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QUESTION 6: ROLE OF UTILITARIAN, DEONTOLOGICAL, RELATIONAL, AND
ECOLOGICAL ETHICS IN THE INSTITUTIONAL REVIEW BOARD PROCESS

Data collection in qualitative research poses various ethical problems. Compare and contrast the four types of ethics (utilitarian, deontological, relational, and ecological) that provide a basis for viewing and resolving ethical issues. Focusing on potential dilemmas, critique the role that each type plays in the federally mandated IRB process.

Introduction

The United States has enacted laws to assure the protection of rights and welfare of human participants involved in some types of research. Other nations (e.g., Great Britain) have instituted similar research review requirements, either (a) to preserve the rights of citizen subjects, (b) to assure similar protections when government funds are used for research outside the country of origin, or (c) both. Such sets of laws, regulations, and policies are framed within a context of ethics and ethical behavior, often derived from philosophical concepts and generally accepted norms or conventions.

Available literature describes at least four types of ethics—deontological, ecological, relational, and utilitarian—that may provide a basis for viewing and resolving ethical issues. This paper compares and contrasts these four ethical perspectives, illustrating some potential dilemmas, and critiques the role that each type plays in the federally mandated institutional review board process.

The first section defines and describes the development of key concepts of duty, ethics, justice, morals, obligations, and rights, and briefly discusses issues such as distinctions between right and wrong, good and evil, and virtue and vice. The second section describes basic deontological, utilitarian, relational, and ecological ethical perspectives of those concepts, followed by a comparative analysis. The third section examines laws, regulations, and guidelines that guide the federally-mandated Institutional Review Board (IRB) process. The fourth section

discusses the apparent role that the each of four types of ethics play in the IRB process. The final section summarizes the paper.

Key Concepts

As noted above, discussion of several key concepts—duty, ethics, justice, morals, obligations, rights, principles of right or wrong, and virtue—are intertwined, so much so that earlier philosophers (e.g., Hume, 1740/2003) noted the difficulty that he experienced while trying to avoid circular reasoning. That is, how might one define morals without defining right and wrong, or ethics without defining morals, or right and wrong without referring to commonly accepted moral standards? To do so without circular logic is seemingly difficult.

A discussion between Socrates and Euthyphro (Plato, 380 B.C./2000) illustrates this difficulty. Socrates asks Euthyphro to define piety and impiety. Euthyphro asserts that piety is what he is doing—in his case, prosecuting a wrongdoer (his father, whom he accuses of murder) no matter whom s/he is, and that not to prosecute is impious. Euthyphro asserts that such actions are right, but acknowledges that others in his society assert that it is wrong for him to prosecute his own father (p. 6).

As the discussion progresses, Socrates asks for a more generalized definition. Euthyphro appeals to his divinities: "what is dear to the gods is pious, what is not is impious" (p. 7). Socrates complements Euthyphro on the clarity of his statement; they then set about to determine the truth of the definition. Eventually they determine that the gods do not all agree—different gods define different things to be just, beautiful, ugly, good, and bad. Some things are considered just (or good, or pious) by some gods and unjust (or bad, or impious) by others. Thus, absent agreement by divine authorities, the definition is deemed flawed and discarded.

Euthyphro next asserts that all the gods would agree on the general principle that whoever kills someone unjustly should pay the penalty. Socrates wonders whether all would agree on (a) who the wrongdoer is, (b) what he did and when, and (c) whether the killing was unjust. Socrates asks Euthyphro for a "clear sign that all the gods definitely believe [Euthyphro's] action [against his father] to be right" (p. 10). Socrates also begins to ask which came first—is piety loved by the gods because it is pious, or is a thing pious because it is loved by the gods? That triggers a discussion of circular logic, after which Euthyphro states: "But Socrates, I have no way of telling you what piety is, for whatever proposition we put forward goes around and refuses to stay put where we establish it" (Plato, p. 13). The discussion continues, exploring the details of alternative definitions and explanations, until Euthyphro eventually returns to his original definition, whereupon Socrates notes that they have arrived where they began and suggests that they should begin the circular examination once again in their quest of truth.

