RESEARCH METHODOLOGY IN SE

AIUB. FALL 2019-2020

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RESEARCH ETHICS AND ITS NECESSITY

- What is Ethics in Research?
- Distinguish between Ethics and Law.
- Why is it Important?
- What are the Ethical norms in Research?
- How to interpret and practice Ethical Norms in Research?

Acknowledgement: David B. Resnik, J.D., Ph.D

 $\underline{https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm}$



- Although codes, policies, and principals are very important and useful, like any set of rules,
 - they do not cover every situation,
 - they often conflict, and
 - they require considerable interpretation.
- Researchers must learn how to
 - interpret, assess, and apply various research rules and
 - how to make decisions and
 - to act ethically in various situations.

The vast majority of decisions involve the straightforward application of ethical rules.

CASE STUDY I

The research protocol for a study of a **drug on hypertension** requires the administration of the drug at different doses to 50 laboratory mice, with chemical and behavioral tests to determine toxic effects. Tom has almost finished the experiment for Dr. Q. He has only 5 mice left to test. However, he really wants to finish his work in time to go to Florida on spring break with his friends, who are leaving tonight. He has injected the drug in all 50 mice but has not completed all of the tests. **He therefore decides to extrapolate from the 45 completed results to produce the 5 additional results**.

- !! Many different research ethics policies would hold that Tom has acted unethically by fabricating data.
- !! If this study were sponsored by a federal agency, such as the NIH, his actions would constitute a form of **research misconduct**, which the government defines as "fabrication, falsification, or plagiarism" (or FFP).
- !! Actions that nearly all researchers classify as unethical are viewed as misconduct.

It is important to remember, however, that misconduct occurs only when researchers **intend to deceive**.

- ✓ honest errors related to sloppiness, poor record keeping, miscalculations, bias, self-deception, and even negligence do not constitute misconduct.
- ✓ Also, reasonable disagreements about research methods, procedures, and interpretations do not constitute research misconduct.

CASE STUDY 2

Dr. T has just discovered a mathematical error in his paper that has been accepted for publication in a journal. The error does not affect the overall results of his research, but it is potentially misleading. The journal has just gone to press, so it is too late to catch the error before it appears in print. In order to avoid embarrassment, Dr. T decides to ignore the error.

- ✓ Dr. T's error is not misconduct nor is his decision to take no action to correct the error.
- ✓ Most researchers, as well as many different policies and codes would say that Dr. T should tell the journal (and any coauthors) about the error and consider publishing a correction or errata. Failing to publish a correction would be unethical because it would violate norms relating to honesty and objectivity in research.

Many acts that the government does not define as "misconduct" but are unethical to most researchers.

- !! Publishing the same paper in two different journals without telling the editors
- !! Submitting the same paper to different journals without telling the editors
- !! 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
- !! Discussing with your colleagues confidential data from a paper that you are reviewing for a journal
- !! Using data, ideas, or methods you learn about while reviewing a grant or a papers without permission
- !! 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 the contributions of other people in the field or relevant prior work.

- !! Stretching the truth on a grant application in order to convince reviewers that your project will make a significant contribution to the field
- !! Stretching the truth on a job application or curriculum vita
- !! Giving the same research project to two graduate students in order to see who can do it the fastest
- !! Overworking, neglecting, or exploiting graduate or post-doctoral students
- !! Failing to keep good research records
- !! Failing to maintain research data for a reasonable period of time
- !! Making derogatory comments and personal attacks in your review of author's submission
- !! Promising a student a better grade for sexual favors
- !! Using a racist epithet in the laboratory
- !! Making significant deviations from the research protocol approved by your institution's Animal Care and Use Committee or Institutional Review Board for Human Subjects Research without telling the committee or the board
- !! Not reporting an adverse event in a human research experiment
- **!!** Wasting animals in research
- !! Exposing students and staff to biological risks in violation of your institution's biosafety rules
- !! Sabotaging someone's work
- !! Stealing supplies, books, or data
- !! Rigging an experiment so you know how it will turn out
- !! Making unauthorized copies of data, papers, or computer programs
- !! Owning over \$10,000 in stock in a company that sponsors your research and not disclosing this financial interest
- !! Deliberately overestimating the clinical significance of a new drug in order to obtain economic benefits



