ETHICS
in Research and Development and Research Proposal Writing

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Why Research Ethics?

- **Tremendous impact of rare misconduct**
- **Ethical dilemmas in many situations**

- Ethics in research is of **growing importance**
- Critical that you **understand the basics** of ethical research and how this might **affect your research or teaching**

Presentation Sources

- **Resources for Research Ethics Education**
  http://research-ethics.net/

- Dr. David B. Resnik's "**What is Ethics in Research and Why is it Important**?"
  - http://www.niehs.nih.gov/research/resources/bioethics/whatis/

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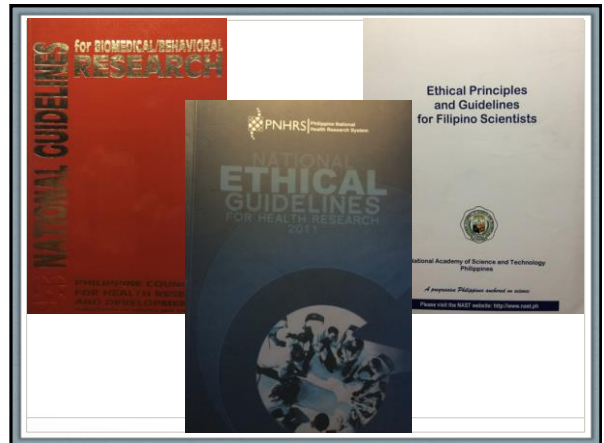

Ethics

Ethical Norms

- **Acquired throughout life**

- **Common but interpret and apply differently**

- **Broader and more informal than laws**

- **Help members to coordinate actions**

Why Adhere to Ethical Norms in Research?

- Promote research aims (knowledge, truth)

- Promote values essential to collaborative work (trust, accountability, respect, fairness)

- Ensure accountability to the public

- Help build public support for research

- Promote other moral and social values (social responsibility, human rights, animal welfare, law compliance, health and safety)

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Ethical Code Development

1947	▸ Nuremberg Code: first modern ethical code
1964	▸ Declaration of Helsinki
1990	▸ WHO International Guidelines on Ethics and Epidemiology
1993	▸ WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects
2004	▸ Medicines for Human Use (Clinical Trials) Regulations 2004
2006	▸ Warner Report ▸ Medicines for Human Use (Clinical Trials) Regulations Amendment 2006
2008	▸ Medicines for Human Use (Clinical Trials) Regulations Amendment 2008
2009	▸ Medicines for Human Use (Clinical Trials) Regulations Amendment 2009

Research Ethics

- The application of fundamental ethical principles to scientific research

- Diverse set of values, norms and institutional regulations that help constitute and regulate scientific activity

- Encompass all stages and all those involved
  inception ➔ completion ➔ publication

Ethics: When in Research?

Before
- **Justice**: fair selection of participants
- **Conflict of interest**: research design
- **Benefit/Harm balance**: ethical review

During
- **Autonomy**: obtaining informed consents
- **Privacy and confidentiality**: protect rights and avoid misuse
- **Integrity**: adequate use of appropriate methods

After
- **Transparency**: bare methodologies and funding sources
- **Integrity**: reporting the results
- **Publication ethics**

Codes and Policies for Research Ethics

Before
- **Justice**
  - Avoid discrimination in participants' selection
  - Distribute benefits and risks of research fairly
- **Legality**
  - Know and obey relevant laws and institutional and governmental policies
- **Social responsibility**
  - Strive to promote social good
  - Prevent harm to society and environment while conducting research

Ethics in Research Proposal Writing

- **Intellectual integrity**
  - Suffuse all parts of a research proposal

- **Title**
  - Clear and understandably reflect the real content and essence of the study
  - Avoid pompous title with highfalutin words and unnecessary scientific jargons

2

Ethics in Research Proposal Writing

- **Intellectual integrity**
  - Suffuse all parts of a research proposal

Aim

- **Aim / Hypothesis**
- Stated aims, objectives and hypothesis must be realistic and as clear as possible
- Do not presume that one's hypothesis will be proven right or affirmed by the research results

Ethics in Research Proposal Writing

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Importance

- **Importance**
- Be moderate in stating the importance of the proposed research
- Avoid preposterous claims of its potential contributions

