THIRD EDITION

Responsible Conduct of Research

ADIL E. SHAMOO

DAVID B. RESNIK

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PREFACE TO THE THIRD EDITION

When the first edition of this textbook went to press in 2002, the field of responsible conduct of research (RCR) was in its infancy. Since then, there has been a great deal of change at many different levels—governmental, institutional, and individual. The Office of Research Integrity (ORI), part of the U.S. government, has funded empirical research, conferences, and course development on RCR. At the institutional level, universities have developed RCR policies and implemented RCR training programs; professional societies have drafted or revised ethics codes and guidelines; and scientific journals have developed rules and policies. At the individual level, researchers have published numerous books and articles on RCR and created RCR courses, class materials, and training modules. Researchers, institutions, and government agencies have also participated in several international conferences on research integrity.

Although much has been accomplished in the last decade or so, many serious ethical challenges remain. Misconduct continues to be a serious problem in research, as illustrated by highly publicized fraud cases involving research on stem cells, nanotechnology, women's health, oncology, and animal behavior. Researchers and institutional leaders continue to wrestle with ethical issues related to collaborations with industry and the commercialization of research, such as conflicts of interest and intellectual property rights. Perennial ethical issues, such as research involving animals or human subjects, as well as new and emerging concerns in fields such as genetics/genomics, synthetic biology, neuroscience, pharmacogenomics, nutrition research, microbiology, and virology, have drawn the attention of the media, the public, and politicians.

Since 1989, the Public Health Service (PHS), which funds National Institutes of Health (NIH) research, has required trainees (such as graduate students and postdoctoral fellows) to receive RCR instruction. In 2009, the National Science Foundation (NSF) began requiring that all recipients of NSF funding have an RCR education plan for all their students on those

grants. Many universities have adopted RCR training requirements that go beyond the federal conditions. Some require all doctoral students or all graduate students to receive RCR instruction. Many countries outside the United States have also begun to consider implementing RCR training requirements.

We published a second edition of the book in 2009 to take into account new developments in RCR, but the field continues to evolve rapidly, so we have decided to publish a third edition, which includes updated references, case studies, policies, and other material useful to students and scholars alike. The book presents a comprehensive introduction to RCR, with 13 chapters ranging in scope from the broad issues relating to social responsibility, research funding, and freedom of inquiry, to more narrow topics such as the ethical aspects of entering data into lab notebooks, designing experiments, citing published works, and deciding authorship matters.

We apologize for any errors or oversights in this third edition. Please feel free to send your comments and suggestions to Adil E. Shamoo, PhD, Department of Biochemistry and Molecular Biology, University of Maryland School of Medicine, 108 North Greene Street, Baltimore, Maryland 21201–1503; e-mail: ashamoo@som.umaryland.edu.

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Responsible Conduct of Research

CHAPTER 1

Scientific Research and Ethics

There is a growing recognition among scientists, government officials, research institutions, and the public that ethical conduct is essential to scientific research. Ethical conduct in research is essential to the foundation and advancement of science. It is also important to foster trust among scientists and the public's support for research. This chapter discusses the importance of ethics in research, the nature of scientific professionalism, and ethical decision making.

Ethical (or moral) problems, issues, and dilemmas occur for most people on a daily basis. Whenever we ask the question "What should I do?" there is a good chance that an ethical issue or concern lurks in the background. In everyday life, such questions frequently arise as we make choices among different interests and commitments, such as career, family, community, church, society, prestige, and money. Professional researchers—scientists, engineers, and scholars—also frequently face ethical problems, issues, and dilemmas. Consider the following cases:

CASE 1

You are a graduate student in pharmacology at a large university working under the direction of a senior researcher. After reading a paper on a new serotonin reuptake inhibitor published by the researcher, you notice that there is a problem with a diagram representing the dose-response curve. You cannot reconcile the diagram with the published data. You are a coauthor on the paper with a postdoctoral fellow, a technician, and your senior researcher (your supervisor). You approach your supervisor

with this problem, and he shrugs it off, saying that you do not understand the research well enough to make a judgment about it. What should you do?

CASE 2

You are a graduate student in psychology working on a dissertation about college students' attitudes toward drug and alcohol use. When you start compiling surveys, you notice some problems with your data. It appears that about 20% of the students misunderstood the Likert-scale questions, because they answered "1" when it appears they meant "5," based on their written comments that accompanied these questions. If you exclude these data from your analysis on the grounds that they are erroneous, this could affect the statistical significance of your results and the analysis and interpretation of the data. How should you deal with this issue?

CASE 3

You are a postdoctoral fellow in epidemiology at a university, and you are collaborating with a senior researcher. You have just read an important paper in your field and contacted the author about it. The paper is one of several the author has published from a large, publicly funded database. You ask the author if you can have access to the database to confirm your own work. The author says he will share data with you only if you agree to a formal collaboration with him and name him as a coauthor in publications that use the database. What should you do?

CASE 4

You are a professor of veterinary medicine and chair of your institution's animal care and use committee, which oversees animal research. The group People for the Ethical Treatment of Animals (PETA) has staged some protests against animal research recently at your institution. A local reporter calls you on the phone and wants to do an interview with you about animal research and animal rights. How should you handle this situation?

These cases illustrate some of the complex ethical dilemmas that can arise in the conduct of research. The purpose of this book is to help enhance science students' and scientists' understanding of the ethical, legal, and social dimensions of research, so that they can act appropriately and make responsible choices.

In recent years, scientists have come to realize that ethical conduct is an essential part of basic, applied, and clinical research. A few decades ago, many scientists would not have accepted this idea. According to a view that has held sway among scientists, humanists, and the general public for centuries, science is objective (Bronowski 1956; Snow 1964) and ethics are subjective, so scientists need not deal with ethical issues and concerns when conducting research. Ethical and social questions, according to this view, occur in the applications of science, but not in the conduct of science. Humanists, politicians, and the public can grapple with the ethical (or moral) aspects of research; the main task of the scientist is to do research for its own sake (Rescher 1965).

