

Laboratory ethics in Biomedical Sciences

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“Ethics” – *Defined*

- Norms for conduct that distinguishes between what is acceptable (right) or not acceptable (wrong)
- **Bioethics:**
- A system of moral principles which enables the understanding and examining of what is “right” and what is “wrong” in biomedical research and practice.

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Responsible Conduct of Research

- Responsible Conduct of Research (RCR) is defined as the practice of scientific investigation with integrity.

It involves the *awareness* and *application* of established **professional norms** and **ethical principles** in the performance of **all** activities related to scientific research.

- *Panee, 2018*

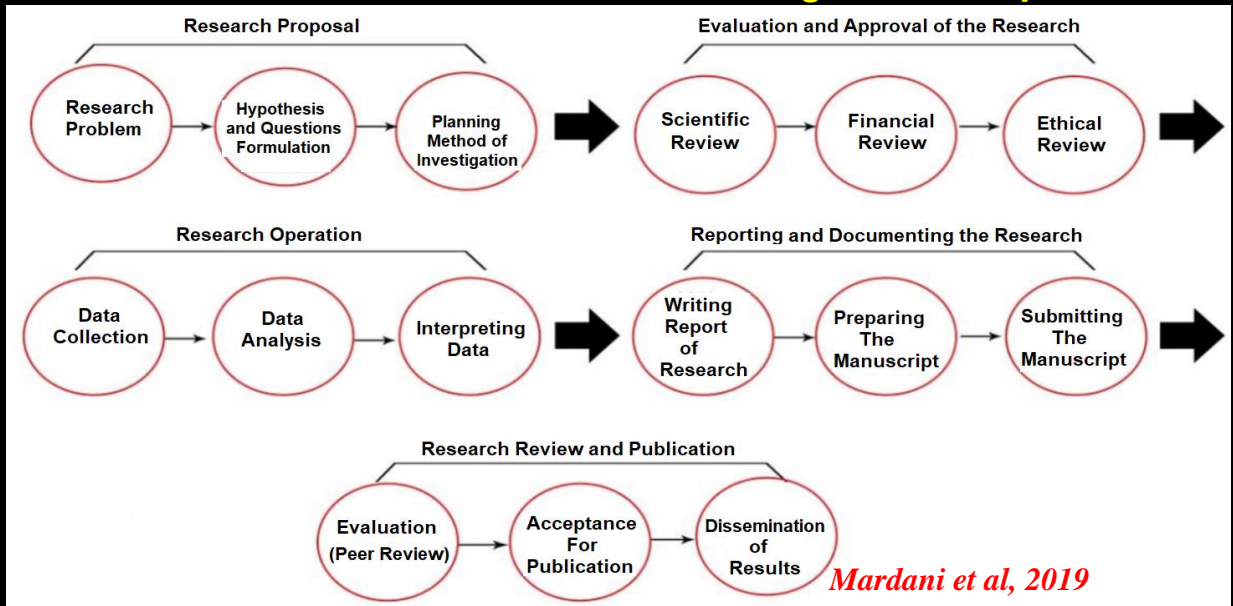
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Scope of presentation

- Ethical considerations covering research activities from research design to publication of findings
- Every stage of the research process is prone to **(unethical)** irresponsible behaviors and research misconducts
- Challenges of biomedical Research in Nigeria will also be discussed

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Biomedical Research Process: Stages and Steps



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Who Prescribes the “Norms”?

In Biomedical Research and Publication:

- Various national and international agencies.
- The Nuremberg Code and Declaration of Helsinki by World Medical Association
- International Committee of Medical Journal Editors (ICMJE) – *for Uniform requirements for manuscripts’ submission to biomedical journals for publication.*

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Biomedical Research Obligations:

- Conduct and communicate research findings in accordance with the highest scientific, professional, and ethical standards.
- Acquire appropriate training on the humane use and care of animals for experiments
- Keep proper laboratory record of all experiments in notebooks or other appropriate media e.g. original data and auxiliary information - to enable others to verify and reproduce results

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Biomedical Conduct Obligations.....

- Appropriately acknowledge ownership of ideas that are generated
- Take responsibility for safety and of co-workers, the environment, human subjects and animals
- Conduct, manage, judge, and report scientific research objectively, honestly, and thoroughly
- Acknowledge all conflicts of interest

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Biomedical Conduct Obligations.....

- Claim authorship in a work only if it entails one's significant intellectual contribution- involving: conception, design, data collection, data analysis, or interpretation and significant contributions to the manuscript's preparation
- Avoid adding "Honorary authors"

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Biomedical Conduct Obligations.....

- Accurately describe research methodology and data processing including the ability to trace all figures and images back to the original data
- Claim and take responsibility for the validity of the raw data and its interpretation in one's area of expertise and for the conclusions as a whole

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Biomedical Conduct Obligations.....

