

WRAP UP- INVESTIGATORS RESPONSIBILITIES

*Training on responsible conduct of
Research and participants protection*



Research Ethics.....

- **Involves the application of fundamental ethical principles to planning, conducting & publishing of research**

Guiding principles

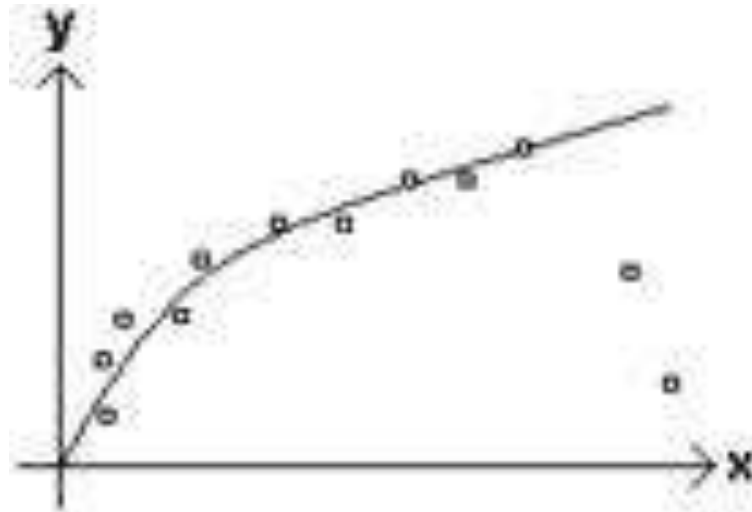
- Autonomy and respect
 - Beneficence
 - Non-maleficence
 - Justice (free from exploitation)
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- Scientific validity
- Honesty

Participant activity

Identifying ethical issues in the following scenarios

Two graduate students have made some measurements on a new material. The data points are as shown. To prove their hypothesis the results should lie on the curve shown. The two students considered omitting the two data points which were off the theoretical curve



- **Unethical as it would amount to falsification of data**
- **Should include outliers and give probable reasons or find out statistically acceptable ways of trimming outliers**

Scenario 2:

A group of medical students conducted a research on the awareness of diabetic diet in medical clinic participants. Their research was recognized as the best undergraduate research and later they submitted the same research paper to two different journals to see which journal publishes it first.

- Unethical as it would result in "inadvertent double-counting or **inappropriate weighting** of the results of a single study, which **distorts** the available evidence.
 - It would give a false idea of the number of publications in a given area
 - Wasting of resources on the review and publication process
- Should submit to one journal and wait for response prior to submitting to another

Students are required to prepare a research proposal during their undergraduate program. Nima developed the idea for his project and discussed with a friend. Several months later, he found that his idea had been submitted as a research proposal by his friend without his knowledge.

- **Unethical as failure to give credit to the person whose idea it is (intellectual property) amounts to plagiarism**
- **Should discuss and include as co-author**



Whaddya mean all my facts are wrong?!?

I copied everything straight off the internet!!

Four friends decide to work together on a research project during the vacation. One of them went abroad during the vacation and did not contribute to the research. The friends include all 4 names in a presentation made at a scientific congress.

- **Unethical as only those who contributed intellectually should be cited as authors**
- **Those who contribute in other ways may be acknowledged**

A group of undergraduate students planned a research project on the detection of fetal abnormalities in the second trimester, by ultrasound scanning. They collected data from the scan room without informing the mothers

- **Unethical as informed consent was not taken**
- **Should have informed mothers of their intent even though there is no particular advantage/disadvantage to the mother in doing so**

A group of undergraduate students collected data from a group of bank officers, with their consent, regarding their working hours and salary with regards to the prevalence of high blood pressure. Subsequently the researchers gave the same data to another group who were in need of same data variables.

- **Unethical as violating principles of consent and confidentiality**
- **Data can be used for a secondary purpose which was not first considered as long as**
 - **informed consent for sharing has been given**
 - **identities anonymized**
 - **due consideration to access restrictions**
- **Possibly develop ethical guidelines for data sharing?**

Why should there be research ethics?

