Ethical Issues in Health and Health-Related Research

Dr. J Montoya

- Advances in health research give rise to issues that challenge research ethics and the stakeholders of research
  - Data privacy
  - PHREB policies and procedures
  - HSS research ethics review
  - Balancing risks vs benefits
  - Research in older patients
  - Engaging patient and the family
- Promoting research and research ethics to larger community

A. Data privacy in health research and clinical practice (Prof. P Sy)

	Issue	Others/ response
Privacy; Decisional privacy	Person determines extent of information communicated to others	RA 10173 Data Privacy Act 2012 – balances right to privacy and information free flow • Safeguards in place • Processing of the data in research
Personal information	• Unique identifiers (e.g., iris) • Sensitive personal information (e.g., race, religion, gene ID, gov't ID) • Research data • Anonymyzed not enough	• Proportionality • Personal information control (processor and processing) • Accountability • Criminal liabilities for breaches
Consent (e.g., purpose, length)	• May be insufficient for protection • Documentation of consent • Below age of consent – sharing of IDs	• Transparency and data retention • National laws
Government agencies' access	Disease registries	Re-contact

A. Data privacy in health research and clinical practice (Prof. P Sy)

	Issue	**Others/ response**
Social Media (e.g. research in FB)	• 'Emotional proportionality (?)' • Nature of the contents	• Accessibility by subject to amend information • Limitation of use disclosure and retention
Government funding	Required to make accessible	
Data	Retention Accuracy, completeness, up-to-dateness Data breaches (e.g., loss, Safeguards	Institutional purging of data Proportionate protection
Compliance to data privacy	As above	Laws

1. Panel Reactors (Data Privacy)

	Dr. FM Dayrit (Academe)	Atty. AT Muyot (Legal)	Dr. AV Laudico (Registries)
Challenges • Control of digital data • Insurance • Personal data vs information known to commercial companies • Power of the state vs the privacy of the individual • Vulnerable groups and reliable of consent • => Authorized body must approve the protocol *et al.* • Disease registries – data collected retrospectively	Utilization of PI by companies	SMS – selling goods and commodities (via credit card Co.s)	
	What must be kept private?	Consent given by all parties concerned esp vulnerable groups – e.g. children experiencing violence at home – reliability of consent and data	
	Genetic information		
	Unknowingly provide health information that may be used for purposes not known to provider/ owner	Who approves the authorization to make PI available to public	Consent • Population-based data • Data collected after the event and consent not possible Data sharing – safeguards?

1. Panel Reactors (Data Privacy)

Response	Dr. FM Dayrit (Academe)	Atty. AT Muyot (Legal)	Dr. AV Laudico (Registries)
	Restrictions	• SC restrictive order – clarity with the use of the PI, • Data privacy act	
Penalties		• Absence of malice in the prohibitive acts • Stiff monetary fines and probation and jail time	
Rules/ provisions		Clear definition of who authorizes the body that approves PI to be made available	

2. Open Forum

Query topic	Responses
Law focused on the data but protection of the data subject lacking	
IRR Data Privacy Act	1. Need to be pro-active; smoothly roll-out the law through – Health privacy code (DoH, DOST) • Best practices of information exchange • Commissioner / authorized body 2. Self-regulation by stakeholders
Consent for PI in disease registries, biobanks	Self-regulation by stakeholders
State vs. individual re: PI	IRR?
DepEd graduate thesis and consent for studies on students (e.g. behavior)	Data privacy act
DPA effect on data mining, publicly available data	Source of data is already de-identified. Scope of DPA is process of anonymizing the data. Caution: unrelated use of PI
Effect of DPA IRR	'Chilling effect' has yet to be proven
Abrogation of the law/ rules (?). Can ECs allow certain research to be exempted?	Under deliberation

B. PHREB Policies and Procedures on accreditation (Dr. MSN Vios)

Universal principle of protection research participants	Underpins PHREB's creation
Mandates	Guidelines and requirements for EC 1. review of research involving human participants 2. Management of the EC 3. Monitor conduct of the research
Coverage	Academe, hospitals, government agencies and consortia, clusters, site-based, health-facility-based (e.g. specialty clinic – derma, ophta)
Health, and health-related research	Impact on health of person and community
	Animal studies – IACUC Biosafety - NCBP
Indigenous communities	Level 2 and 3
Animals involved	ACUC
Biorisk and biosecurity	Biosafety - NCBP

B. PHREB Policies and Procedures on accreditation (Dr. MSN Vios)

Accreditation	Criteria-based 1. Structure, function and composition 2. Adherence to guidelines and policies 3. Compliance to SOPs (10 core) 4. Completeness of review-process 5. After review process 6. Administrative support 7. Recording and archving system
Levels - bases	1. Type of research 2. Degree of risk in the research protocol (minimum
Levels of accreditation	1 – minimal risk 2 – more than minimal risk; except clinical trials; post-marketing studies; functional database; part time staff 3 – All types of registration including products for FDA registration; ICH GCP standards; functional database and fulltime staff
Process	Document review, accreditors site visit
Post- accreditation	Monitoring, annual report, renewal of the certificate (q 3 yrs)
Accreditation	May be withdrawn
Enforced in 2016	Registration upon application, on-going accreditation 1-yr probation, Sanctions for non-compliance

