



National Institute of
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What is Ethics in Research & Why is it Important?

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When most people think of ethics (or morals), they think of rules for distinguishing between right and wrong, such as the Golden Rule ("Do unto others as you would have them do unto you"), a code of professional conduct like the Hippocratic Oath ("First of all, do no harm"), a religious creed like the Ten Commandments ("Thou Shalt not kill..."), or a wise aphorisms like the sayings of Confucius. This is the most common way of defining "ethics": **norms for conduct** that distinguish between acceptable and unacceptable behavior.

Most people learn ethical norms at home, at school, in church, or in other social settings. Although most people acquire their sense of right and wrong during childhood, moral development occurs throughout life and human beings pass through different stages of growth as they mature. Ethical norms are so ubiquitous that one might be tempted to regard them as simple commonsense. On the other hand, if morality were nothing more than commonsense, then why are there so many ethical disputes and issues in our society?

One plausible explanation of these disagreements is that all people recognize some common ethical norms but different individuals interpret, apply, and balance these norms in different ways in light of their own values and life experiences.

Most societies also have legal rules that govern behavior, but ethical norms tend to be broader and more informal than laws. Although most societies use laws to enforce widely accepted moral standards and ethical and legal rules use similar concepts, it is important to remember that ethics and law are not the same. An action may be legal but unethical or illegal but ethical. We can also use ethical concepts and principles to criticize, evaluate, propose, or interpret laws. Indeed, in the last century, many social reformers urged citizens to disobey laws in order to protest what they regarded as immoral or unjust laws. Peaceful civil disobedience is an ethical way of expressing political viewpoints.

Another way of defining 'ethics' focuses on the **disciplines that study** standards of conduct, such as philosophy, theology, law, psychology, or sociology. For example, a "medical ethicist" is someone who studies ethical standards in medicine. One may also define ethics as a **method, procedure, or perspective** for deciding how to act and for analyzing complex problems and issues. For instance, in considering a complex issue like global warming, one may take an economic, ecological, political, or ethical perspective on the problem. While an economist might examine the cost and benefits of various policies related to global warming, an environmental ethicist could examine the ethical values and principles at stake.

Many different disciplines, institutions, and professions have norms for behavior that suit their particular aims and goals. These norms also help members of the discipline to coordinate their actions or activities and to establish the public's trust of the discipline. For instance, ethical norms govern conduct in medicine, law, engineering, and business. Ethical norms also serve the aims or goals of research and apply to people who conduct scientific research or other scholarly or creative activities. There is even a specialized discipline, research ethics, which studies these norms.

There are several reasons why it is important to adhere to ethical norms in research. First, norms **promote the**

aims of research, such as knowledge, truth, and avoidance of error. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the truth and avoid error. Second, since research often involves a great deal of cooperation and coordination among many different people in different disciplines and institutions, ethical standards promote the **values that are essential to collaborative work**, such as trust, accountability, mutual respect, and fairness. For example, many ethical norms in research, such as guidelines for authorship, copyright and patenting policies, data sharing policies, and confidentiality rules in peer review, are designed to protect intellectual property interests while encouraging collaboration. Most researchers want to receive credit for their contributions and do not want to have their ideas stolen or disclosed prematurely. Third, many of the ethical norms help to ensure that researchers can be held **accountable to the public**. For instance, federal policies on research misconduct, conflicts of interest, the human subjects protections, and animal care and use are necessary in order to make sure that researchers who are funded by public money can be held accountable to the public. Fourth, ethical norms in research also help to build **public support** for research. People more likely to fund research project if they can trust the quality and integrity of research. Finally, many of the norms of research promote a variety of other important **moral and social values**, such as social responsibility, human rights, animal welfare, compliance with the law, and health and safety. Ethical lapses in research can significantly harm human and animal subjects, students, and the public. For example, a researcher who fabricates data in a clinical trial may harm or even kill patients, and a researcher who fails to abide by regulations and guidelines relating to radiation or biological safety may jeopardize his health and safety or the health and safety of staff and students.