- Welcome constructive criticism of one's personal scientific research and offer the same to colleagues in a mutually-respectful and objective manner
- Submit research results for publication only when they represent substantive new contributions to the field

Ethical Standards

- Strict adherence to ethical standards is mandatory for teachers/researchers, students and professionals - in order to appreciate what constitutes “**research misconduct**”

Why Do We Need To Act Ethically?

- Protect personal and organizational reputation
- Acting ethically can enrich one's work and personal life
- The penalties for misconduct for both researcher and organization can be substantial

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Improper Practice

- A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.

- Wells and Lytle, 2013

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Laboratory Fraud

- The deliberate falsification of analytical or quality assurance results, where failed method requirements are made to appear acceptable during reporting.
- The **intentional** recording or reporting of incorrect information
- An intentional gross deviation from method specified for analytical practices, combined with the intent to conceal the deviation.

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Fraud....

The incidence of Fraud in Science is highest in **single-authored** research publications!!

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Difference Between Fraud and an Improper Practice

- Fraud is purposeful and intentional
- Fraud is **not a mistake**.
- Fraud is an intentional misrepresentation of lab data to **hide** known or potential problems.
- Fraud makes data look better than they really are, with the **intent to deceive**.
- Sometimes the difference between fraud, improper practice and honest mistake is simply **lack of proper documentation**.

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Research Ethics Committee

- Ensures compliance with guidelines
- Committee should **help, not hinder** conduct of research
- **Activities include:**
- Examining Research proposals and interviewing investigators in person, if necessary.
- Ordering a limited pilot study and (based on the experience gained), subsequent approval for more extensive study

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Research Ethics Committee

- Scrutinizing Participant Information sheet for approval
- Scrutinizing the Consent Form - to ensure that participants are given adequate information before giving their consent.

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Key Perspectives in Biomedical Research

No	Component	Remark
1	Research design	Design, Data Collection and Interpretation
2	Confidentiality	For subjects and personnel records
3	Acknowledgement	Always, to avoid plagiarism
4	Knowledge advancement	Advance Knowledge NOT Self ; Avoid duplicate Publication
5	Risk/benefit	Protect the subjects/patients used; minimizing risks & maximizing benefits
6	Animal design	Use animals humanely , only if necessary

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Conflicts of interest (COI)

- Usually, mainly financial
- Conform only to the guidelines of the International Committee of Medical Journal Editors (ICMJE) but not to those of the WAME (World Association of Medical Editors).
- In a survey of 17 medical journals, Breimer et al (2019) reported "religious interest" as a conflict of interest in Brit. J. O & G and one other journal included "personal belief" (Journal of Obstetrics and Gynaecology of India).

To maintain their scientific credibility, medical journals may start requiring disclosure of such (religious) ties.

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Challenges of biomedical research in Nigeria

- As expected, Nigerian biomedical scientists conduct scientific research and communicate their findings in scholarly publications
- It is apt to examine the enabling environment in Nigeria, for the conduct of biomedical research, publication of findings and also discuss suggestions for improvement

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Challenges.....

Biomedical research is immensely hindered by :

- lack of infrastructure (energy supply, water, ICT etc.),
- Institutional support and
- Funding support from government.
- Weak Partnerships/Collaborations etc

Inadequate funding in particular, continues to be a major cause of the poor research environment in Nigeria.

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Challenges..

- Virtual absence of funding agencies –
- In Britain, for example, one of the numerous funding agencies (THE WELLCOME TRUST) has an endowment of around **£20.9 billion** and disburses about **£1 billion** annually, for Biomedical Research!!
- Nigeria's TETFUND – not quite as structured as South Africa's NRF

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Grants

- Grants are sums of money awarded to finance particular activities and not to be paid back.
- Why should anyone give you money?
 - *Because you fulfill their goals!!*

How do we fund Research?

- Not uncommon to find students and lecturers funding their researches from personal funds
- Considerable financial burden associated; this leads to cost-saving strategies

Outcome:

- Poor quality materials used
- Poor quality of research

In normal climes:

Various Grants Sources are available for biomedical research

Funders

- Research your potential funders thoroughly and focus on their goals and grant programmes.
- Decisions are based on the applicant's ability to fit the proposed research activities to the interests of the funding body.

Dissemination of findings

For research findings to be beneficial, **they must be communicated by:**

- Oral presentation at a scientific meetings/conferences or
- Publication (Thesis, dissertation, Journal article, Book/Book chapter, monograph)

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Scientific Publishing : Finding the right Journal - Criteria

- Quality of the research work (as adjudged by Supervisor/mentor/established investigators as collaborators)
- Recommendation from colleagues/Supervisor
- Random search of the web
- Previous reputation of the journal
- Online Journal Suggester

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Characteristics of a good scholarly journal

- Publication timely and regular
- Contents must be of high quality
- Content must be current
- Peer Review

About Scholarly journals:

- Intended for an audience with knowledge of the subject concerned.
- Written for an audience with prior basics, who wants in- depth knowledge, such as the latest research studies.
- Contain citations.
- Do not exist to make money; Profit-making **does not** determine what they publish.

