RESEARCH ETHICS

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)**
- **Scientific validity**
- **Honesty**

Summary of Nuremberg Code (1)

- Voluntary consent of the human subject is essential
- Experiment should yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature
- Experiment should be so designed on a knowledge of the problem under study that the anticipated results will justify the performance of the experiment.
- Experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
- No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur

Summary of Nuremberg Code (2)

- The degree of risk should never exceed the humanitarian importance of the problem to be solved by the experiment
- Adequate facilities should be provided to protect the experimental subject against even remote possibilities of injury, disability, or death
- The experiment should be conducted only by scientifically qualified persons
- The human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation seems to him to be impossible
- The researcher must be prepared to terminate the experiment at any stage, if he has probable cause to believe, that a continuation is likely to result in injury, disability, or death to the experimental subject

Typical research involving ethical risk

- Vulnerable groups – such as children and young people, those with learning disabilities or special needs
- Sensitive topics – for example, sexual or illegal activities, or people's experience of abuse or violence
- Subjects can only be accessed via a gatekeeper – for example, some ethnic or cultural groups
- Element of deception such as covert observation used without a participant's full or informed consent
- Access to confidential records or information
- Activities leading to stress, anxiety or humiliation amongst target groups

Ethical principles

Ethical principles, then, fall into four main areas, namely, the need to:

- Avoid harm to participants (and producing benefits)
- Ensure informed consent of participants
- Respect the privacy of participants
- Avoid the use of deception

Avoiding harm to participants

Research will be considered harmful if it causes a participant to be

- Embarrassed
- Ridiculed
- Belittled or generally subject to mental distress
- Anxious
- Stressed
- Subject to negative emotional reactions

Beyond avoiding harm….

Research should produce positive benefits such as:

- Adding to human knowledge
- Yielding accurate and valid results
- Providing feedback to respondents (if possible) to promote greater self-understanding (if desired)

Informed consent (1)

Researcher should provide information on:

- The aims of the research
- Who will be undertaking it
- Who is being asked to participate
- What kind of information is being sought
- How much of the participant’s time is required

Informed consent (2)

- That participation in the study is voluntary
- That responding to all questions is voluntary
- Who will have access to the data once it is collected
- How anonymity of respondents will be preserved
- Who should it be returned to and by when

Respecting privacy

- Respondents must give informed consent
- Respondents have the right to withdraw at any time
- Data (in electronic and manual forms) must be kept securely

Avoiding deception

Best achieved by being open and transparent about the research including:

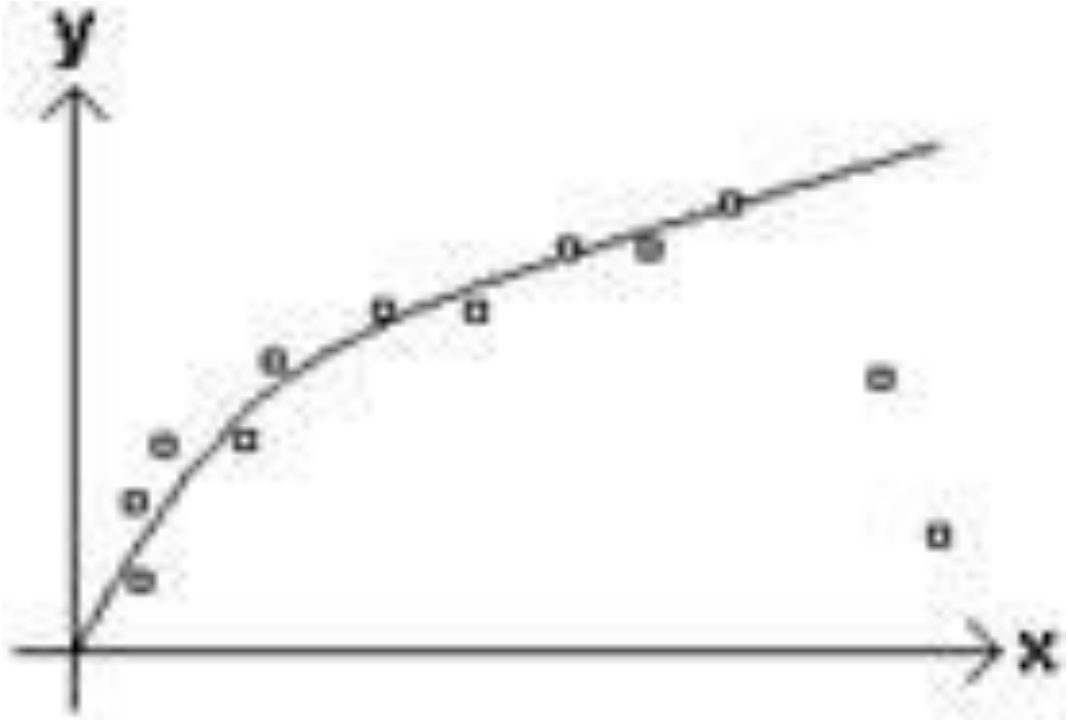
- Its objectives
- Methods
- Uses
- Role of respondent, including time and any other commitments