- ✓ Most academic institutions in the US require undergraduate, graduate, or postgraduate students to have some education in the responsible conduct of research (RCR).
- ✓ No one is accusing you of acting unethically.
- ✓ Indeed, the evidence produced so far shows that misconduct is a very rare occurrence in research, although there is considerable variation among various estimates.
- ✓ The rate of misconduct has been estimated to be as low as 0.01% of researchers per year (based on confirmed cases of misconduct in federally funded research) to as high as 1% of researchers per year (based on self-reports of misconduct on anonymous surveys).

- ✓ So far there is no evidence that science has become ethically corrupt, despite some highly publicized scandals.
- ✓ Even if misconduct is only a rare occurrence, it can compromise the integrity of research, erode the public's trust in science, and waste time and resources.
- ✓ Will education in research ethics help reduce the rate of misconduct in science? It is too early to tell.
 - ✓ The answer to this question depends, in part,
 - ✓ on how one understands the causes of misconduct.



- ✓ There are two main theories about why researchers commit misconduct.
 - ✓ According to the "bad apple" theory, most scientists are highly ethical.
 - ✓ Only researchers who are morally corrupt, economically desperate, or psychologically disturbed commit misconduct.
 - ✓ Only a fool would commit misconduct because science's peer review system and self-correcting mechanisms will eventually catch those who try to cheat the system.

- ✓ According to the "stressful" or "imperfect" environment theory,
 - ✓ Misconduct occurs because various institutional pressures, incentives, and constraints.
 - ✓ Such as pressures to publish or obtain grants or contracts, career ambitions, the pursuit of profit or fame, poor supervision of students and trainees, and poor oversight of researchers (see Shamoo and Resnik 2015).
 - ✓ Misconduct probably results from environmental and individual causes, i.e. when people who are morally weak, ignorant, or insensitive are placed in stressful or imperfect environments.
- ✓ Moreover, defenders of the stressful environment theory point out that science's peer review system is far from perfect and that it is relatively easy to cheat the system.
- ✓ Erroneous or fraudulent research often enters the public record without being detected for years.

ETHICAL EDUCATION

- ✓ Education in research ethics should be able to help researchers grapple with the ethical dilemmas they are likely to encounter by introducing them to important concepts, tools, principles, and methods that can be useful in resolving these dilemmas.
- ✓ Scientists must deal with a number of different controversial topics, such as **human embryonic stem cell research**, **cloning, genetic engineering, and research involving animal or human subjects**, which require ethical reflection and deliberation.

- ✓ A course in research ethics can be useful in helping to prevent deviations from norms even if it does not prevent misconduct.
- ✓ IT can help people get a better understanding of ethical standards, policies, and issues and improve ethical judgment and decision making.
- ✓ Many issues raises just because researchers <u>simply do not know or have never thought</u> seriously about some of the ethical norms of research.
 - ✓ **For example**, some unethical authorship practices probably reflect traditions and practices that have not been questioned seriously until recently.
 - ✓ If the director of a lab is named as an author on every paper that comes from his lab, even if he does not make a significant contribution, what could be wrong with that? That's just the way it's done, one might argue.

- ✓ **Another example**, where there may be some ignorance or mistaken traditions is conflicts of interest in research.
- ✓ A researcher may think that a "normal" or "traditional" financial relationship, such as accepting stock or a consulting fee from a drug company that sponsors her research, raises no serious ethical issues.
- √ Or
- ✓ Perhaps a university administrator sees no ethical problem in taking a large gift with strings attached from a pharmaceutical company.