C. Case studies in ethics review of health social science research (Dr. LD de Castro)

We are at a crossroad with DPA but this must not hinder well-guided and responsible research

(confidentiality of the data and participant's privacy)

1. Informed consent –
   - Whose? family, community, person
   - How truthful is the information?
2. Investigator
   - Responsibility for observations in addition to the research objective
   - Respect of culture
     - Prior-consent
     - Personal information
3. Impact of the research on the community

- Case #1: Observations of general newborn care and provisions of care
  - Informed consent obtained from mother and healthcare giver (must include father)
  - DoH – consent from all involved
- Investigators were instructed to just observe
- Observations:
  - Mother used water from faucet for milk formula. *intervene?*

- *Dec of Helsinki*
  - *Consent*
  - *Interest of the participant must take precedence over all other interests*

C. Case studies in ethics review of health social science research (Dr. LD de Castro)

- Case #2 –
  - Online survey of alcohol drinking
  - Subjects - < 18 y/o
  - Randomized – controlled
    - Treatment group – questions on drinking habits – ill effects of drinking; how to limit drinking – were given written advice on this; after 6 months, were asked on drinking habits
    - The objective of the survey was not revealed at the start; was withheld
    - *What should have been done? Would this be a cause for waiving informed consent? Disclosing full info – will this affect extent of participation*
    - A: Informed consent must be based on participant being informed; revise the method
    - Non-treatment group -
  - *Conundrum: Putting the objective in the context of research – more stringent requirement*
  - *Research for public health intervention; be upfront with the objective to the EC*

C. Case studies in ethics review of health social science research (Dr. LD de Castro)

- Case #3 –
  - Negotiating safe-sex practices
  - Participants: female sex workers
  - Method
    - participant observation
    - Interview on practices - how, why and with whom
    - Rescued by accomplice
  - EC approved but journal reviewer declared deception was involved. Was the deception justified?
  - Giving full information – what data will be used for?
  - Where will the compromise be?

⇒*Minimize deception; Methods of obtaining informed consent*

⇒*Participant is benchmark on effect of the method used - If harm is not known at the start, apply the method on a small number (i.e., social preparation)*

⇒*UNESCO guideline on social science research*

Case #4 – STD research and minors

- *Responsibility in handling sensitive information that may have adverse effects on certain groups*
- Background –
  - 27% new diagnosed 15-24 y/o;
  - 86% of STIs were MSM – 54% were age group .. .;
  - PEP + safe sex are effective in the age groups concerned
- Issues
  - Parental permission required for certain age groups; low enrolment rate affects validity of the results
  - Parental consent?

- *Legal impediment – RH Law; Constitution*
- *DPA*

D. Balancing risks and benefits in ethics review (Dr. SE Bongala)

- Levels of risk were defined
- Assessing risk
  - Vulnerability of population
  - Types of risk
  - Scientific validity
    - Rationale
    - Objectives -> research design -> procedures
  - Investigator qualifications
- Risk/benefit ratio; subject privacy and confidentiality and protection

⇒*Application of the ethical research principles – autonomy, justice and non-maleficence/beneficence*

⇒*Would you recommend participation in this study? How can study be improved*

⇒*Balance must be in favor of the participant*

E. Research with older persons (Dr. G Orteza)

- National guidelines are being updated
- Rationale for research in elderly - increasing size of population and under-represented in research
- Challenges
  - Variability of health status and functional capacity
  - Decision-making process and ability to give valid informed consent
- Guidelines focus on informed consent
  - Investigator identify hindrances and use best strategy to impart information on the research
  - Cognitive assessment tools and checklists for 'competency'
- Recommendations

⇒ *Every adult has the capacity to make decisions*

⇒ *Appreciation of risks, benefits and alternatives to the decision*

⇒ *'Decisional capacity' is preferred terminology - thresholds*

⇒ *Tools*

- ⇒ *Informed consent quiz*
- ⇒ *MacCAT, others (expert member in the IRB)*

F. Patient and family engagement (Ms. CV Auste)

- Engagement (mutual understanding; give and take) and empowerment
- People (and family)-centered health care
  - Communication and care
  - Respect in addition to responsible and responsive services
- Capacitate patient and family to be fully engaged
- Core value of an organization
- Families are
  - untapped resources for better care and outcome
  - Key stakeholders in health care and in research
  - Experience parallels that of the patient
- Levels of engagement in research but must be from the start (e.g. conceptualizing some procedures)
- Patient (and family) -oriented research – partners, priorities, desired outcome (inclusiveness, respect, purpose, experience is part of process)
- Benefits of the engagement

- *Family – key in promotion of health and wellness of a patient; family and patient must be equally valued*
- *Research that engages family and patient => innovative and meaningful research*
- *4 keystone questions for EC e.g., interpretation of information, benefit*