Student activity

Identify ethical issues in the following scenarios

Case 1

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**

Case 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.

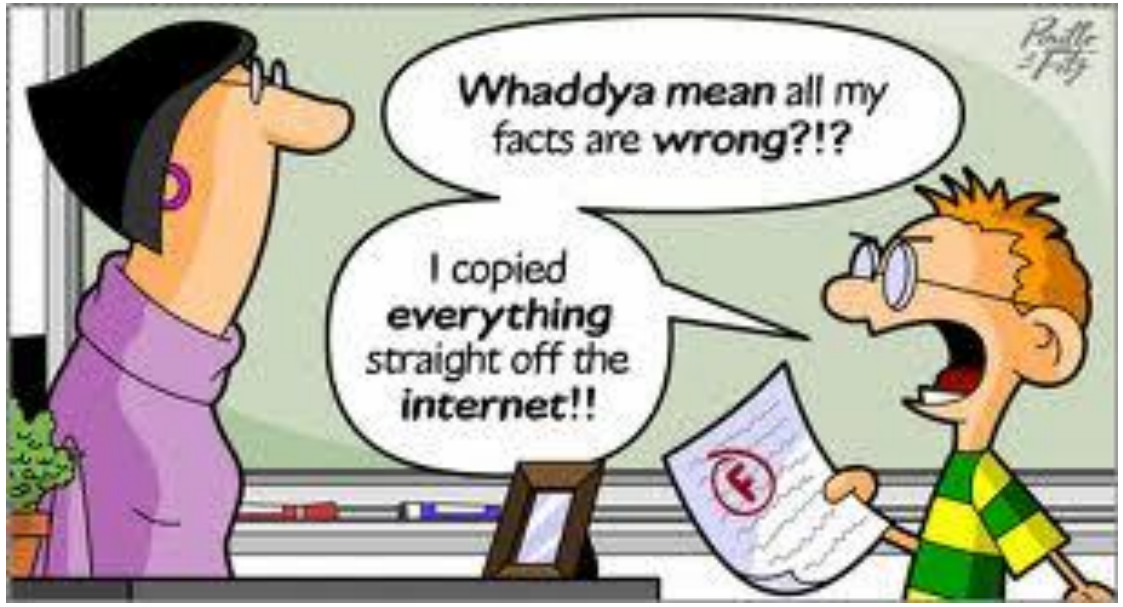
- **Unethical as it would result in "inadvertent double-counting or inappropriate weighting of the results of a single study, which distorts the available evidence**

  -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**

- **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**

Case 3

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**

Case 4

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**

Group 5

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 anonymised**
  - **due consideration to access restrictions**
- **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**

To protect participants/patients/society/resources

- **Protect from harm**
- **Show respect**

  -privacy /confidentiality

  -Informed consent
- **Refrain from Coercion and undue inducement When do incentives amount to coersion/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**

high social value: **use of stem cells to improve quality of life for Huntington's disease patients**

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

- **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 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 ‘vaguing up’ information
- Keep data and material for 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**
- **Should be reviewed Independently by unaffiliated individuals**

To protect intellectual and property rights

- **Citation and authorship**

  inclusion-Writing and significant scientific contribution

  order- order of contribution

  -actual researchers

  -approval must be sought to 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**

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 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 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**