While it is important for scientists to strive for objectivity, this does not mean that ethical questions, problems, and concerns have no place in research conduct. Indeed, ethical behavior plays a key role in promoting objectivity, since ethical transgressions, such as data fabrication or falsification, and ethical concerns, such as conflicts of interest, can lead to biased or erroneous research.

Scientists need to pay special attention to research ethics in their own work and in teaching students about how to conduct research for several reasons (Shamoo 1989; Shamoo and Dunigan 2000; Sigma Xi 1986). First, modern science is a social activity in which researchers, students, and staff work together to achieve common goals (Merton 1973; Ziman 1984). Many different aspects of science, including mentoring, education, collaborative research, data sharing, peer review, and publication depend on cooperation based on shared expectations and understandings. Unethical behavior in science can destroy the trust that holds together the social fabric of research (Committee on Science 2009; Hull 1988; Macrina 2013; Resnik 1998a; Steneck 2006).

Second, most scientists receive considerable public support, such as funding and access to resources and facilities. Even those researchers who are not funded by government contracts or grants most likely received their education at a university that benefited from public support. Public support for research is based on trust and accountability. The public trusts that scientists will perform ethical research that has the potential to benefit society, and the public may hold scientists accountable for their conduct. Over the years, political leaders have held dozens of hearings on the integrity of scientific research and have enacted laws and regulations to ensure that scientists act responsibly. Unethical and illegal conduct in science can compromise the integrity of research and lead to scandals and negative political fallout that erode public trust and support for research (Resnik 2011).

Third, all members of society, including scientists, have some basic ethical obligations and duties (Resnik 1998a). Everyone has an obligation not to lie, cheat, or steal, for example. In science, the obligation not to lie, cheat, or steal implies duties not to fabricate or falsify data or plagiarize research. Everyone also has an obligation not to harm or dehumanize other people. In science, this obligation implies duties to protect the rights and welfare of human research subjects, as well as a duty to not publish research results that could be used by others to cause significant harm to society.

For these reasons and many others, universities, funding agencies, research institutions, professional societies, and scientists are now very much aware of the importance of ethics in research (Committee on Science 2009). Responses to these ethical concerns include the development of laws and regulations, institutional policies, journal policies, and professional guidelines pertaining to research ethics; investigations of research misconduct by institutions and the government; government hearings on research integrity and oversight; research on research ethics issues, including the publication of articles and books; workshops and international conferences on research ethics; and mentoring and formal education in research ethics (or the responsible conduct of research, RCR).

SCIENCE AS A PROFESSION

Research ethics can be understood according to the professional model (Resnik 1998a; Shrader-Frechette 1994; Steneck 2006). Each profession has its own ethical standards, which govern the practices in the profession. In medicine, physicians abide by rules such as "do no harm," "promote the patient's health," "maintain confidentiality," and "honor the patient's right to make decisions" (Beauchamp and Childress 2001). Science also has its own standards, which we discuss below. Professions usually adopt codes of ethics to signal to members of the profession and the public the type of behavior that is expected in the profession (Bayles 1988). Since the 1980s, many different scientific organizations, such as the American Anthropological Association (2012), the American Physical Society (2002), the American Society for Microbiology (2005), and the American Statistical Association (1999), have adopted ethics codes and guidelines. In 2010, over 340 researchers and government and institutional officials from 51 countries adopted the Singapore Statement on Research Integrity at the 2nd World Conference on Research Integrity (Singapore Statement 2010).

In addition to adopting ethical guidelines, scientific disciplines share several other characteristics with recognized professions. First, a profession is more than an occupation; it is a career or vocation (Davis 1995a). The first people to be recognized as professionals were physicians and ministers, who viewed themselves as being "called" to serve and devoted their lives to serving society. Most scientists view their work as a career and not just an occupation. Second, professionals have social responsibilities and can be held publicly accountable (Davis 1995a). Physicians, for example, have professional duties to promote the health of not only their patients but also the public. As noted above, scientists also have social responsibilities and can be held publicly accountable. Third, professionals are allowed to be self-regulating: Professionals can make their own standards and rules, provided that they obey the law and fulfill their public responsibilities (Bayles 1988). Physicians, for example, set their own standard of care and determine what it takes to become a qualified member of the profession. Scientists are also self-regulating: Scientists make their own rules for designing experiments, drawing inferences from data, publishing results, and so on. Scientists determine what counts as "good scientific practice." Finally, professionals are recognized as having expertise. Physicians, for example, have expertise when it comes to diagnosing, treating, and preventing diseases (Bayles 1988). Scientists are recognized as experts within their domain of knowledge and professional practice.

Prior to the Scientific Revolution (ca. 1500–1700 A.D.), science was more of an avocation than a vocation. Scientists often worked in isolation and financed their own research. They did not publish very frequently—the printing press was not invented until the mid-1400s—and when they did, their works were not peer reviewed. There were no professional scientific societies or journals until the mid-1600s. Universities taught only a small number of scientific subjects, and many scientists could master several different subjects. For example, Newton made major contributions to mechanics, astronomy, optics, and mathematics (Newton 1687 [1995]). Private businesses and governments saw little reason to invest in research. Science also did not have a great deal of social status or impact—the church and the state battled for social influence and political power (Burke 1995; Ziman 1984).

Science has changed dramatically in the last 500 years. Today, there are thousands of scientific societies and professional journals. Peer review plays a key role in funding and publications decisions. Scientists now work in research groups, which may include laboratory assistants and data analysts as well as postdoctoral, graduate, and undergraduate students. Universities

now offer study in hundreds of different scientific subjects, and it is virtually impossible to achieve scientific expertise without specialization. Governments and private corporations now invest billions of dollars each year in science. Science has become one of the most influential social institutions in society (Ziman 1984). Most of the technologies and many of the ideas in our modern world are the direct or indirect result of scientific research. Scientists now publish millions of articles a year, and the information boom continues to increase. Scientists give expert testimony to congressional committees and government agencies, and they provide advice to presidents, governors, generals, and corporate executives. Children learn about science in school, and most professional careers require some type of scientific and technical knowledge.

