Challenges in Ethical Review in Mindanao

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Objectives

1. What were the challenges met by the ERCs in Mindanao in ethical reviews ?
2. How were these challenges addressed?
3. Where these challenges resolved?
4. What are the implications of these challenges on the ERCs in Mindanao?

Challenges Met by ERCs in Mindanao

1. Risks and Benefits Assessment

2. Adherence to International , National, Institutional Guidelines and Policies

3. Adequacy of Standard Operating Procedures (SOP) and Consistency of Implementation and Compliance

4. Cultural - Determination of sample size in a research on Ips

5. Difficulty in synergizing members commitment with their professional and personal commitments

Challenges….

6. Clarity of National Unified Health Research Agenda (NUHRA) and the Regional Unified Health Research Agenda (RUHRA)

7. Clarity of the Terminologies (ERC vs. ERB) especially on the privileges, authority as reviewing bodies

8. Clarity on the qualification of ERC to review Clinical Trials?

Challenges…..

9. Consistency of decisions in review

10. Staff to man the REC

11. Trainings for New Members

12. Updating of Old Members

1. Risks vs Benefits Assessment

- How to determine balance between risks and benefits?
- That assessment most often is a judgment although it may be informed by expert opinion, the literature and current best practices , there is rarely an objective metric to make the assessment.
- Different investigators, community groups and /or ethics committee may come up with different assessment .This can present problems and can cause delays, particularly for multi-site research.
- Differences in perception of risk and benefit

- A study was submitted to test an IND with babies as study population.
- Questions were asked how adverse reactions if ever it occurs, be handled?
- A conflict ensues on the risks met when giving the IND to babies

2. Adherence to International , National, Institutional Guidelines and Policies

- ERC should have copies of pertinent guidelines and policies (Declaration of Helsinki 2008, WHO operational guidelines to ERCs, ICH-GCP, DOST/DOH/CHEDS AOs)
- Inadequacy in certain specific issues (ex. National Policy on research grants for collaborative research between private entities and academe
- Ex. A group of Plant growers / private entity wishes to ask the technical assistance from academe to conduct a clinical trial concerning pharmacologic/ therapeutic claims.

- During the review, one of the member of the IRB inquired about the benefits this research would have on the community.
- Will the community receive economic benefits from the research?
- ERC lacked the knowledge on the updated national policy on this type of grants.
- Hence, the ERC decided to invite an expert from DOST to explain to all members the current guidelines and policies relevant to the query / to elaborate on specific issues in the protocol.

3. Adequacy of Standard Operating Procedures (SOP)

- Formal Turnover of responsibilities to new composition of REC members- Transition
- Due to this there was a delay in the review of researches- miscommunications and misunderstanding ensued
- Does the ERC conduct Continuing review process (follow-up)?

4. Consideration of sample size in a research on IPs

- A graduate research was conducted on IPs
- The researcher had difficulty on sticking to the calculated sample size as IPs flocked to the dental examination site when assessment of dental oral condition of study population.
- Researcher then considered all who were present.

5. Difficulty in synergizing ERC members' commitment with their professional and personal commitments

- Difficulty in maintaining a diverse membership
- Absences in meetings
- Sustainability of interest

6. Clarity of National Unified Health Research Agenda (NUHRA) and the Regional Unified Health Research Agenda (RUHRA)

- Rejection of a research proposal because the research did not fall under the NUHRA and RUHRA priorities.

7. Clarity of the Terminologies (ERC vs. ERB) especially on the privileges, authority as reviewing bodies

- ERCs – no authority
- ERBs – has authority
- Only Level II accredited ERC s can review clinical trials?

8. Clarity on the qualification of ERC to review Clinical Trials?

Level 1-accreditation qualifies an ERC to review researches involving human participants except clinical trials

Level 2 accreditation qualifies ERC to review clinical trials protocol not intended for registration of new drugs.

Level 3 accreditation gives the ERC the privilege to be part of the Ethics Resource Committees of the Philippines FDA. Required for ERCs that review investigational New Drugs (IND) or device protocols…

9. Consistency of Implementation and Compliance

- Completeness and Accessibility of SOPs (func tion/responsibilities of the ERC, Compliance with SOPs in meetings, completeness of review process- continuing review process)
- One of the ERC members suggested coming up with a monitoring list (issues /.cases and their corresponding decision or sanctions) for tracking.
- If the same case will be encountered during the review , the ERC will be consistent in their assessment.

10. Inadequacy of REC's Staff/ Office

- Administrative support for the implementation and documentation of activities (office, equipment, support staff, budget)
- Efficiency of recording and archiving system (record keeping, retrieval, database, etc.)

11. Trainings for New Members

- There is a need to train new members in SOPs, GCP, etc.

12. Updating of Old Members

- There is a need to ensure continuing training of members

Implications of these challenges

1. There is a need to prepare the SOPs
2. There is a need to allow old members to update on GCPs and SOPs
3. There is a need to orient new members regarding ethics review
4. There is a need to organize the IRB or ERCs or ERBs for organizations conducting research involving Human participants.
5. Finally, there is a need to submit voluntarily for accreditation.

- Our Voices have been heard ….
- We hope to learn….
- We act on it now….
- We partner for researches for better health!

Thank you and Good Day!