory requirements related to
  - Study participants that require legally authorized

Informed consent process and forms reviewed by IRB1 and IRB2 in accordance with national and international guidelines.

Institutional Responsibilities- IRB Initial Review

- The IRB determines the capacity of the investigators to undertake the research project.

  Investigator and Staff Qualifications

  Qualified and duly licensed medical personnel should be responsible for the medical care of research subjects, and for any medical decision made on their behalf.

IRB1 and IRB2 examine submitted CVs of investigators and determine their capacity to undertake the research projects.

Institution 1 provides opportunities for capacity building for research ethics and GCP for investigators and IRB members.

Institutional Responsibilities – IRB Initial Review

- **Review documents**
  - Protocol / protocol amendments
  - Patient information sheets
  - Consent forms / updates
  - Subject recruitment procedures (advertisements)
  - Investigator's Brochure
  - Safety information
  - Incentives for study participants
  - Investigator's CV
  - Others

Institutional Responsibilities- IRB Continuing Review

- The IRB/IEC monitors compliance of protocol implementation with the approved protocol.

  Protocol Compliance

  Research involving humans should be conducted in compliance with the approved protocol.

- The IRB/IEC should require continuing review reports from investigators to ensure safety of human subjects.

  Continuing Review / Ongoing Benefit-Risk Assessment

  Research involving humans should be continued only if the benefit-risk profile remains favorable.

IRB1 and IRB2 require progress reports from investigators and conduct continuing review.

Institutional Responsibilities – IRB Continuing Review

- **Progress report**
- **Investigators required to report**
  - Protocol changes/deviations to eliminate hazards to trial subjects
  - Changes increasing risks to patients or affecting trial conduct
  - All adverse drug reactions (serious and unexpected)
  - New information that affect conduct of trial

Institutional Responsibilities – IRB Continuing Responsibilities

- **Records**
  The IRB/IEC should maintain orderly files of active protocols and set up its archives for completed studies.
- **Confidentiality/Privacy**
  The IRB/IEC should ensure confidentiality of records and privacy of study participants.

Institutional Responsibilities – IRB Continuing Responsibilities

- **Good Manufacturing Practice**
  The IRB/IEC should ensure the safety of investigational products.
- **Quality Systems**
  IRB/IEC should adopt systems that ensure quality of every aspect of the trial/study.

IRB1 and IRB2 have been surveyed and recognized by SIDCER/FERCAP.

Research Outputs and Outcomes

- Institutions 1 and 2
  - Research results published in international scientific journals
  - Research results have described disease resurgence and has led to a better understanding of co-morbidities and results of effective interventions
  - Research results have been utilized for planning including resource allocation and for policy by the disease control program in its revised guidelines

Strengthening Education in Research Ethics for Investigators

- Respect cultural traditions of study populations and communities
- Develop culturally meaningful approach to informed consent
- Apply appropriate standards of care and provisions for medical treatment
- Provide on-going feedback to the study participants and the community
- Investigators should make efforts to strengthen the local health infrastructure and to provide for the continuation of effective research interventions and programs.

Strengthening IRBs/IECs

- “Gate-keeping” function
- Strengthen capacity for independent ethical review of protocols
- Quality systems
- Survey and recognition

Summary

- Adherence to GCP standards ensures protection of human subject participants and scientific quality of researches
- Institutions should provide adequate support for IRBs to operate in accordance with national and international standards
- Institutions should provide opportunities for training in research ethics for investigators
- Communities should benefit from research projects as study sites in terms of improvement in local health infrastructure