Science is now also a sizable part of the world's economy: Total (private and public) research and development (R&D) investments account for at least 2.5% of the gross domestic product (GDP) in developed countries such as the United States, United Kingdom, and Germany. Economic activity directly related to scientific research is estimated to be about 6% of the U.S. GDP (Resnik 2007). The indirect impacts of research are much larger than the direct impacts, because R&D investments have led to economically significant innovations, such as computers, the Internet, airplanes, automobiles, nuclear energy, and radar. As the 21st-century economy becomes more dependent on information, investments in R&D are likely to continue the upward trend that began in World War II (Dickson 1988). Literally millions of scientists are employed in universities, research institutions, private laboratories, or other organizations that conduct research (National Science Foundation 1997). It is estimated that there are more scientists alive today than all of the scientists who have lived during the past 2,500 years of human history (Dickson 1988).

Science's increased economic, social, and political influence carries added ethical responsibilities. Although laws and regulations, institutional and journal policies, and professional codes of conduct can provide valuable guidance for scientists, they have significant limitations. First, laws, regulations, policies, and codes do not cover every situation that may arise in research. For example, none of these rules say anything about authorship order on a scientific paper, which is often important. Second, the rules need to be interpreted and applied to particular situations. For example, to apply a prohibition against fabricating data to a particular study, one must understand particular details concerning the study's methodology and assumptions. Second, these different rules sometimes conflict. For example, funding agency and journal requirements to share data may conflict with the duty to protect confidential information concerning

human research subjects. Fourth, the rules themselves need to be evaluated and critiqued. For example, when a journal revises its policies pertaining to authorship, it must draw insights or inspiration from something beyond those policies (such as ethical considerations). Policies and other rules do not stand on their own: They must be based on more fundamental goals or concerns.

For these and other reasons, it is important for science students and working scientists to have a fuller understanding of research ethics. It is not enough to try to be familiar with a list of rules developed by governments, institutions, journals, or other organizations. To make responsible decisions involving ethical issues, one must also understand the deeper rationale for ethical rules and standards and how to deal with ethical dilemmas and problems in a rational way. To help achieve these goals, we provide an overview of ethics and ethical decision making.

WHAT IS ETHICS?

Ethics can be understood as (1) standards of conduct and as (2) an academic discipline that studies standards of conduct and ethical decision making. Ethics as an academic discipline is concerned with answering age-old questions about duty, honor, integrity, virtue, justice, and the good life (Frankena 1973). Scholars and scientists study ethics from a normative or descriptive point of view. The questions addressed by normative ethics have to do with how one *ought* to live or how society *ought* to be structured. These are the traditional questions addressed by philosophers, theologians, and political theorists. Various disciplines in the social and behavioral sciences, including psychology, neurobiology, sociology, and anthropology, take a descriptive approach to ethics and attempt to describe and explain ethical beliefs, attitudes, emotions, judgments, decisions, and behaviors (de Waal 2009; Haidt 2007; Miller 2008). Although the facts discovered by descriptive ethics have some bearing on normative questions, they cannot, by themselves, provide complete answers to normative questions because questions require normative answers.

For example, suppose that someone is trying to decide whether to cheat on her income taxes. Her question might be, "Should I cheat on my income taxes?" Suppose that a social scientist conducts a study showing that 65% of people cheat on their income taxes. This scientific study still would not answer the person's question. She wants to know not how many people cheat, but whether *she* should cheat. The fact that most people cheat does not justify cheating. The person asking the ethical questions is requesting

a normative justification for a particular course of action, but scientific studies do not provide this. Science delivers facts and explanations, not values and justifications.

The study of normative ethics can be subdivided into theoretical ethics, which studies general theories, concepts, and principles of ethics; meta-ethics, which studies the meaning and justification of ethical words, concepts, and principles; and applied (or practical) ethics, which studies ethical questions that arise in specific situations or areas of conduct, such as medicine or business (Frankena 1973). Research ethics is a branch of applied ethics that studies the ethical problems, dilemmas, and issues that arise in the conduct of research.

In this book, we do not explore meta-ethical issues in great depth, but we mention one issue that has some relevance for research ethics. One of the key questions of meta-ethics is whether ethical standards are universal (Frankena 1973; Pojman 1995). According to one school of thought, the same ethical (or moral) standards apply to all people at all times in all situations. A contrasting school of thought holds that different ethical standards apply to different people in different situations: There are no universal moral rules or values. We mention this issue here because in some situations in research ethics one must take a stand on this dispute (Angell 1997a, 1997b; Emanuel et al. 2000; Resnik 1998b). For example, different countries have various views on human rights, including the right to informed consent. In some countries, a woman's husband or older male relative (such as her father) provides consent for the woman. Scientists who conduct research in these countries must face the question of whether they should follow local customs concerning informed consent or Western standards, which require the individual to consent (Hyder and Wali 2006).

Returning to our focus on ethics as a standard of conduct, it is important to compare and contrast ethics and the law. Societies have had laws since ancient times. Laws are like ethical standards in several ways. First, laws, like ethics, tell people how they ought or ought not to behave. Second, ethical and legal standards share many concepts and terms, such as duty, responsibility, negligence, rights, benefits, and harms. Third, the methods of reasoning used in law and ethics are quite similar: Both disciplines give arguments and counterarguments, analyze concepts and principles, and discuss cases and rules.

