



Updates on Philippine Research Ethics

12th PNHRs

Synthesis and Recommendations

Ethics in Public Health Research & Practice

- There is a need to distinguish PH research and PH practice
- Code of Ethics for PH includes professional competence, respect for rights of individuals and protection of confidentiality of information, as well as empowerment of community members and timely action.
- Perception of stakeholders needed to come up with ethical guidelines on PH research

Ethics in Public Health Research & Practice

- KII results:
 - requirements for ethics oversight
 - administrative role of practitioners should be separate from research undertakings
 - addressing conflicts of interest
 - training to distinguish PH practice from research
 - research should not delay interventions

Ethics in Public Health Research & Practice

Recommendations

- Research COI should be addressed by having Co-I from PH office
- PH review mechanisms should be responsive to the needs of participants
- Consolidated, independent IRB (PHEC) – with clear mandate and institutional support
- Training of IRBs on distinguishing PH research from practice
- Two informed consents for outbreaks or emergency programs with research components

Public Health Ethics Oversight

- Single site oversight by Institutional RECs
- Multiple site oversight by SJREB
- While we can adopt international guidelines, there are still gray areas
- DOH shall constitute PHEC as an advisory body that will determine whether the program is research or not
- PHEC review will be at point of 2nd stakeholders consultation, after draft policy issuance

Public Health Ethics Oversight

- PHEC review shall cover interventional PH policies and activities identified as high risk
- PHEC proposed provision is expedited review for emergency and disaster situations
- Guidelines for PHEC operationalization in place
 - Secretariat role defined
 - Membership will include patient groups (lay member)

Public Health Ethics Oversight

Recommendations

- Policy issuance on operationalizing PHEC
- Development of SOPs for PHEC review

Ethics Dumping

- TRUST project to address/counter ethics dumping in LMICs
- Global Code of Conduct for Research in Resource-Poor Settings (for HIC researchers)
 - Values emphasized: fairness, respect, care, honesty
 - Influence guidelines on research with aboriginal communities
- Book on Case Studies from North South Research Collaborations – exploitative
- Dumping practices include studies on indigenous groups, unfair compensation for participants and researchers

Ethics Dumping

- The TRUST Code has guidelines that PHREB may want to consider
- NEGHHR 2017 sections that address Ethics Dumping
 - Responsibilities of Foreign Researcher
 - International Collaboration
- Overseas Development Assistance (ODA) “protection”
 - support coop/collab programs with clear benefits
 - basic concept is if it’s not beneficial to the Philippines, why do it here

Ethics Dumping

Recommendations

- Ensure that standard of care in country is given
- Check quality of informed consent
- Follow PHREB Guidelines adopted from Commission for Research Partnerships with Developing Countries
- Enable research participants and communities to protect their rights

Patient Perception of Clinical Trials

- Study on perception of clinical trials by cancer patients – with or without CT experience
 - Ability to make decisions
 - Whom to consult
 - Who should give consent
 - What information before joining CT
- Related expense and side effects are top concerns before joining CT of those with CT experience
- Study doctor responsibilities and side effects are top concerns of those with no CT experience

Patient Perception of Clinical Trials

- Both CT and non-CT participants need support on info on drug efficacy, continued consultation with study doctor, continuous info on new treatments, membership in survivor support groups
- Use KAP data to develop interventions, *i.e.* educational intervention
- Results of pre and post intervention surveys are significantly different

Patient Perception of Clinical Trials

- More positive perception of benefits and safety after the educational intervention
- Better understanding of role and qualification of doctor and role of sponsor after educational intervention
- Current educational interventions may not be suitable for specific patient groups thus, the need for perception research first

Patient Perception of Clinical Trials

Recommendations

- Need to educate patients about treatment opportunities in CTs
- Sponsors, institutions, patient groups should conduct patient education about CTs
- Provide more funding for intervention researches that make the patients more informed

Responsiveness & Post-Trial Access

- The issue of responsiveness and post-trial access must be seen in the context of health equity
- Responsiveness and PT access in Helsinki 2013, UNESCO Declaration on Bioethics and Human Rights, CIOMS 2016
- Number of PT protocols submitted per year is decreasing
- PT provisions seen in the Philippines include access to results, standard of care outside of trial

Responsiveness & Post-Trial Access

- Real PT access is different from market availability

Recommendations

- PT access should be access to safe and effective drugs
- Phase 4 trials should be scientific

Establishing RECs

- Instigation or Inspiration
- Support from administration
- Operational planning
- Consultation, confirmation, cooperation
- Preparation for Accreditation
- Application for Accreditation

Establishing RECs

- In accreditation, PHREB looks at the institutional system – the different panels
- Is there still a need for IRB if faculty members already know how to assess ethical issues in a protocol/proposal? – need to certify the review and compliance to research ethics guidelines

Conflict of Interest in Research

- Beneficial collaboration of researchers with industry
- COI threatens scientific integrity and fidelity
- Financial ties may duly influence professional judgments
- Empirical studies have shown how COI works
- Biases can be mitigated by awareness of the bias and “such awareness must have the effect of reducing the bias”
- Should there be a limit for PI honorarium?

Conflict of Interest in Research

Recommendations

- Intensive education programs to train physicians about gifts from and interactions with industry
- Require investigators submitting proposals to RECs to disclose all financial ties to companies that could financially benefit from the results
- Establish benchmarks for addressing COI

Take home messages

- It is timely and relevant to establish PHEC
- The process (ISOC) of establishing the PHEC is not different from the process of establishing RECs
- Upholding the ethical principles should include patient/participant empowerment through appropriate interventions and real post-trial access
- Continuing research ethics education and stakeholders forums on timely issues – proactive, not just reactive