Nozick (2001) postulates that philosophers have long sought to identify and establish permanent (absolute, objective, and universal) truths in an enduring framework of thought. Ideally "details might remain to be filled in, but the essentials were meant to be in place and to stand firm for all time" (p. 1). Their goal was to define "absolutely secure foundations for knowledge and values.... One by one, these purportedly certain, indubitable, and unassailable points have been shaken" (p. 1). Inductively, Nozick believes that such a search for *ethical truth* is unpromising because truth corresponds to the facts; mankind has been unable to discover ethical truths via observation, scientific experimentation, or theorizing (p. 236). In essence, Socrates was engaged in a search for "ethical truth" and reasoned his way out of every definition that Euthyphro offered.

Nozick suggests that some recent philosophers have established ethical objectivity as a more modest and, hopefully, achievable goal. The hope is that if an objective process exists, it might lead people to accept certain ethical statements and serve as a surrogate for ethical truth. But, Nozick asks, is there "an objective process that will lead *all* people to accept certain ethical statements? (p. 236, emphasis added)." Does such an objective process thereby establish ethical truths? Or, if such truths do not exist, would such a process lead to agreement on principles or statements that could serve as a practical basis for our common life? Furthermore, are our ethical intuitions a product of societal forces and cultural conditioning? If so, are ethics contingent and variable? And, if so, why should we continue to give these intuitions normative weight?

Concepts that Aid in Defining Ethics

Guralnik (1984) defines "ethics" as (a) the study of standards of conduct and moral judgment; (b) a treatise on this study; (c) the system or code of morals of a particular person, religion, group, profession, etc. (p. 481). Cognitive Science Laboratory (2002) indicates that the term typically reflects either (a) motivation based on ideas of right and wrong or (b) the philosophical study of moral values and rules. Furthermore, an ethical or moral code can mean either (a) the principles of right and wrong that are accepted by an individual or a social group or (b) a system of principles governing morality and acceptable conduct. Roland and Hellyer (1996) note that the term "ethics" describes:

A system of moral principles, rules or standards that govern the conduct of members of a group. Ethical codes of conduct approach human behavior from a philosophical standpoint by stressing objectively defined, but essentially idealistic, standards (or laws) of right and wrong, good/evil, and virtue/vice such as those applicable to the practices of lawyers and doctors (§ 2).

Wojtczak (2002) defines ethics as “the branch of philosophy that deals with distinctions between right and wrong and with the moral consequences of human actions. Cambridge Institute for Research, Education, and Management (2004) indicates that “ethics” is a generic term for various ways of understanding and examining the moral conduct of human behavior and actions. Some ethical evaluations use a normative approach—focusing on standards of right or good action—while others are descriptive—reporting about individual beliefs and actions (§ 51).

Regarding normative approaches, Nozick (2001) compares the relationships between normative statements, norms, and the internalization process:

A normative statement is a statement that a person or group of persons ought (or is required, or is permitted) to do act A in circumstances C. A *norm* is an organized or institutionalized pattern of social rewards and punishments for doing or not doing A in circumstances C. A norm, then, corresponds to a normative statement that is generally enforced. And a person *internalizes the norm* when the person has a disposition to behave in accordance with a normative statement in the absence of social sanctions for deviation from the normative statement. The usefulness of the internalization of norms is clear, both in reinforcing and protecting other modes of cooperation to mutual benefit, and in filling the gaps that these other modes leave (p. 247).

Nozick (2001) suggests that the basis and status of ethical truths are unclear because biasing factors vary from realm to realm and our ethical intuitions might largely be due to societal forces and cultural conditioning. He therefore concludes that “we cannot present an account of ethics and of its function that starts with the notion of ethical truth and the desire to do what is right” (p. 239). Instead, he suggests that coordination of individual actions within a society for mutual benefit comprises the background that gives rise to ethics:

My actions are connected with yours when the outcome of some action of yours varies, depending upon what I do. My actions can affect the outcome of one of your actions. Our actions are mutually connected when my actions are connected with yours and yours with mine. Frequently, the actions of different people are mutually connected and the outcomes are nontrivially affected . . .