However, ethics differs from the law in several important ways as well. First, the scope of ethics is not the same as the scope of law. There are many types of conduct that might be considered unethical but are not illegal. For instance, it may be perfectly legal to not give credit to someone

who makes a major contribution to a research project, but this action would still be unethical because it would violate principles of fairness and honesty. We can think of ethics and law as two different circles that overlap in some areas. Because laws are enforced by the coercive power of government, societies usually make laws pertaining to a behavior only when there is a social consensus concerning that behavior. The law usually sets a minimal standard of conduct, but ethics can go beyond that standard (Gert 2007).

Second, people can appeal to moral or ethical standards to evaluate or judge legal ones. People may decide that there needs to be a law against some type of unethical behavior, or they may decide that an existing law is unethical. If we consider a law to be unethical, then we may be morally obligated to change the law or perhaps even disobey it. For example, many people who considered South Africa's system of apartheid to be unethical fought to change the system. Some of them made a conscious decision to protest apartheid laws and engaged in a kind of law-breaking known as civil disobedience.

Third, ethical standards tend to be more informal and less technical than legal standards; ethical standards are not usually legalistic. In many cases, ethical standards are not even written down, but legal standards always are.

Because ethics and the law are not the same, scientists must consider and weigh both legal and ethical obligations when making ethical decisions.

It is also important to distinguish between ethics and politics. Politics, like ethics, deals with standards for human conduct. However, political questions tend to focus on broad issues having to do with the structure of society and group dynamics, whereas ethical questions tend to focus on narrower issues pertaining to the conduct of individuals within society (Rawls 1971). Many of the controversial areas of human conduct have both ethical and political dimensions. For instance, abortion is an ethical issue for a woman trying to decide whether to have an abortion, but it is a political issue for legislators and judges who must decide whether laws against abortion would unjustly invade a woman's sphere of private choice. Thus, the distinction between ethics and politics is not absolute (Rawls 1971). Although this book focuses on the ethics of research, many of the issues it covers, such as government funding of science and research with animal or human subjects, have political dimensions.

The distinction between ethics and religion is also important for our purposes. Ethical theories and religious traditions have much in common in that they prescribe standards of human conduct and provide some account of the meaning and value of life. Many people use religious

teachings, texts, and practices (e.g., prayer) for ethical guidance. We do not intend to devalue or belittle the importance of religion in inspiring and influencing ethical conduct. However, we stress that ethics is not the same as religion. First, people from different religious backgrounds can agree on some basic ethical principles and concepts. Christians, Jews, Muslims, Hindus, and Buddhists can all agree on the importance of honesty, integrity, justice, benevolence, respect for human life, and many other ethical values despite their theological disagreements. Second, the study of ethics, or moral philosophy, is a secular discipline that relies on human reasoning to analyze and interpret ethical concepts and principles. Although some ethicists adopt a theological approach to moral questions and issues, most use secular reasoning methods, concepts, and theories. While our book focuses on research ethics, many of the issues it addresses have religious aspects as well. For instance, various churches have developed opinions on specific issues arising from science and technology, such as cloning, assisted reproduction, DNA patenting, and genetic engineering.

ETHICAL THEORIES

To understand what a normative ethical theory is, it will be useful to compare normative ethical theories to scientific ones. Scientific theories include laws or generalizations that explain and predict observable phenomena. For example, the kinetic theory of gases includes the ideal gas law (PV = nRT), which explains and predicts how gases respond to change in temperature, pressure, and volume under certain conditions. Ethical theories include principles or norms that justify and prescribe behavior. For example, one might appeal to a theory of human rights to justify prohibitions against torture and reprimand governments for engaging in torture.

To test a scientific theory, one must produce empirical evidence (i.e., observations and data) that could support or undermine the theory. For example, measurements of continental drift and studies of volcanic activity patterns provided evidence for the plate tectonics theory. If evidence emerges that contradicts a theory, then scientists may reject the theory or modify it to account for the new evidence. For example, scientists rejected the theory of spontaneous generation of life from inert matter (such as rotting meat) on the basis of experiments showing that living organisms did not emerge from inert matter when the matter was shielded from flies and other contaminants.

Normative ethical theories are tested by appealing not to empirical evidence but to our judgments of right/wrong or good/bad in particular cases. For example, suppose that an ethical theory includes a principle like "promote human life." The theory should be able to provide a satisfactory account of judgments concerning the ethics of killing in particular situations, such as murder, self-defense, and war, and the importance of saving human lives. To test this theory, we could consider a hypothetical case (or thought experiment) where a doctor has an opportunity to use the organs from a patient to save the lives of five people. The patient is now in a persistent vegetative state as a result of a massive stroke. Before he had the stroke, he told the doctor and his family that he did not want to donate his organs because he believes that the human body is sacred. Should the doctor use the organs from the patient, against his wishes, to save the five people, or should he allow the patient to die without damaging his body? The theory implies that the doctor should take the organs, because this would promote human life. If we judge that this would be the wrong thing to do in this situation because we think the patient's wishes should be respected, then this would constitute evidence against this simple theory. If enough evidence of this sort emerges, we may reject the theory or develop a different one that does a better job of handling this and other cases. Over time, our theories can become better at systematizing our ethical judgments. This method for testing ethical theories is known as reflective equilibrium (Harman 1977; Rawls 1971).

Moral judgments are different from perceptual judgments. To make the judgment "this stop sign is red," I apply my beliefs and concepts to my sensory experience. For example, I might apply the concepts of "red" and "stop sign" to my visual experience to judge that "this stop sign is red." Although we have five senses that we use to make perceptual judgments, we have no sensory organ that provides input for moral judgments. Instead, we make moral judgments by forming a holistic impression of the situation we are presented with, based on our beliefs, concepts, and emotional reactions (Haidt 2007). For example, suppose I observe Jane Doe cutting John Doe with a knife, and I also believe that Jane is trying to kill John. I may experience revulsion, fear, anxiety, disgust, and other negative emotions. I may conclude, from this whole impression, that what is happening is wrong. However, I might not arrive at this judgment if I observe the same act of cutting (i.e., the same perceptual experience) when I believe that Jane is a skilled surgeon performing an emergency tracheotomy in an attempt to save John's life. Under these circumstances, I may experience no negative emotions, except perhaps some disgust at seeing John being cut. The difference between judging that an action is a vicious

assault and judging that an action is a commendable deed is a function of my beliefs about the act.