Codes and Policies for Research Ethics

Given the importance of ethics for the conduct of research, it should come as no surprise that many different professional associations, government agencies, and universities have adopted specific codes, rules, and policies relating to research ethics. Many government agencies, such as the National Institutes of Health (NIH), the National Science Foundation (NSF), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the US Department of Agriculture (USDA) have ethics rules for funded researchers. Other influential research ethics policies include the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors), the Chemist's Code of Conduct (American Chemical Society), Code of Ethics (American Society for Clinical Laboratory Science) Ethical Principles of Psychologists (American Psychological Association), Statements on Ethics and Professional Responsibility (American Anthropological Association), Statement on Professional Ethics (American Association of University Professors), the Nuremberg Code and the Declaration of Helsinki (World Medical Association).

The following is a rough and general summary of some ethical principals that various codes address*:

Honesty

Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, granting agencies, or the public.

Objectivity

Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected

or required. Avoid or minimize bias or self-deception. Disclose personal or financial interests that may affect research.

Integrity

Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

Carefulness

Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

Openness

Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

Respect for Intellectual Property

Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give credit where credit is due. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

Confidentiality

Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

Responsible Publication

Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

Responsible Mentoring

Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

Respect for colleagues

Respect your colleagues and treat them fairly.

Social Responsibility

Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

Non-Discrimination

Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors that are not related to their scientific competence and integrity.

Competence

Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

Legality

Know and obey relevant laws and institutional and governmental policies.

Animal Care

Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

Human Subjects Protection

When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

* Adapted from Shamoo A and Resnik D. 2009. *Responsible Conduct of Research, 2nd ed.* (New York: Oxford University Press).

Ethical Decision Making in Research

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. It is therefore important for researchers to learn how to interpret, assess, and apply various research rules and how to make decisions and to act in various situations. The vast majority of decisions involve the straightforward application of ethical rules. For example, consider the following case,

Case 1:

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. Consider the following case:

Case 2:

Dr. T has just discovered a mathematical error in a 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, including ECU's policies, would say that Dr. T should tell the journal 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.

There are many other activities that the government does not define as "misconduct" but which are still regarded by most researchers as unethical. These are called "other deviations" from acceptable research practices and include:

- 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
- 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
- Rejecting a manuscript for publication without even reading it
- 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

These actions would be regarded as unethical by most scientists and some might even be illegal. Most of these would also violate different professional ethics codes or institutional policies. However, they do not fall into the narrow category of actions that the government classifies as research misconduct. Indeed, there has been considerable debate about the definition of "research misconduct" and many researchers and policy makers are not satisfied with the government's narrow definition that focuses on FFP. However, given the huge list of potential offenses that might fall into the category "other serious deviations," and the practical problems with defining and policing these other deviations, it is understandable why government officials have chosen to limit their focus.

Finally, situations frequently arise in research in which different people disagree about the proper course of action and there is no broad consensus about what should be done. In these situations, there may be good arguments on both sides of the issue and different ethical principles may conflict. These situations create difficult decisions for research known as **ethical dilemmas**. Consider the following case:

Case 3:

Dr. Wexford is the principal investigator of a large, epidemiological study on the health of 5,000 agricultural workers. She has an impressive dataset that includes information on demographics, environmental exposures, diet, genetics, and various disease outcomes such as cancer, Parkinson's disease (PD), and ALS. She has just published a paper on the relationship between pesticide exposure and PD in a prestigious journal. She is planning to publish many other papers from her dataset. She receives a request from another research team that wants access to her complete dataset. They are interested in examining the relationship between pesticide exposures and skin cancer. Dr. Wexford was planning to conduct a study on this topic.

Dr. Wexford faces a difficult choice. On the one hand, the ethical norm of openness obliges her to share data with the other research team. Her funding agency may also have rules that obligate her to share data. On the other

hand, if she shares data with the other team, they may publish results that she was planning to publish, thus depriving her (and her team) of recognition and priority. It seems that there are good arguments on both sides of this issue and Dr. Wexford needs to take some time to think about what she should do. One possible option is to share data, provided that the investigators sign a data use agreement. The agreement could define allowable uses of the data, publication plans, authorship, etc.

The following are some steps that researchers, such as Dr. Wexford, can take to deal with ethical dilemmas in research:

What is the problem or issue?

It is always important to get a clear statement of the problem. In this case, the issue is whether to share information with the other research team.

What is the relevant information?

Many bad decisions are made as a result of poor information. To know what to do, Dr. Wexford needs to have more information concerning such matters as university or funding agency policies that may apply to this situation, the team's intellectual property interests, the possibility of negotiating some kind of agreement with the other team, whether the other team also has some information it is willing to share, etc. Will the public/science be better served by the additional research?

What are the different options?