The functions of ethics, of ethical norms and ethical beliefs, is to coordinate our actions with those of others to mutual benefit in a way that goes beyond the coordination achieved through evolutionary instilled desires and patterns of behavior (including self-sacrificing behavior toward biological relatives). The coordination that ethics achieves is more extensive and better adapted to new and changing circumstances and opportunities (p. 240).

These varying definitions suggest that the term “ethics” (a) may mean different things to different people, (b) may be determined via different methods, and (c) may reflect different perspectives (e.g., social systems and cultural norms). All of these definitions have common threads: right and wrong, virtue and vice, and morality, supposedly expressed in (a) systems of standards and codes or (b) individually held morals. Nozick suggests that while we cannot develop a precise, universally agreed upon definition, a rough criterion might be as follows:

An ethics is the most weighty principles or values concerning interpersonal relations (or relations of self and other, including self and animals, or self and environment) that mandate behavior that may be opposed to one's desires of the moment, where these principles or values are not backed solely (or predominantly) by the consideration that other people will punish you if you deviate (p. 248).

But how does mankind and society determine what is good and what is evil, what is vice and what is virtue, what is moral, and what is ethical? A review of the literature suggests that such a determination rests on concepts such as rights, duties, and obligations.

Rights

While discussing the rights of sovereigns to wage war, Dutch philosopher Hugo Grotius (1625/1814/2001) wrote:

There is another signification of the word RIGHT, different from this, but yet arising from it, which relates directly to the person. In which sense, RIGHT is a moral quality annexed to the person, justly entitling him to possess some particular privilege, or to perform some particular act. This right is annexed to the person, although it sometimes follows the things, as the services of lands, which are called REAL RIGHTS, in opposition to those merely PERSONAL. Not because these rights are not annexed to persons, but the distinction is made, because they belong to the persons only who possess some particular things. This moral quality, when perfect is called a FACULTY; when imperfect, an APTITUDE. The former answers to the ACT, and the latter to the POWER, when we speak of natural things.

Civilians call a faculty that Right, which every man has to his own; but we shall hereafter, taking it in its strict and proper sense, call it a right. This right comprehends the power, that we have over ourselves, which is called liberty, and the power, that we have over others, as that of a father over his children, and of a master over his slaves. It likewise comprehends property, which is either complete or imperfect; of the latter kind is the use or possession of any thing without the property, or power of alienating it, or pledges detained by the creditors till payment be made. There is a third signification

which implies the power of demanding what is due, to which the obligation upon the party indebted, to discharge what is owing, corresponds (pp. 7-8, emphasis in the original).

Grotius also discusses an individual's right to liberty and a right to have debts repaid. Curiously (by today's western societal standards) juxtaposed with the right of liberty is the concept of power which, according to Grotius, if we possess it, is a right we can wield over our children and our slaves. However, Grotius later notes that “By the law of nature , . . no men can be slaves: and it is in this sense that legal writers maintain the opinion that slavery is repugnant to nature” (p. 305); but he also recognizes that prevailing human institutions, customs, and the laws of nations that existed during his lifetime permitted enslaving prisoners of war, criminals, and populations of defeated nations. Thus, one may surmise that the customs of the day awarded some persons greater rights (e.g., power) than others due to circumstance.

Grotius's “third signification”—the right to demand what is due, was recognized by Hammurabi (c1780 B.C./1898). Several of Hammurabi’s laws specify the fees that clients are to pay builders, physicians, and veterinarians for services. In return, the laws also make clear—via penalties specified for various negligent or incompetent practices—that clients have a right to adequate construction, medical, and veterinary practice. If, for example, a slave died because of medical malpractice, the physician would be obligated to replace the slave; whereas, should a free man die, the physician's hands would be cut off (laws 218-219). While by today's standards we might debate whether the differences in penalties reflect true, equitable justice, one should note that the physician was owed a lesser fee for treating a slave than for treating a free man (laws 221-223). Thus, an ancient citizen might logically conclude that a lesser fee perhaps

equated to the lesser risk posed to the citizen (although not to the slave—by law an individual without rights) and, therefore, warranted a lesser penalty.