While the analogy between ethical and scientific theories is useful, it only goes so far. Scientific theories are different from ethical ones because they have greater objectivity. Although controversies concerning scientific theories (such as evolution and global warming) abound, scientists have made considerable progress over the years and have produced many theories that are widely accepted on the basis of substantial evidence, such as the ideal gas theory, plate tectonics, general relativity, atomic theory, chemical bonding theory, and so on. Philosophers have argued about ethical theories since the time of Plato (427–347 B.C.E.) and no consensus has emerged. One reason why consensus is so difficult to achieve in philosophy is that ethical judgments are strongly influenced by social, cultural, economic, and religious biases, which play only a minor role in perceptual judgments. Two people with very different religious beliefs and cultural backgrounds can look at a stop sign and agree that it is red if they have the concepts "red" and "stop sign" in their mental repertoire, but the same two people who witness an abortion or a public execution may not agree whether it is right or wrong. While there is some rough agreement on basic ethical principles (such as "don't lie, cheat, or steal") there is little agreement about theories. The method of reflective equilibrium may help philosophers move toward some consensus on ethical theories, but there is no guarantee that this will happen.

Given the lack of philosophical consensus about philosophical theories, we will not defend any particular theory as the "correct" or "best" one. Instead, we will describe (below) several prominent theories for students and scientists to consider when making ethical decisions and reflecting on the philosophical basis of the ethical guidelines for the conduct of research. These theories capture different insights about the nature of morality (Hinman 2002). Some focus on moral rules; others focus on moral virtues. Some emphasize the good of the individual, while others stress the good of society (Beauchamp and Childress 2001).

KANTIANISM

Kantianism is a theory, developed by the German Enlightenment philosopher Immanuel Kant (1724–1804), that has been revised and fine-tuned by modern-day Kantians (Korsgaard 1996). The basic insight of Kantianism is that ethical conduct is a matter of choosing to live one's life according to moral principles or rules. The concept of a moral agent

plays a central role in Kant's theory: A moral agent is a self-governing (or autonomous) person who can distinguish between right and wrong and choose to obey moral rules. For Kant, the motives of agents (or reasons for action) matter a great deal. One should do the right action for the right reason (Pojman 1995). To decide what the right thing to do is in a particular situation, one must apply a principle known as the categorical imperative (CI) to that situation (Kant 1753 [1981]). According to one version of the CI, the right thing to do in a particular situation is to follow a rule for action that could become a universal law for all people. For example, suppose that I am considering making a promise that I do not intend to keep in order to obtain money from someone. The CI implies that making this false promise would be wrong, because if everyone made false promises, no one could trust anyone and promises wouldn't mean anything anymore. So making false promises is a self-defeating rule for action that could not become a universal law. According to the respect-for-humanity version of CI, one should treat humanity, whether in one's own person or in another person, always as an end in itself, never only as a means. Making a false promise would be wrong, according to this version of the CI, because it would treat another person as a mere means to obtain something. The basic insight in this version of the CI is that all human beings have intrinsic, equal moral dignity or worth: We should not abuse, manipulate, harm, exploit, or deceive people in order to achieve specific goals. As we discuss later in this book, this concept has important applications in the ethics of human research.

UTILITARIANISM

The English philosophers and reformists Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873) developed the theory of utilitarianism in the 1800s. Utilitarians hold that the right thing to do is to produce the best overall consequences for the most people. We should maximize good consequences and minimize bad ones (Frankena 1973; Pojman 1995). Philosophers have introduced the term "consequentialism" to describe theories, such as utilitarianism, that evaluate actions and policies in terms of their outcomes or consequences (good or bad). "Deontological" theories, on the other hand, judge actions and policies insofar as they conform to moral principles or rules, and these theories do not appeal to consequences directly. Kantianism is a deontological theory because it holds that actions are morally correct insofar as they result from moral motives and conform to moral principles. Different utilitarian theorists emphasize different types

of consequences. Mill and Bentham thought that the consequences that mattered were happiness and unhappiness. According to Mill's Greatest Happiness Principle, one should produce the greatest balance of happiness/unhappiness for the most people (Mill 1861 [1979]). Due to problems with defining the term "happiness," some modern utilitarians hold that one should maximize preferences, welfare, or other values. Different utilitarian theorists stress different ways of evaluating human conduct. For instance, act utilitarians argue that we should apply the principle of utility to different actions when deciding what to do, whereas rule utilitarians argue that we should apply the principle of utility to a set of rules for society and that we should follow the rules that maximize utility. A number of different approaches to social problems are similar to utilitarianism in that they address the consequences of actions and policies. Cost-benefit analysis examines economic costs and benefits, and risk-assessment theory addresses risks and benefits. In this book, we will discuss how the utilitarian perspective applies to many important ethical questions in research and science policy.

VIRTUE ETHICS

The virtue ethics approach has a long history dating to antiquity. Virtue theorists, unlike Kantians and utilitarians, focus on developing good character traits. Their key insight is that ethical conduct has to do with living a life marked by excellence and virtue (Aristotle 330 B.C.E. [1984]; Pojman 1995). One develops morally good character traits by practicing them: A person who acts honestly repeatedly develops the virtue of honesty. Although virtue theorists do not emphasize the importance of moral duties, they recognize that one way of becoming virtuous is by honoring our moral obligations or duties. For example, a person who follows the rule "be honest" will become honest. Some of the frequently mentioned virtues include honesty, honor, loyalty, courage, benevolence, fairness, humility, kindness, fairness, and temperance. We will mention the virtue ethics approach again when we discuss scientific mentoring, because good mentors should model scientific virtues, such as honesty, courage, flexibility, and fairness (Pellegrino 1992; Resnik 2013).

