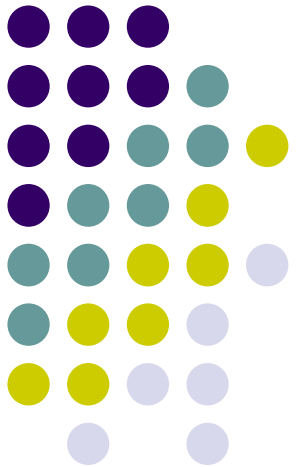
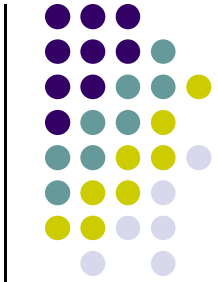
Ethical Issues for Biostatisticians



Introduction

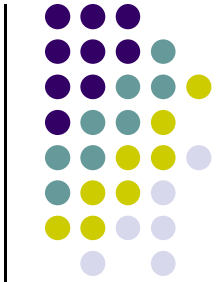
March 30, 2011

Outline



- **Introductory concepts**
  - What is ethics and why is it important in research?
  - Ethical principles for scientific research
  - Ethical dilemmas
  - Ethical reasoning and decision-making
- **Overview of course**
  - Review of syllabus
  - Description of assignments
  - Student responsibilities
- **Case study discussion**

What is Ethics?



Ethics is:

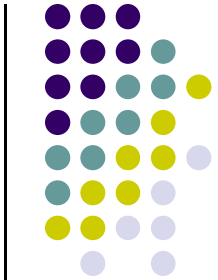
- A branch of philosophy that encompasses right conduct
- Norms or standards for conduct
  - Distinguish between acceptable and unacceptable behavior
    - Ethical standards are typically broader and more informal than legal rules
    - Actions can be legal but unethical, or illegal and ethical
- Methods, procedures, or perspectives for deciding how to act

Distinguishing rules, norms/standards, and principles:

- **Rules** are the most constraining and rigid, often provide a "bright line" for acceptable conduct
- **Norms** are standards that guide decisions and provide a framework for balancing competing factors
- **Principles** are either used interchangeably with standards or are considered to be a more general and abstract form of guidance for decision-making

Sources: Resnik http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm
Legal theory lexicon http://lsolum.typepad.com/legal_theory_lexicon/2004/03/legal_theory_le_3.html

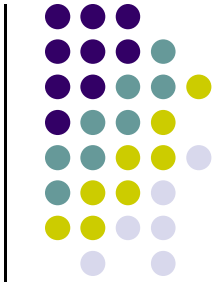
Why is Ethics Important in Research?



- Scientific goals and the scientific method are the basis for ethical standards in scientific research
  - Methodological and ethical standards in research are closely connected
- Ethical norms:
  - Promote the aims of research
    - Knowledge, truth, avoidance of error and biases
  - Promote values that are essential to collaborative work
    - Trust, accountability, mutual respect, fairness
  - Help ensure researchers can be held accountable to the public
  - Help build public support for research
  - Promote moral and social values
    - Social responsibility, human rights, animal welfare, compliance w/ the law, health & safety

Source: Resnik http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

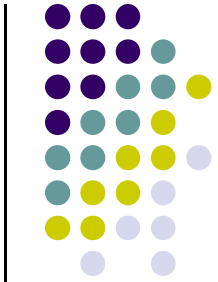
Overarching Ethical Principles for Scientific Research



- **Honesty**
  - Most important scientific principle (and basis for many rules)
  - Honestly report data, results, methods, procedures, publication status
  - Do not deceive
  - Dishonesty often involves production and reporting of data –
    - Falsification, fabrication, misreprentation (trimming, cooking, fudging)
- **Carefulness**
  - Avoid careless errors and negligence
    - Honest mistakes happen, but serious and repeated errors = negligence
    - Types of errors: experimental, methodological (including of statistics), misuse of theoretical assumptions, human (sloppiness, inattention, indiscretion), self-deception
  - Critically examine your work and that of others
  - Keep good records
- **Competence**
  - Maintain and improve your own professional competence
  - Promote competence in science as a whole

Source: Resnik 1998 and http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

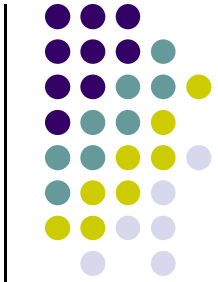
Overarching Ethical Principles for Scientific Research



- **Openness**
  - Share data, results, ideas, resources
  - Be open to criticism and new ideas
- **Freedom**
  - Scientists should be free to pursue new ideas and criticize old ones
- **Objectivity**
  - Strive to avoid bias and minimize self-deception
  - Disclose conflicts of interest
- **Integrity**
  - Keep promises and agreements
  - Act with sincerity
  - Strive for consistency of thought and action
- **Confidentiality**
  - Protect confidential information

