Research Ethics and Integrity
An Overview

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Lecture Objectives

To

1. Provide an overview of research ethics and ethical conduct of research.

2. Discuss briefly scientific integrity and mention common research ethics misconducts.

Introduction

- Research connotes different meanings to different individuals
- The core principles of research ethics is to provide guidance on how to balance the obligation to protect individuals from harm with the desire to maximize the benefits to human well-being that research may provide.
- These core principles have been specified in *National and International Codes* which together form the frameworks for the protection of the rights and welfare of human subjects of research.

Regulatory definition of “Research”

“a systematic investigation, including research development , testing and evaluation, designed to develop or contribute to generalizable knowledge” (Nigerian National Code of Health Research Ethics available at www.nhrec.net)

- **Systematic**: An organized, formally structured,deliberate procedure to obtain new knowledge.
- It commonly implies the development of a research protocol with clearly stated objectives.
- **Generalizable:** The obtained knowledge is intended to have a broad or general application beyond the group that participated in the research

Research Ethics

- a set of rules that inform research design, conduct, analysis, dissemination and implementation

- There are several institutional, local, national and international guidelines available
- Some of the international guidelines are the Nuremberg Code, the Helsinki Declaration and the Council for International Organizations of Medical Sciences (CIOMS). In Nigeria, the Federal Ministry of Health developed in 2007 a national code to regulate conduct of health research in the country (FMOH, 2007).

The Nigerian National Code

- National Code Of Health Research Ethics (NCHRE, 2007)
- The national code was developed in 2007; there have been 9 revisions to the code (www.nhrec.net)
- NHREC created to provide oversight for all ethics committees in the country
- Ethical principles and guidelines for HREC's approval of research are listed in the Section F of the NCHRE in items a - j. These can be summarize as follows:

For research to be ethical:

a. Research must have social or scientific value to either the participants, the population they represent, the local community, the host country or the world.

b. must have scientific validity

NCHRE - Section F contd

e. must undergo independent review by Health Research Ethics Committee (HREC)

f. Informed consent is a sine qua non for ethical conduct of research.

g. Respect for potential and enrolled participants.

h. Nothing must be done to undermine the trust relationship that is the heart of the researcher(s)-participant(s) relationship.

i. The interest of the participants, the researchers, sponsors and communities must be protected.

j. must be conducted in accordance with the principles of good clinical and laboratory practices.

The Four Principles of Biomedical Ethics (I)

The existing research guidelines emphasize the role of the four universal ethical principles that should be applied to all research involving human participants (Beauchamp and Childress, 2001).

The principles are: Respect for persons, Beneficence, Non-maleficence and Justice.

- **Respect for persons**: The principle of respect for persons recognizes the fact that all persons have the rights to determine whether or not they will participate in a research. This principle is applied in practice through the process of informed consent.

- **Beneficence**: requires investigators to minimize risk and maximize benefits of participation in research. This principle acknowledged the fact that all research have inherent risks and benefits and that it is the duty of the researcher to not only identify potential risks and benefits but also ensures that all persons who participate in the research enjoy full benefits and are exposed to minimal risks.

The Four Principles of Biomedical Ethics (II)

- **Non-maleficence**: compels researchers not to cause any harm to study participants. It also requires that the researcher should at least not make the conditions of participants worse if he/she cannot make it better.

- **Justice**: requires fairness in the process of recruitment of persons into any study.

This principle acknowledged the fact that there are individuals who have diminished capacity to take actions to protect their own interests [CIOMS, 2002]. Such individuals are referred to as vulnerable.

In Nigeria, examples of vulnerable persons include children, students, adolescents, patients with mental illness, prisoners, and the elderly persons. Researchers are therefore expected to take action to ensure that the rights of vulnerable persons are protected when such persons participate in research.

Six Phases of Research

1.Development of proposal (conceptualization of idea)

2. Submission, review, and approval by an ethics committee

3. Data collection

4. Analysis of the data

5. Report writing

6. Dissemination of findings (workshop, conference, publication)

- ✓ **Integrity matter in all stages of Research**

Ethical Requirement in the 6 phases of Research

Phase	Activities	Ethical requirement
1	Development of Research Plan – Conceptualization of idea	Do extensive literature review, identify knowledge gap, write a Study Protocol/Proposal
2	Submission of the plan to an Ethics Review Committee (ERC) for review and approval	Approval of study protocol by Ethics Committee/ Informed consent document is very important
3	Collection of information from field or laboratory	• Implement the study as approved by the ERC • Train personnel who will collect data on their behalf to prevent injuries or harm to study participants • Provide adequate supervision to trained staff to ensure that data collected are reliable and valid

Phase	Activities	Ethical requirement
4	Processing, analyzing and interpreting the information	• Select the method of analysis to prevent the occurrence of avoid Type 1 error/Type II error. Type I error occur when a conclusion is reached that there is an effect between two variables when there is actually none. Type 11 error occur when a researcher concludes that there is no relationship between two variables when there is actually one. • Store all primary and secondary data in secure and accessible form, have them documented and archived for a substantial period. The Nigerian National Code requires that researchers store their data for a minimum of five years post completion of the research (FMOH, 2007). • Restrict access to data/de-identify data/ensure confidentiality of data collected. Researchers can use password protected computers
5	Writing a report of the process	Present the data as collected and **include as authors only those who deserve it**.
6	Dissemination of findings through workshops, presentations at conferences and publications in peer-review journals.	Data should be disseminated as soon as they are available to ensure their timely use.