INTEGRITY

Integrity has become a frequently used buzzword in research ethics (Macrina 2013). Scientists, scholars, and government or institutional officials

frequently talk about "threats to scientific integrity," "promoting research integrity," and so on. People use this word often without defining it clearly. What does integrity in research mean? We will distinguish between two different senses of "integrity": a rule-following sense and virtue sense. According to the rule-following sense, to act with integrity is to act according to rules or principles. Integrity in science is a matter of understanding and obeying the different legal, ethical, professional, and institutional rules that apply to one's conduct. Actions that do not comply with the rules of science threaten the integrity of research. According to the virtue approach, integrity is a kind of meta-virtue: We have the virtue of integrity insofar as our character traits, beliefs, decisions, and actions form a coherent, consistent whole. If we have integrity, our actions reflect our beliefs and attitudes; we "talk the talk" and "walk the walk" (Whitbeck 1998). We think both senses of integrity can play an important role in discussions of research ethics, and we will use them both throughout this book.

CRITIQUES OF ETHICAL THEORIES

Each of the theories we described has strengths and weaknesses. The strengths reside in their ability to provide insight into different aspects of morality. The weaknesses relate to their inability to deal with some difficult cases or provide useful guidance for decision making.

One of the main critiques of Kantianism is that it cannot deal with situations in which most people would say that we should sacrifice the rights or welfare of an individual for the common good. For example, suppose an estranged, angry husband is looking for his wife and two children, and he comes to your door asking for her whereabouts. He is carrying a gun and says that he will kill them all. You know that they are hiding in the house next door. Most people would agree that you could tell the husband a lie—"they are out of town on vacation," for example, in order to protect the wife and two children. Kantian theory seems to imply that you should not lie to the husband to save three people because this would be treating him as a mere means to saving other people. Lying is wrong as a matter of principle, even for a noble cause. Kantians have tried to interpret the theory so that it does not have this unacceptable implication, but one can construct similar examples that challenge Kantian principles (Korsgaard 1996).

One of the main problems with utilitarianism is that it does not seem to provide adequate protection for individual rights and welfare: utilitarians are apt to sacrifice individuals for the common good. For example,

suppose that a 20-year-old healthy male has been admitted to the hospital for a drug overdose. He has suffered severe brain damage and will probably never be able to walk, speak, or lead a normal life again. His vital organs are in good shape, however. There are four people waiting for organs they need to live (i.e., heart, lungs, two kidneys, and a liver). They will die soon if they do not receive these organs, and no organs appear to be forthcoming. Utilitarians would favor killing the brain-damaged patient and using his organs to save four lives because this would produce a greater balance of good/bad consequences than the other options. Most people, however, would not favor this option because it would involve taking an innocent life. Utilitarians have tried to interpret their theory so that it does not have this unacceptable implication. For example, rule utilitarians would say that accepting a rule like "kill innocent people to save the lives of other people waiting for organ transplants" would not produce an overall net utility because it would make people distrust the medical profession, would devalue human life, and so on. However, philosophers have constructed other examples that challenge utilitarian thinking about ethics (Pojman 1995).The main criticism of virtue ethics is that it does not provide adequate guidance for dealing with ethical dilemmas. For example, suppose you have promised to attend your son's baseball game. Just before you leave for the game, you notice that your neighbor has just collapsed in the yard. You could stay with your neighbor and help her receive medical attention by taking her to the hospital or possibly calling an ambulance. Either of these choices will result in your missing your son's game. Acting according to different virtues would favor different choices. The virtues of loyalty would favor going to the game, since you promised you would go, but the virtue of benevolence would favor helping the neighbor. Virtue ethics theories do not include a decision procedure for dealing with conflicts like this one, because there is no method for prioritizing virtues. Virtue ethicists have tried to interpret theory so that it can provide a way of dealing with ethical dilemmas like this one, but philosophers have constructed other examples that challenge this approach. Thus, while virtue theories can provide useful guidance most of the time, they seem to break down when you face difficult ethical choices (Pojman 1995).

Examining the strengths and weaknesses of different ethical theories in detail is beyond the scope of this book. However, we think it is important for the reader to have a basic grasp of some influential theories, since they can provide some guidance regarding ethical conduct and decision making. For further discussion of the strengths and weaknesses of different ethical theories, see Pojman (1995).

ETHICAL PRINCIPLES

In addition to these different theories, moral philosophers and theologians have developed a variety of ethical principles (or general rules), which can be useful in thinking about ethical questions, problems, and decisions. There are several advantages to using ethical principles to frame ethical questions, problems, and decisions. First, principles are usually easier to understand and apply than are theories because they are not as abstract or complex as theories (Fox and DeMarco 1990). It is much easier to understand and apply a rule like "don't kill innocent human beings" than Kant's moral theory. Second, many ethical principles have widespread theoretical and intuitive support (Beauchamp and Childress 2001). The principle "don't kill innocent human beings" is implied by many different moral theories, including Kantian ethics, rule utilitarianism, and virtue ethics. Different societies around the world accept some version of this principle. In this book, we will defend a principle-based approach to ethics in research.