Source: Resnik 1998 and http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

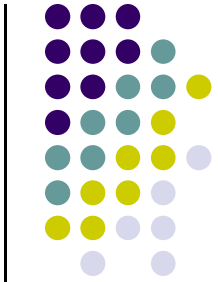
Overarching Ethical Principles for Scientific Research



- **Respect for research subjects**
  - Minimize harms and risks while maximizing benefits
  - Respect human dignity, privacy, autonomy
  - Take special precautions with vulnerable populations
  - Strive to distribute benefits and burdens of research fairly
- **Credit; respect for intellectual property**
  - Give credit where credit is due, not where it is not due
    - Don't plagarize
    - Responsibility comes with taking credit
    - Guest, ghost, and honorary authorships are not OK
    - Give proper acknowledgement
  - Honor patents, copyrights, etc.
  - Don't use unpublished materials without permission
- **Use resources efficiently**
  - Don't conduct unnecessary or poorly designed experiments
  - Show proper respect for animals in research

Source: Resnik 1998 and http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

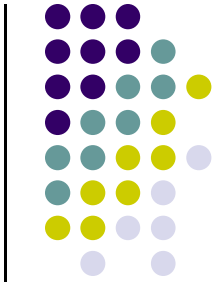
Overarching Ethical Principles for Scientific Research



- **Respect for colleagues and students**
  - Treat colleagues and students fairly and with respect
  - Science is built on cooperation and trust; this breaks down when there is no respect
- **Responsible mentoring**
  - Help educate, mentor, advise students
  - Promote student welfare; allow students to make their own decisions
- **Responsible publication**
  - Publish to advance research and scholarship, not just to advance your own career
  - Avoid wasteful and duplicative publication
- **Legality**
  - Know and obey relevant laws and institutional policies
- **Social responsibility**
  - Strive to promote social good, and prevent or mitigate social harms
  - Scientists have an obligation to conduct socially valuable research, participate in public debates, help make science policy, debunk junk science

Source: Resnik 1998 and http://www.niehs.nih.gov/research/resources/bioethics/whatis.cfm

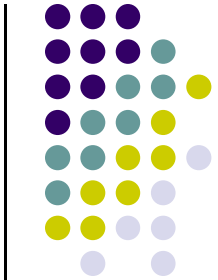
Basic Moral Principles of Medical Ethics (Norms)



- **Respect for autonomy**
  - People have the right to make informed and rational decisions for themselves
- **Justice**
  - Fairness – risks and benefits of research should be equally distributed across all groups
- **Beneficence**
  - Making efforts to secure the well-being of persons
- **Non-maleficence**
  - Do not intentionally harm patients, through errors of omission or commission

- Notes:
  - Respect for autonomy, beneficence, and justice are the foundation of the Belmont Report that governs human subjects research
  - Non-maleficence is not in the Belmont Report but is part of the Hippocratic oath

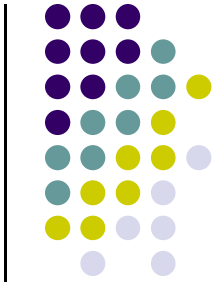
Ethical Misconduct (Rules)



- Only some ethical lapses are considered misconduct
- Nine major offenses:
  1. Fabrication of data
  2. Plagiarism
  3. Abuse of confidentiality
  4. Falsification
  5. Dishonesty in publication
  6. Deliberate violation of regulations
  7. Property violations
  8. Failure to report major offenses
  9. Retaliation

University of Michigan Policy Statement on the Integrity of Science:
http://www.rackham.umich.edu/policies/gsh/add/

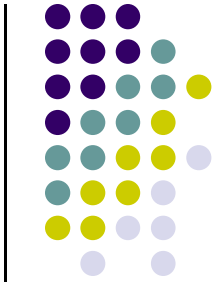
Some General Guidelines



- Accept personal responsibility
- Avoid conflict of interest
- Reject bribery in all its forms
- Maintain your technical competence
- Seek, accept and offer honest criticism
- Treat people fairly (regardless of who they are)
- Avoid injuring others
- Assist others in behaving ethically

Based on IEEE code of ethics

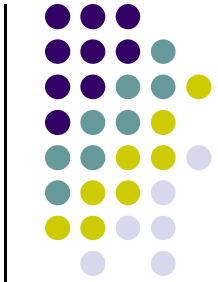
Limitations and Ambiguities of Ethical Standards



- Ethical standards
  - May conflict
  - Do not cover all situations
- Application of ethical standards often depends on implicit or explicit assignment of weights to each standard
- There may not be broad consensus about what should be done in specific situations
- Because of their informality and ambiguity, ethical standards may lead to **ethical dilemmas**