Thus, the fact that individuals have rights appears to be a fairly ancient concept. However, (a) equality of rights, (b) the determination of who or what has rights, and (c) what rights each person or thing owns are more recently recognized topics that will be discussed in later sections of this paper.

Duties and Obligations

One could argue that the counterpart of the right that a fee-payer has to a worthwhile service is the obligation that a practitioner has to provide it. That is, if a practitioner offers a service and a client agrees to pay a reasonable fee for that service, the practitioner is obligated to provide satisfactory service to the client. Grotius ties the concept of “rights” closely to the concepts of duties and obligations:

There is also a third signification of the word Right, which has the same meaning as Law, taken in its most extensive sense, to denote a rule of moral action, obliging us to do what is proper. We say OBLIGING us. For the best counsels or precepts, if they lay us under no obligation to obey them, cannot come under the denomination of law or right. Now as to permission, it is no act of the law, but only the silence of the law it however prohibits any one from impeding another in doing what the law permits. But we have said, the law obliges us to do what is proper, not simply what is just; because, under this notion, right belongs to the substance not only of justice, as we have explained it, but of all other virtues. Yet from giving the name of a RIGHT to that, which is PROPER, a more general acceptance of the word justice has been derived. The best division of right, in this general meaning, is to be found in Aristotle, who, defining one kind to be natural, and the

other voluntary, calls it a **LAWFUL RIGHT** in the strictest sense of the word law; and some times an instituted right. The same difference is found among the Hebrews, who, by way of distinction, in speaking, call that natural right, **PRECEPTS**, and the voluntary right, **STATUTES**... (Book I, Chapter 1, ¶ 9).

Clearly Grotius asserts that we have obligations, some derived from laws and some derived from moral precepts. What might those precepts be or entail?

Further examination of the laws of Hammurabi (c1780 B.C./1898) reveals an underlying purpose. Hammurabi indicates his desire

to bring about the rule of righteousness in the land, to destroy the wicked and the evil-doers; so that the strong should not harm the weak; so that I should rule over . . . and enlighten the land, to further the well-being of mankind (Hammurabi, ¶ 1).

It is clear that Hammurabi aspired to accomplish more than just live a comfortable life himself—he wanted to do good things for others. As king, he was the law—the determiner of right and wrong. He might have chosen to behave as did some other kings—e.g., sending a soldier to death in battle while coveting the individual's wife or property or imprisoning, enslaving, or beheading citizens on a whim. But instead, Hammurabi refers to himself as “the salvation-bearing shepherd” (Epilogue, ¶ 1). Furthermore,

I cherish the inhabitants of the land of Sumer and Akkad; in my shelter I have let them repose in peace; in my deep wisdom have I enclosed them. That the strong might not injure the weak, in order to protect the widows and orphans, I have in Babylon the city where Anu and Bel [two Babylonian gods] raise high their head, in E-Sagil [a third god], the Temple, whose foundations stand firm as heaven and earth, in order to bespeak justice in the land, to settle all disputes, and heal all injuries, set up these my precious words,

written upon my memorial stone, before the image of me, as king of righteousness
(Epilogue, ¶ 1).

Hammurabi expresses a love for his people and acknowledges a desire for peace. He demonstrates a recognition that the weak and powerless sometimes need protection from the rich and powerful. One might argue that these statements suggest that some early cultures believed that some rights (but not all—Hammurabi's law clearly permits slavery) were owed to people regardless of position, wealth, or power—rights such as protection from injustice and freedom from incompetent construction, medical, and veterinary practices. However, one also might argue that Hammurabi was attempting to establish order solely to preserve his reign and avoid expending resources and effort to quell riots and rebellions. Whatever his reasons were, by writing and posting his laws for all to see, he began the process of declaring basic moral and legal precepts.

Virtue and Vice, Good and Evil, and Justice

By today's Western societal standards, we might acknowledge that Hammurabi exhibited some virtuous traits. As noted above, he wanted to protect the weak from the strong. He established a system of justice supported by clearly written laws, posted on a monument for all to examine and understand. He sought peace and order, wanted to enlighten his people, and further the well-being of mankind. He did this, he asserts, at the direction of Marduk, the chief deity of Babylon: “When Marduk sent me to rule over men, to give the protection of right to the land, I did right and righteousness in . . . , and brought about the well-being of the oppressed” (¶ 3).