Research Ethics vs Research Integrity

- Research integrity can be defined as ‘the quality of possessing and steadfastly adhering to high moral principles and professional standards, as outlined by professional organizations, research institutions and government and public code of conduct.
- In research, questions of integrity often relate to *methodological and procedura*l issues.

- In research ethics, we are concerned with moral problems related to the practice of research involving living participants (animals,humans, individuals, groups and societies).
- The focus here (ethics) is more on *protecting participants, ensuring their interests and rights, and on assessing risks and protecting confidentiality, among other issues.*
- Deplorable research behavior violates these norms deliberately. These practices come in the form of Plagiarism, Falsification, and Fabrication, or PFF

Definition of Misconduct

- Practices that seriously deviate from those that are commonly accepted within scientific community for proposing, conducting, or reporting research
- Shortcomings in professional conduct of researchers
- Misconduct does not include
- Honest error or differences in interpretations or judgment of data
- Other misconduct (sexual, financial)

Examples of Research Ethics Misconduct - Plagiarism

- *Plagiarism* (literary theft) is the act of appropriating the work (or ideas) of others and passing it off as your own.
- Its different from the appropriate uses of other people's work such as the discussion or critique of certain viewpoints, summarizing and paraphrasing of particular ideas, and the use of quotations. These all require the original source or author to be clearly identified.
- There are two moral problems attached to plagiarism:
- (1) Taking credit for work you have not done (Deception)
- (2) It a scientific misconduct because science's reputation is built upon trust and accountability.
- Failing to acknowledge referenced material **is serious misconduct** that can create even legal consequences when copyrights are infringed upon.

Plagiarism - Forms

- Copy and Paste
- Self-plagiarism (‘passive self-citation’)
- Translation plagiarism
- Peer review / Reviewer misconduct (pressure to publish)
- *Plagiarism software* is good at spotting similarities between texts and can identify the sources of the text but may not be to identify who plagiarized whom

Examples of Research Ethics Misconduct - Fabrication, Falsifying

Fabrication involves the presentation and reporting of fake or non-existent research procedures, data, and findings. Fabrication is a form of cheating.

Falsifying entails forms of manipulation that allow researchers to use a dataset that supports biased or even erroneous claims. It includes ‘trimming’ (leaving out certain findings) and ‘massaging’ (slightly changing) data, as well as altering images, misrepresenting results, and simply not reporting findings.

Examples of Research Ethics Misconduct - Authorship

- ***Complementary/honorary/gift authorship***: Inclusion of someone's name on a paper when he/she do not deserve to be an author
- ***Undeserved exclusion in authorship***: this occurs when someone who has made substantial contribution to project is not included as an author
- ***Ghostwriting/Ghost Authorship***: Submitting work written by a third party.

- Examples

– supervisor publish students' research project without including student as co-author

– Supervisor presents students research project at conference without knowledge or approval by student

Other examples - *Confirmation bias*

- Research starts with asking questions; asking good questions demands a self-critical attitude, and a readiness to address and counter one's own preconceptions.
- *Confirmation bias* consists of the tendency of individuals to judge new information in a way consistent with their preexisting ideas or convictions. People thus prefer supporting information rather than conflicting information and tend to overlook or disregard information that does not fit into their worldview.
- Confirmation bias undermines open and critical thinking and runs against creativity.

Integrity in All Stages of Research

- Manage & store data adequately, ensure confidentiality;
- Report and disseminate findings of research as collected
- Prioritize dissemination and feedback to study participants
- Admit, correct, and report errors when you detect them
- Include as authors only those who deserve it;
- Acknowledge contributions of study participants and others
- Send a manuscript to one journal at a time

Requirements for Authorship

- Someone is eligible to be an author when he/she:

1. Made substantial contributions to the development of the research protocol
2. Participated in implementation of research
3. Performed analysis and interpretation of the data
4. Contributed to writing of the manuscript and can claim responsibility of the contents of the paper
5. Of these, the writing of the manuscript is the most important criterion for authorship

Publication Infractions

- Simultaneous submission of a manuscript to multiple journals. This is unacceptable because: – It is a lie/deception

– It is a waste of resources when two or more journals review same manuscript at the same time

• Fragmentation (salami slicing): inappropriate division of study outcomes or components into several articles. This is unacceptable because: – It inflates the number of papers in curriculum vitae for

promotion & other purposes

- – It emphasizes quantity instead of quality

Nine Best Practices in Publication

1. Publish results in an open, transparent and accurate manner, as soon as possible
2. All authors should be fully responsible for the contents of the publication.
3. Complimentary or gift authorship should be avoided
4. The criteria for establishing the sequence of authors should be agreed by all, ideally at the start of the project
5. Contributions by collaborators and assistants should be acknowledged, with their permission.

9 Best Publication Practices contd

6. All authors should declare any conflict of interest
7. Intellectual contributions of others should be acknowledged and correctly cited
8. Honesty and accuracy should be maintained in communication with the public and the social media
9. Financial and other support for research should be acknowledged

References

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END

- Thank you for your attention