Ethics in Research Proposal Writing

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Review of Literature

- **Review of Literature**
- Fairly reflects the state of knowledge in the topic in question
- Ensure that opposing views on the topic are equitably presented

Ethics in Research Proposal Writing

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Methodology

- **Methodology**
- Must be consistent with the rigors of scientific method
- Avoiding harm and minimizing risk should be embedded in research design

Codes and Policies for Research Ethics

During

- **Objectivity**
  - Avoid bias in experimental design and data analysis
  - Disclose personal interests that may affect research
- **Carefulness**
  - Avoid errors and negligence
  - Keep good records of research activities and correspondence
- **Honesty**
  - Do not fabricate, falsify or misrepresent data
  - Do not deceive colleagues, granting agencies or public

Codes and Policies for Research Ethics

During

- **Autonomy**
  - Secure actual permission of the participants
  - Obtain informed consent in signed documents
- **Confidentiality**
  - Protect participants' rights, privacy and sensitivities
  - Protect communications and patients' records
- **Respect**
  - Treat participants and colleagues fairly
  - Minimize harms and risks and maximize benefits
  - Take special precautions with vulnerable populations
  - Show proper care for animals when using them

Best Practices for Informed Consent

- **Simplify the form**: limit to one page, use simple language.
- **Offer choice** of multiple languages.
- **Make oral 'forms'** available: read the form by volunteers.
- **Discuss and explain** the protocol to potential volunteers.
- **Provide question and answer** sessions after project explained.
- **Facilitate consultation**: allow participants to discuss their possible participation with others before making final decision.

Codes and Policies for Research Ethics

During

- **Openness**
  - Share ideas, results, tools and resources
  - Be open to criticism and new ideas
- **Competence**
  - Maintain and improve your expertise
  - Ensure adequate use of appropriate methods
- **Responsibility**
  - Help to educate, mentor and advise students
  - Promote welfare and allow them to make decisions

Codes and Policies for Research Ethics

After

- **Transparency**
  - Ensure honesty and clarity in reporting the results
  - Disclose financial interests that may affect research
- **Integrity**
  - Keep your promises and agreements
  - Act with sincerity and strive for consistency of action
- **Publication ethics**
  - Never commit scientific misconduct
  - Safeguard publication ethics

Definition of Scientific Misconduct

fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results

- **Fabrication** is making up results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment or processes, or changing or omitting data or results.
- **Plagiarism** is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Some Publication Ethics

Honesty and Integrity

duty of each author, reviewer and member of editorial board

Author

- Do not publish or submit the same paper in two different journals without telling the editors
- Do not trim outliers from a data set without discussing your reasons in the paper
- Do not use inappropriate statistical technique in order to enhance the significance of your research
- Acknowledge the contributions of other people in the field
- Guarantee right to authorship and their listing

Some Publication Ethics

Honesty and Integrity
duty of each author, reviewer and member of editorial board

Authorship Credit should be based on:

- (1) Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- (2) Drafting the article or revising it critically for important intellectual content
- (3) Final approval of the version to be published

Some Publication Ethics

Honesty and Integrity
duty of each author, reviewer and member of editorial board

Reviewer
- Do not discuss with colleague confidential data from a paper that you are reviewing
- Do not bypass the peer review process by premature announcement
- Do not make derogatory comments and personal attacks in review of author's submission
- Do not reject a manuscript for publication without even reading
- Do not make unauthorized copies of data, papers or programs

Some unethical issues in research

- Stretching the truth on a grant application to convince reviewers
- Making significant deviations from the approved research protocol without telling the ethics review board
- Not reporting an adverse event in human research experiment
- Rigging an experiment so you know how it will turn out
- Deliberately overestimating the clinical significance of a new drug in order to obtain economic benefits
- Wasting animals in research
- Exposing students and staff to biological risks in violation of biosafety rules
- Not informing a collaborator of your intent to file a patent in order to make sure that you are the sole inventor

Ethics in Research

Scientific research, whether done by high school students or professional researchers, is built on foundations of TRUTH and TRUST.

Ethics in Research Proposal Writing

One must truly BELIEVE that the research they propose to undertake is NECESSARY and USEFUL.

Thank you!

5