



Emerging Issues in Research Ethics

Synthesis & Recommendations

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Opening Remarks

Dr. Leonardo De Castro



Opening Remarks

Dr. Leonardo De Castro

- From preventing unethical research TO ENABLING ETHICAL RESEARCH
- Unreasonably slow ethics review is also unethical
 - **may require training and best practices in administrative aspects of ethics review to facilitate efficiency**
- Emphasis on socially relevant research for international research collaborations
- Emphasis on collaboration of agencies in protection and empowerment of IPs and ICCs
- Validation that social science research IS health research



Introducing the 2017 NEGHR

Dr. Marita Reyes

Introducing the 2017 NEGHR

Dr. Marita Reyes

- Responds to evolving scientific problems in changing environment (e.g. stem cell research; disaster contexts); international and local changes in the policy / regulatory landscape (e.g. Data Privacy Law)
- Official approval by PHREB and publication at the Official Gazette (Php!)
- Definition of **health** and **health-related** research
- **Social Value** and **Transparency** highlighted in General Guidelines (Elements of Ethical Research)

Introducing the 2017 NEGHR

Dr. Marita Reyes

- Expanded guidelines for the various **stakeholders** in the research process (e.g. research adviser; *Gabay Para sa Kalahok sa Pananaliksik*)
- Highlight on **international collaborations**
- New guidelines on **research areas**: Cosmetics, Environmental health, Mental health, Stem Cell research, Emerging technologies



Introducing the 2017 NEGHR

Dr. Marita Reyes

- New guidelines on **new methods** : use of online/digital tools, human data & samples from biobanks, registries, databases
- New guidelines on **specific populations** : military personnel, persons with disabilities
- Clarified the criteria on **authorship**



Introducing the 2017 NEGHR

Dr. Marita Reyes

- Clarified criteria for **exemption** from ethics review – but still to be validated by the ERC
- Clarified criteria for **waiving** the a) informed consent process, b) use of signed informed consent form, and c) elements of the informed consent form



Privacy in Health & Health-related Research

Prof. Peter A. Sy

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RA 19173 – Data Privacy Act of 2012

- What are the synergies between the provisions of law/IRR and research ethics guidelines and review procedures? → **would require harmonization**
 - human participants are both research subjects and “data subjects”
 - implications for informed consent process and forms → require more information on the purpose and extent of processing, period of effectivity
 - coordination with Data Privacy Officer; Privacy Risk Assessment; Privacy Management Program/Manual



Privacy in Health & Health-related Research

Prof. Peter A. Sy


Principles

1. Transparency
2. Legitimate purpose
3. Consent (necessary but not sufficient)
4. Proportionality
5. Accountability
6. Access
7. Limited Use, Disclosure, Retention
8. Security
9. Compliance

Privacy in Health & Health-related Research

Prof. Peter A. Sy

- What are the limits to provisions of law? Are all provisions applicable to all research activities?
 - research where deception may be necessary
 - conditions when signed informed consent or elements of informed consent may be waived
 - research using Internet technologies (what is private?)
- Require more technical training of researchers, ethics reviewers / RECs on the implications of the law for research and ethics review processes
 - e.g. de-identification, enhancing security (encryption)



FPIC Process in Academic Research

Dir. Carlos Buasen, Jr.

FPIC Process in Academic Research

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Basis for FPIC in research with IPs/ICCs

- recognition of and respect for the unique cultures, histories, circumstances of different IPs/ICCs
- multidimensional nature of historical injustices
- RA 8371 : upholding the rights + improving the welfare; recognition, promotion, and protection of IPs/ICCs

FREE. PRIOR. INFORMED. CONSENT.

- third parties enter into an equal and respectful relationship with IPs/ICC – **entered into with the community** - based on the principle of informed consent

FPIC Process in Academic Research

Dir. Carlos Buasen, Jr.

Certification Precondition (CP) – attesting that the researcher has complied with requirements to secure FPIC from the IPs/ICCs

AO 1 – community-initiated research; academic research; research in aid of policy; social research; research necessary to implement NCIP mandates

- **Process** → application, to MOA signing, and CP issuance
- output validation and certificate of validation prior to publication of output; IPs/ICCs can decide output that will be published



FPIC Process in Academic Research

Dir. Carlos Buasen, Jr.

- To Be Amended / New guidelines
 - Guidelines for different types of research
 - Sanctions and penalties
 - Misappropriation and misrepresentation of cultures of IPs/ICCs
 - Community intellectual rights – collectively owned; include belief systems and traditional products
 - Greater efficiency in the process of issuing CP – reconsider calibrating costs, etc. accdg to diff activities



FPIC Process in Academic Research

Dir. Carlos Buasen, Jr.