Scholarly journals.....

- Peer-reviewed or refereed.
- Citation in Search Engines e.g. DOAJ, Plos One, Bioline International, Infobase Index, PubMed, Google Scholar, EBSCO, ScienceDirect, AJOL, Ingenta Connect, JSTOR, Scopus etc.
- Impact Factor (Measures citation of articles already published in the journal, how quickly articles are cited, and the average "half-life" of the articles)
- H-Index (Measures productivity and citation impact of the publications of a scholar).

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Publishers of Acceptable journals

- **Well-established publishers** of books and journals with editorial teams consisting of recognised and experienced experts in the field e.g. Elsevier, Springer, Cambridge University Press Oxford, Taylor and Francis, Blackwell, Wiley, Thieme, etc.
- **University-based** academic departments or research institutions affiliated to universities
- **National/Regional/International academic/professional Societies**

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Unacceptable Journal publishers

- Institutions below the status of university: polytechnics, colleges of education, etc.
- Branches or local chapters of professional societies/associations outside the one being published by the national professional body/association.
- Individuals or private companies with no established peer review process or questionable editorial boards

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Unacceptable....

- Unrecognised associations or bodies
- Journals with no ISSN or fake ISSN
- Online/open access with no evidence of peer reviewing, no editorial board or identifiable address of publisher/ownership.

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“Publish or Perish”

- An expression used for university lecturers to describe the pressure in academia to rapidly and continually **publish** academic research works in order to sustain or further advance one's career.

Predatory Journals

“Journals established primarily as a business venture - charging publication fees to authors without providing the editorial and publishing services associated with legitimate journals”.

- *Ahmadu Bello University's Promotions guidelines*

Features of Predatory Journals

- Scanty publishing operations information. e.g. false (masked) location.
- Claim of stringent peer review and false indexing
- Non-existing editorial board members
- Extra-rapid acceptance of articles without quality control
- Aggressively campaigning for academics to submit articles or become reviewers or members of editorial boards
- Improper use of ISSNs/ISBN

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Features of Predatory Journals....

- Fake or non-existent impact factors.
- Choose a name nearly identical to an established well-respected publisher

For Example:

- There are two Academic Journals publishers (one in Africa with addresses in Kenya and Nigeria, and the other one in USA- the only difference is that one has in addition, the word “Inc, ” added to it)

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Authorship of Publications

Conditions for Authorship

The author must have:

- Contributed substantially to the conception and design of the study, the acquisition of data, or the analysis and interpretation
- Drafted or provided critical revision of the article
- Provided final approval of the version to publish
- Agreed to be accountable for all aspects of the work and provide answers in respect of accuracy and integrity.

Authors' Contribution

- Many Editors now require statements concerning Authors' contributions
- Compliance with Authorship criteria is also required
- Authors are required to acknowledge individuals that make contributions to the work but do not justify authorship

Common methods for listing authors

- **Relative contribution.** Main contributor **first** and others in descending order. In biomedical Sciences, usually, the last author in a group is the principle investigator/supervisor.
- **Alphabetical list**
- **Multiple “first” authors.** - Additional “first” authors can be noted by an **asterisk or other symbol**, with an explanatory note; however, the first name listed on a paper will still enjoy greatest visibility
- **Multiple “last” authors** - Similar to recognizing several first authors
- **Negotiated order** – Usually applied for “middle authors” – through persuasion!

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How do we Promote Quality Research?

- Leadership, focus, passion, dedication, investments, & commitment to act.
- A concerted effort to build partnership for a World-class capacity development in biomedical research:
- Leverage our relatively poor financial resources for maximum impact through partnerships and collaborations.
- Build centers of excellence in specific fields
- **Set-up a National Science Foundation. Current TETFUND intervention, not effective**

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Final notes on Ethics

- Four main ethical theories form the basis of research ethics:

1. Utilitarianism OR consequentialist theory:

- Greatest Good
An action that leads to beneficial consequences is right or moral; one that leads to harmful consequences is wrong or immoral.
- 2. **Kantian Ethics: Duties and Rights**
Doing something in a particular way because it is the “right thing to do.”

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Final notes on Ethics

- 3. **Rawlsian Ethics: Justice or Fairness**
Justice involves protecting individual rights, or preventing an injustice to an individual. Means treating people fairly.

4. **Aristotelian Ethics: The Virtuous Life**

What distinguishes humans from all other creatures is our ability to reason.

A good character is an achievement, not a natural endowment.

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Research Ethics and Academic Integrity



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Remember!

Research is to see what everybody else has seen, and to think what nobody else has thought.

Albert Szent-Gyorgyi

 BrainyQuote

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Thank You

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