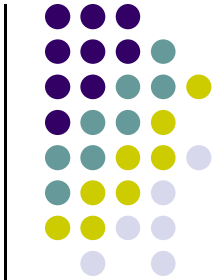
Sources: Cournand 1977; Resnik NIEHS

Ethical Dilemmas



- An **ethical dilemma** is the need to make a choice between different actions where each is supported by some standard of conduct
  - Could be the lesser of two evils, or the greater of two goods
  - Can involve:
    - Two different ethical standards where the ethical principles conflict
    - Good arguments on both sides of the issue
    - Conflict between ethics and the law

Ethical Analysis to Address Ethical Dilemmas

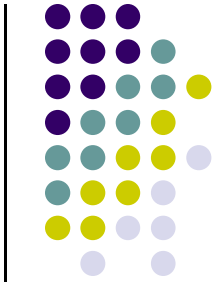


Ethical analysis provides a means to clarify a dilemma, identify the values involved, and determine a course of action. A useful approach is to think in terms of the following steps:

Recognition	*What are the issues being raised? What is the underlying ethical concern? How does this issue impact me?*
Reasoning	*What values are at stake? Are there competing points of view? What are the potential benefits and harms of different actions? Are there any rules or guidelines that can help?*
Responsibility	*What are my responsibilities? Do others have responsibilities also?*
Action	*What should I do – and why?*

Source: Biomedical Research Integrity Program and Kelly Fryer-Edwards, UW Department of Bioethics and Humanities

Steps in Moral and Ethical Reasoning and Decision-making



Steps:

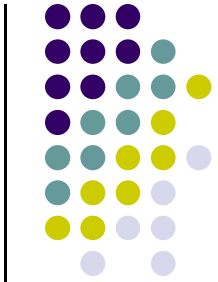
1. Define the problem. What are the conflicts and clashing ideals?
2. Gather all relevant information (factual, technical, moral)
3. Delineate or construct different options
4. Relate each option to the values or principles at stake
5. Evaluate each option in light of different values or principles, and the facts. Seek advice and input in this evaluative process
6. Arrive at a carefully reasoned judgment after weighing all the relevant moral factors and reasons in light of the facts (this is the HARD step)

- This is casuistry: case-based moral reasoning

Source: Ratner, UW bioengineering; Resnik, NIEHS

Challenges of Application

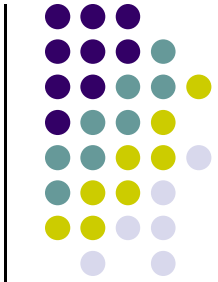
Overview of Course



- 20 hours in class
- Combination of guest speakers, discussion, and case studies
  - Details in the second half of the quarter still being finalized
- Combination of statistics, science, and public health concerns
- Goals:
  - Short-term: Learn rules and conventions guiding research practice; understand ethical considerations in research
  - Long-term: Develop ethical sensitivity, critical thinking skills, and habits to prepare you to effectively resolve situations that commonly confront statisticians

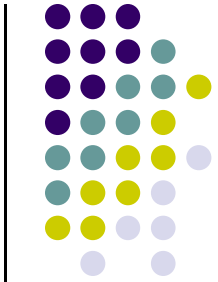
- Syllabus review and introductions

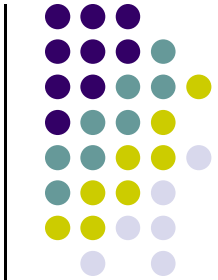
Learning Objectives Stated Differently



- Stimulate the moral imagination
- Recognize ethical issues
- Develop ethical analysis skills
- Elicit a sense of moral obligation and responsibility
- Learn to cope with moral ambiguity

Case Study Discussion





As a professional statistician, you are called by a colleague to examine and "bless" a biomedical experimental report. You are urged to do it quickly because the report has already been submitted and accepted for publication in a prestigious journal in the author's field. One of the reviewers, however, had suggested that a quick review by a statistician might be in order. To your horror, the report appears to be utter statistical nonsense. The data were not sampled according to any plan, but rather were drawn from various similar experiments done for different purposes. There is no reason to assume the observations were random or independent within or among data sets. There was no definition of how many data points had been originally available or how those used had been selected. The scatter plots within the paper were plainly skewed, but the computer statistical tests which had been run would have presumed a normal distribution. You explain gently that the statistical work is not an asset to the paper and could prove embarrassing to the author and the institution if published. You suggest that he eliminate the statistical portions and describe his work based on the qualitative reasoning which he obviously used. Initially very angry, he calms down and says, "I'll leave the contents alone, but I will add you as a coauthor. How's that?"