OPERATING PRINCIPLES

1. Empowerment
2. Cultural integrity
3. Transparency and clarity
4. Primacy of customary law
5. Consensus-building and decision-making process
6. Community intellectual rights
7. Peace-building
8. Intergenerational responsibility
9. Ancestral domain as the basic operational unit



Intellectual Property Rights and Indigenous Peoples

Atty. Robert Nereo Samson



Intellectual Property Rights and IPs

Atty. Robert Nereo Samson

- Intellectual property right as a human right and constitutional and statutory right, encoded in the IP Code (RA 8293)
 - scientific and artistic innovations for the common good, for advancement and benefits
 - protection of exclusive right (but limited terms)
- Interface between IPR and Indigenous Peoples (Community Intellectual Rights)
 - traditional knowledge, cultural expressions
 - past, present, and future manifestations



Intellectual Property Rights and IPs

Atty. Robert Nereo Samson

Interface between IPR and Indigenous Peoples (Community Intellectual Rights)

- similar principles of control/exclusive rights
- traditional knowledge, creative works as precursor to modern knowledge and creative works
- documentation and recognition of traditional knowledge can enhance evaluation of IPR applications; may prevent misappropriation



Managing Research Involving Human Filipino Ethnolinguistic Groups and Filipino DNA and Genetic Data

Prof. Frederick Delfin

Research Involving Fil Ethnolinguistic Groups

Prof. Frederick Delfin

- presents a specific example of a research framework and process (molecular anthropology)
- **Iterative Consent Process, Dynamic Consent Process**
 - involvement of participants in design, objectives, and **validation** of the study findings
 - orientation, immersion, education, involvement, FPIC
 - full disclosure of data processing procedures
 - in English and the vernacular
 - clarifies misconceptions, anxieties, concerns
 - ensuring participants **UNDERSTAND** the information
 - allowing participants to take **time** to decide



Ethical Issues in Collaborative Research

Dr. Eva Maria Cutiongco de la Paz



Ethical Issues in Collaborative Research

Dr. Eva Maria C. de la Paz

- Collaborative research – researchers, communities or participants, stakeholders
- more complex problems = need for more diverse and complementary skills
 - allow researchers to work on problems they otherwise could not have investigated
- Six Principles for Effective Collaborative Research
 - communication; goals, roles, expectations; authorship; data and material management; intellectual property issues; manage accountability

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Ethical Issues in Collaborative Research


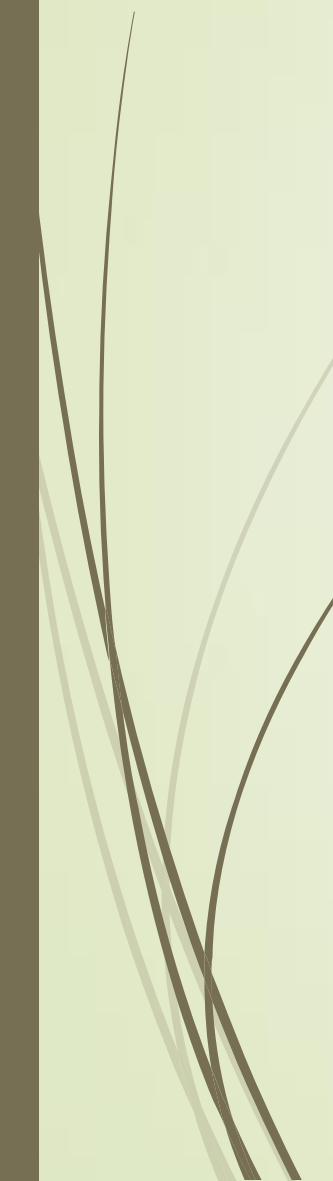
Dr. Eva Maria C. de la Paz

Ethical issues

- Authorship – just and fair distribution of authorship credit (esp for LMICs)
 - power differential; different cultural practices and expectations between HIC and LMIC
- Ethical Data Sharing
 - value of data sharing, minimizing harm, fairness and reciprocity, trust



RECOMMENDATIONS

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1. Capacity-building for specific and emerging research & ethical issues: for researchers and RECs
 - Continuing education – technical; skills; best practices
 - REC members “specialize” in specific topics/areas?
 2. Coordination among different agencies
 - PHREB / RECs
 - National Commission on Indigenous Peoples
 - National Privacy Commission [insti: Data Privacy Officer]
 - Intellectual Property Office [insti: IP Office/Policy]
 3. Greater efficiency in administration and review processes of different agencies – streamlining guidelines, processes, (costs)



Thank you for your attention!