People may fail to see different options due to a limited imagination, bias, ignorance, or fear. In this case, there may be another choice besides 'share' or 'don't share,' such as 'negotiate an agreement.'

How do ethical codes or policies as well as legal rules apply to these different options?

The university or funding agency may have policies on data management that apply to this case. Broader ethical rules, such as openness and respect for credit and intellectual property, may also apply to this case. Laws relating to intellectual property may be relevant.

Are there any people who can offer ethical advice?

It may be useful to seek advice from a colleague, a senior researcher, your department chair, or anyone else you can trust (?). In the case, Dr. Wexford might want to talk to her supervisor and research team before making a decision.

After considering these questions, a person facing an ethical dilemma may decide to ask more questions, gather more information, explore different options, or consider other ethical rules. However, at some point he or she will have to make a decision and then take action. Ideally, a person who makes a decision in an ethical dilemma should be able to **justify** his or her decision to himself or herself, as well as colleagues, administrators, and other people who might be affected by the decision. He or she should be able to articulate **reasons** for his or her

conduct and should consider the following questions in order to explain how he or she arrived at his or her decision: .

- Which choice could stand up to further publicity and scrutiny?
- Which choice could you not live with?
- Think of the wisest person you know. What would he or she do in this situation?
- Which choice would be the most just, fair, or responsible?
- Which choice will probably have the best overall consequences?

After considering all of these questions, one still might find it difficult to decide what to do. If this is the case, then it may be appropriate to consider others ways of making the decision, such as going with one's gut feeling, seeking guidance through prayer or meditation, or even flipping a coin. Endorsing these methods in this context need not imply that ethical decisions are irrational or that these other methods should be used only as a last resort. The main point is that human reasoning plays a pivotal role in ethical decision-making but there are limits to its ability to solve all ethical dilemmas in a finite amount of time.

Promoting Ethical Conduct in Science

Many of you may be wondering why you are required to have training in research ethics. You may believe that you are highly ethical and know the difference between right and wrong. You would never fabricate or falsify data or plagiarize. Indeed, you also may believe that most of your colleagues are highly ethical and that there is no ethics problem in research.

If you feel this way, relax. No one is accusing you of acting unethically. Indeed, the best evidence we have 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). See Shamoo and Resnik (2009), cited above.

Clearly, it would be useful to have more data on this topic, but so far there is no evidence that science has become ethically corrupt. However, even if misconduct is rare, it can have a tremendous impact on research. Consider an analogy with crime: it does not take many murders or rapes in a town to erode the community's sense of trust and increase the community's fear and paranoia. The same is true with the most serious crimes in science, i.e. fabrication, falsification, and plagiarism. However, most of the crimes committed in science probably are not tantamount to murder or rape, but ethically significant misdeeds that are classified by the government as 'deviations.' Moreover, there are many situations in research that pose genuine ethical dilemmas.

Will training and 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. Moreover, 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. In any case, a course in research ethics will have little impact on "bad apples," one might argue. According to the "stressful" or "imperfect" environment theory, misconduct occurs because various institutional pressures, incentives, and constraints encourage people to commit misconduct, 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. 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. To the extent that research environment is an important factor in misconduct, a course in research ethics is likely to help people get a better understanding of these stresses,

sensitize people to ethical concerns, and improve ethical judgment and decision making.

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. In any case, a course in research ethics is useful in helping to prevent deviations from norms even if it does not prevent misconduct. Many of the deviations that occur in research may occur because researchers simply do not know or have never thought seriously about some of the ethical norms of research. For example, some unethical authorship practices probably reflect years of tradition in the research community 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. If a drug company uses ghostwriters to write papers "authored" by its physician-employees, what's wrong about this practice? Ghost writers help write all sorts of books these days, so what's wrong with using ghostwriters in research?

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. Maybe a physician thinks that it is perfectly appropriate to receive a \$300 finder's fee for referring patients into a clinical trial.

If "deviations" from ethical conduct occur in research as a result of ignorance or a failure to reflect critically on problematic traditions, then a course in research ethics may help reduce the rate of serious deviations by improving the researcher's understanding of ethics and by sensitizing him or her to the issues.

Finally, training in research ethics should be able to help researchers grapple with ethical dilemmas by introducing researchers to important concepts, tools, principles, and methods that can be useful in resolving these dilemmas. In fact, the issues have become so important that the NIH and NSF have mandated training in research ethics for graduate students.

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