PRINCIPLES FOR ETHICAL CONDUCT IN RESEARCH

We will now consider some principles pertaining to a particular area of conduct: scientific research. To understand these principles, it is important to distinguish between general ethical principles and special ethical principles. General ethical principles (or morals) apply to all people in society. For example, the rule "be honest" applies to everyone, regardless of their social role. Special ethical rules, however, apply only to people who occupy specific social roles. Such social roles include professions (e.g., doctors or lawyers), positions (e.g., mayors or legislators), and relationships (e.g., parents or siblings) (Bayles 1988). The rule "do not fabricate data" applies to scientists but not necessarily to those in other social roles. As noted earlier, people who enter a profession agree to abide by the special ethical rules of the profession. Special ethical principles systematize our ethical judgments concerning particular social roles. Special ethical principles are not simply the application of general ethical principles to particular social roles: Special principles take into account the unique features of social roles. In making judgments of right and wrong pertaining to social roles, we draw on our understanding of the general principles of ethics and our understanding of a particular social role. Special ethical principles should take into account the unique features of a social role, that is, what it is and what it does. For example, a principle of honesty in

science takes into account the unique features of science that require honesty, such as recording, reporting, or analyzing data. As a result, honesty in science may be different from honesty in a different social role. For example, a scientist who exaggerates when reporting data would be acting unethically, but a salesperson who exaggerates when selling a car might be acting appropriately. Though both have a duty to be honest, honesty in science is different from honesty in selling cars.

We now briefly describe some principles for ethical conduct in research (in bold) and some subsidiary rules.

1. Honesty: Honestly report data, results, methods and procedures, publication status, research contributions, and potential conflicts of interest. Do not fabricate, falsify, or misrepresent data in scientific communications, including grant proposals, reports, publications, and curriculum vitae.
2. Objectivity: Strive for objectivity in experimental design, data analysis, data interpretation, publication, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required.
3. 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, consent forms, and correspondence with agencies or journals.
4. Credit: Allocate credit fairly on publications, patents, and other materials.
5. Openness: Share data, results, ideas, tools, materials, and resources. Be open to criticism and new ideas.
6. Confidentiality: Protect confidential communications, such as papers or grants submitted for publication, personnel records, proprietary information, and records that identify individual research subjects or patients.
7. Respect for colleagues: Respect collaborators, peers, students, and research staff. Do not harm colleagues; treat them fairly. Do not discriminate against colleagues on the basis of sex, race, ethnicity, religion, or other characteristics not related to scientific qualifications. Help to educate, train, mentor, and advise the next generation of researchers.
8. 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. Do not plagiarize.

9. Freedom: Do not interfere with freedom of thought and inquiry.
10. Protection of animals used in research: Protect the welfare of animals used in research. Do not conduct animal experiments that are unnecessary or poorly designed.
11. Protection of human research subjects: Protect the rights, dignity, and welfare of human research subjects. Obtain informed consent from competent, adult subjects; minimize research harms and risks and maximize benefits; take special precautions with vulnerable populations; and distribute the benefits and burdens of research fairly.
12. Stewardship: Make good use of human, financial, and technological resources. Take care of materials, tools, samples, and research sites.
13. Respect for the law: Understand and comply with relevant laws and institutional policies.
14. Professional responsibility: Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole through mentoring, education, or leadership. Report misconduct and illegal or unethical activities that threaten the integrity of your profession.
15. Social responsibility: Promote good social consequences and avoid or prevent bad ones through research, consulting, expert testimony, public education, and advocacy.

A few words about these principles are in order. First, many of these principles may seem familiar to readers who have some experience with professional codes of ethics in research (Shamoo and Resnik 2006a), government-funding requirements, oversight agencies, sponsors, or journal policies. Our principles complement but do not undermine existing ethics codes and policies. Some readers may wonder whether these principles are redundant or unnecessary, because other rules and guidelines have already been stated publicly. However, we think the principles above have several important uses, because they may cover problems and issues not explicitly covered by existing rules or guidelines, they can be helpful in interpreting or justifying existing rules and guidelines, and they can apply to new and emerging disciplines or practices that have not yet established ethical codes.

Second, the principles we describe here, like the other ethical principles, may conflict with each other or other rules or values in some circumstances. For example, the principles of openness and confidentiality conflict when a researcher receives a request to share data pertaining to human biological samples. When conflicts like this arise, researchers must

prioritize principles in light of the relevant facts. We discuss conflict resolution in greater detail below. Researchers who work for private industry or the military may face restrictions on information sharing that conflict with the principle of openness. In these situations, researchers must choose between honoring their professional responsibilities and loyalty to the organization and its goals and rules. We will discuss conflicts in more detail below.

Third, the principles imply many different subsidiary rules. We have already stated some of the rules above, and we will discuss others in this book. Subsidiary rules play an important role in connecting general principles to specific decisions or actions (Richardson 2000). For example, the principle "protection for human research subjects" implies many different rules pertaining to informed consent that apply to particular situations involving consent (Richardson 2000).

ETHICAL DECISION MAKING

Having described some ethical theories and ethical principles for scientific research, we are now ready to discuss ethical decision making (also known as moral reasoning). Ethical decisions involve choices that have ethical implications. For example, choosing between different flavors of ice cream is probably not an ethical decision, because the choice is a matter of personal preference, with almost no impact on other people. However, purchasing an automobile probably is an ethical decision, because the choice can have a significant impact on other people and the environment. Because many of our choices have some impact on other people, and are not simply a matter of personal preference, many of the choices we make in life have ethical dimensions.

Ethical decisions that are particularly challenging are known as ethical dilemmas. An ethical dilemma is a situation where two or more options appear to be equally supported by different ethical theories, principles, rules, or values (Fox and DeMarco 1990). A person facing an ethical dilemma may find it difficult to decide what to do. Consider Case 1 (above) again. The student is attempting to decide whether to do anything about problems she has noticed with a diagram in a senior investigator's published paper. She suspects there may be an error or possibly something worse, such as data fabrication or falsification. What should she do?

There are many different ways of making decisions at the student's disposal: she could consult an astrologer, psychic, a pollster; she could read tea leaves, flip a coin, or pray; she could look for an answer on the Internet

by using Google. A rational approach to ethical decision making is different from all of these methods. A person who is using a rational approach to make an ethical decision uses his or her judgment and intellect to carefully examine the different options in light of the relevant facts and ethical values. He or she considers the interests of all of the affected parties and then examines the choice from different points of view. A rational, ethical decision need not be perfect, but it should represent a sincere attempt to do the right thing for the right reason.