- **To protect participants /patients /society /resources /researcher?**
- **To ensure accuracy of scientific knowledge**
- **To protect intellectual and property rights**

Protection of participants/patients/society/resources from harm

Show respect through:

- privacy /confidentiality
- Informed consent
- Refrain from Coercion and undue inducement

Question:

When do incentives amount to coercion/undue inducement?

- **Refrain from exploitation of vulnerable participants. Who are the vulnerable groups?**
- **Refrain from indiscriminate use of resources**
- **Ensure Favorable Risk-Benefit Ratio: risk should be minimized & potential benefit to society must outweigh risks**

- **Must be of social value: improvement of health/knowledge for the benefit of society/science e.g. high social value: use of stem cells to improve quality of life for Huntington's disease patients**

Example of less social value:

Drug studies conducted to obtain data that allows a new drug to compete in the healthcare marketplace even though existing effective and often cheaper therapeutics are already available

To ensure accuracy of scientific knowledge

- Research should be methodically rigorous - **Scientific validity**
- Fair subject selection: with inclusion / exclusion criteria & a valid number of subjects in order to project results to the population
- State research method clearly so that another person can conduct advanced study in future by using publication

Is it ethical to copy the methodology from a published paper?

- **Do not gloss over research method**
- **Should not falsify/modify/omit data**
- **Use actual data for analysis/cannot include someone else's data**
- **Report errors**
- **Be aware of conflict of interest**
- **Should not withhold and/or 'vague up' information**
- **Keep data and material for minimum of 5 years**
- **Data and material should be available to others**

- **Do not present/publish paper from incomplete research or from anticipated outcomes**
- **Should not duplicate publications and submissions**
- **Avoid piecemeal publication**
- **Your proposal should be reviewed Independently by unaffiliated individuals- Ethics Review Committee**

To protect intellectual and property rights

- **Citation and authorship**
 - Inclusion-Writing and significant scientific contribution**
- **Order: in terms of order of contribution**
 - actual researchers**
 - approval must be sought before you include a name**

- **Whenever somebody else's work is quoted reference should be made to the original author (Piracy vs plagiarism)**
- **Acknowledgement should include the names of person who helped you in making the research successful**

Breach of ethics in research
would amount to scientific
misconduct

Scientific misconduct

- **Fraud : invention/fabrication of data**
- **Plagiarism : copying data, ideas, text without acknowledgement of source**
- **Piracy : infringement of a copyright**
- **Submitting/Publishing the same paper to different journals**

Scientific misconduct ...

- **Not informing a collaborator of your intent to file a patent in order to make sure that you are the sole inventor**
- **Including a colleague as an author on a paper in return for a favor even though the colleague did not make a serious contribution to the paper**

- **Trimming outliers from a data set without discussing your reasons in paper**
- **Using an inappropriate statistical technique in order to enhance the significance of your research**
- **Bypassing the peer review process and announcing your results through a press conference without giving peers adequate information to review your work**

- **Conducting a review of the literature that fails to acknowledge contributions of others**
- **Stretching the truth on a grant application in order to convince reviewers that your project will make a significant contribution to the field**
- **Giving the same research project to two graduate students in order to see who can do it the fastest**

- **Overworking, neglecting, or exploiting research students**
- **Making derogatory comments and personal attacks in your review of author's/investigator's submission**
- **Making significant deviations from the research protocol approved by the Review Board without informing the committee**

- **Not reporting an adverse event in a human research experiment**
- **Wasting animals in research**
- **Exposing students and staff to biological risks**
- **Rejecting a manuscript for research/publication without even reading it**

- **Sabotaging someone's work**
- **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**

Ethics review committee (Health Research Ethics Committee)

You are convened to

- maintain ethical standards of practice in research**
- ensure protection of subjects/research workers from harm or exploitation**
- to provide reassurance to the public**
- protect researchers from unjustified criticism**

Procedure for ethical clearance

- **Fill ethical clearance form and attach proposal, questionnaires, informed consent forms, information leaflets etc., and submit**
- **When ethical clearance is granted, data collection can commence according to the approved methodology**

FINAL TEASER

- **A group of undergraduate students planned a research on family planning practices of Nigerian females. As they were close to the deadline for presenting their results, they started collecting information from participants before formal approval by the ethics review committee**

- **How should members of ethics review committee handle this? Even though the research was approved after all.**
- **Is it possible to develop a SOP on this?**

THANK YOU