Philosophers, ethicists, and other scholars have debated about three distinct approaches to rational, ethical decision making: (a) a top-down, theory-based approach; (b) a bottom-up, case-based approach known as casuistry; and (c) a mid-range, principle-based approach known as principlism (Beauchamp and Childress 2001). According to the top-down approach, to make a decision about what to do in a particular situation, one must appeal to a moral theory and infer a course of action from the theory. If the theory says to choose a particular option instead of the alternatives, then one should choose that option and implement it. The top-down approach has been popular among moral philosophers for many years. While we agree the theories can be an important part of an ethical analysis of a decision, they have significant limitations, as we have discussed earlier. Therefore, we do not recommend this approach.

In response to problems with theory-based approaches to ethical reasoning, some philosophers have defended a case-based approach known as casuistry (Johnsen and Toulmin 1988; Strong 2000). According to this method of ethical decision making, one should make decisions about particular cases by comparing those cases to previous cases. If cases are similar in relevant ways, then the decisions that one reaches should be the same. If cases are different, then one should reach different decisions. The method is like the case-based approach used in legal reasoning, in which past cases set precedents for future ones. For example, to decide whether one should exclude five data outliers from a dataset, one should compare this situation to previous cases in which the scientific community judged it was ethical to exclude data outliers. If the current situation is similar to those other cases, then excluding the data outliers is ethical and one may exclude them. If the current situation is different from those previous cases, or is similar to cases in which excluding outliers was regarded as unethical, then excluding the five outliers may be unethical (Penslar 1995). The method of casuistry is also known as situational ethics, because matters of right and wrong depend on factors inherent in the particular situation.

The casuist approach offers many useful insights for ethical decision making. First, it emphasizes the importance of understanding and appreciating the facts and circumstances concerning cases. In ethics, the details matter. For example, the difference between appropriate exclusion of outliers and falsification of a data often depends on the details concerning methodology, analysis, and communication. The difference between plagiarism and proper citation may come down to the placement of quotation marks. Second, the casuist approach emphasizes the importance of learning from the past and other cases. If we are to make any progress in ethics, we must learn from good decisions (and bad ones) (Strong 2000).

However, the casuist approach also has some flaws that hamper its ability to guide ethical decision making. First, the casuist approach has no systematic way of comparing cases (Beauchamp and Childress 2001). We need some method or procedure for determining which features of a case are relevant for ethical analysis, because cases have many features that we do not need to consider. For example, if we compare two cases where authors have excluded data from a publication, what aspects of data exclusion should we focus on? The percentage or amount of data excluded? The type of data excluded? The effect of the data exclusion on the results? To answer questions like these, we need ethical principles, rules, or methods for comparing cases, but the casuist approach does not provide these.

Second, the casuist approach does not offer satisfactory justifications for ethical decisions. People are frequently asked to justify their ethical decisions to colleagues, supervisors, governmental officials, or the public. To justify his or her conduct, a person should be able to do more than explain how she or he examined cases—the person should also be able to explain how the decision followed from a rule or principle that transcends those cases (Gibbard 1992). For example, a researcher who wants to defend herself from the charge of plagiarism should be able to do more than say that her conduct is similar to other cases that were not regarded as plagiarism; she should also be able to explain why her conduct does not fit the definition of plagiarism and therefore does not violate any rules against plagiarism.

Some proponents of casuistry have responded to objections like those mentioned above by admitting that casuistic reasoning needs to be supplemented with rules or principles. But making this admission changes the approach from a pure case-based method to one that appears to be principle based. Indeed, there would seem to be very little difference between casuistry that includes rules or principles and principle-based approaches (Iltis 2000).

We therefore favor the principle-based approach for many of the reasons noted above. Ethical principles are less controversial than ethical

theories. They are also easier to interpret and apply. Ethical principles provide a framework for comparing different cases. So, the principle-based approach does not have the same problems as the other two approaches. One of the most influential books in bioethics, Beauchamp and Childress's *Principles of Biomedical Ethics* (2001), takes a principle-based approach to ethical problems in medicine and health care. We are following their example by articulating a principle-based approach to ethical problems in scientific research (Shamoo and Resnik 2006b).

The principle-based approach is not flawless, however. Because it straddles the fence between theory-based and case-based approaches, it is susceptible to attacks from both sides. Proponents of theory-based approaches argue that principle-based approaches are nothing but an amalgam of different theories, a hodgepodge. Principle-based approaches have no way of settling conflicts among principles: They lack philosophical unity and coherence (Gert 2007). Proponents of case-based approaches argue that principle-based approaches are too abstract and general to provide sufficient guidance for ethical decision making. Principle-based approaches are not practical enough (Strong 2000). We acknowledge these problems but think the principle-based approach can overcome them (for further discussion, see Beauchamp and Childress 2001).

Having made these general comments about rational, ethical decision making, we now describe a method for making ethical decisions. We do not claim to be the originators of this method, because many other writers have described methods very similar to this one (Beauchamp and Childress 2001; Fox and DeMarco 1990; Shamoo and Resnik 2006a; Swazey and Bird 1997; Weil 1993; Whitbeck 1996). Nevertheless, it will be useful to review the method here and make some clarifying comments.

A METHOD FOR ETHICAL DECISION MAKING

Our method for ethical decision making involves six steps:

Step 1: Define the problem, question, or issue.
Step 2: Gather relevant information.
Step 3: Explore the viable options.
Step 4: Apply ethical principles, institutional policies, or other rules or guidelines to the different options.
Step 5: Resolve conflicts among principles, policies, rules, or guidelines.
Step 6: Make a decision and take action.