For Grotius, the sources of moral precepts are God, justice, and nature. That is, some acts are (a) “either forbidden or commanded by God” (1625/1814/2001, p. 9)—divinely revealed, dictated by “right reason” (justice), or laws of nature. Regarding the latter, Grotius includes such

givens as “two and two must make four” (p. 10) and the certainty that some actions are simply evil—“nor, again, can what is really evil not be evil” (p. 10). In essence, Grotius asserts that some duties are fixed, unchanging, and comprise the chief obligations of natural law (Feiser, 2001).

In attempting to logically define virtue, David Hume (1740/2003) refuted the idea that one could identify specific virtues via reason:

Reason is the discovery of truth or falshood (sic). Truth or falshood consists in an agreement or disagreement either to the real relations of ideas, or to real existence and matter of fact. Whatever, therefore, is not susceptible of this agreement or disagreement, is incapable of being true or false, and can never be an object of our reason. Now it is evident our passions, volitions (sic), and actions, are not susceptible of any such agreement or disagreement; being original facts and realities, compleat (sic) in themselves, and implying no reference to other passions, volitions, and actions. It is impossible, therefore, they can be pronounced either true or false, and be either contrary or conformable to reason (p. chapter71.html).

Hume also asserts, if reason cannot immediately prevent or produce actions, then reason cannot be the source of moral good or evil:

Actions may be laudable or blameable (sic); but they cannot be reasonable: Laudable or blameable, therefore, are not the same with reasonable or unreasonable. The merit and demerit of actions frequently contradict, and sometimes controul (sic) our natural propensities. But reason has no such influence. Moral distinctions, therefore, are not the offspring of reason. Reason is wholly inactive, and can never be the source of so active a principle as conscience, or a sense of morals (p. chapter71.html).

Instead, Hume believes that moral good and evil spring from passions:

Wilful (sic) murder, for instance. Examine it in all lights, and see if you can find that matter of fact, or real existence, which you call vice. In which-ever (sic) way you take it, you find only certain passions, motives, volitions and thoughts. There is no other matter of fact in the case. The vice entirely escapes you, as long as you consider the object. You never can find it, till you turn your reflection into your own breast, and find a sentiment of disapprobation, which arises in you, towards this action. Here is a matter of fact; but it is the object of feeling, not of reason. It lies in yourself, not in the object. So that when you pronounce any action or character to be vicious, you mean nothing, but that from the constitution of your nature you have a feeling or sentiment of blame from the contemplation of it. Vice and virtue, therefore, may be compared to sounds, colours, heat and cold, which, according to modern philosophy, are not qualities in objects, but perceptions in the mind: And this discovery in morals, like that other in physics, is to be regarded as a considerable advancement of the speculative sciences; though, like that too, it has little or no influence on practice. Nothing can be more real, or concern us more, than our own sentiments of pleasure and uneasiness; and if these be favourable to virtue, and unfavourable to vice, no more can be requisite to the regulation of our conduct and behaviour (p. chapter71.html).

Contrary to Grotius's view, Hume objects to the notion that whether something is good or evil emanates from divine revelation. Instead, he suggests that pleasure and pain, satisfaction and uneasiness, and similar sensations indirectly reflect virtue and vice (p. chapter72.html). He asserts that virtuous actions derive merit only from virtuous motives (p. chapter73.html), noting some commonly accepted obligations without citing a source: e.g., the obligation of a parent to

care for a child; of a rich man to aid the poor. (Today such obligations are recognized as widely held, although not necessarily universal, cultural norms.)

Hume believes that justice arises from human conventions, that while we jealously guard our own interests (e.g., possessions), we establish and mutually agree to honor societal rules that stabilize ownership of possessions (p. chapter74.html). Thus, Hume asserts, justice is founded on mankind's inherent selfishness and confined generosity. In fact, according to Hume, if everything were in abundance, we would have no need (a) to protect our possessions and, therefore, (b) for justice. That is, we could quickly replace stolen goods without stress or anguish. Were such to occur, he reasons, the concept of justice would be destroyed—rendered unnecessary and invalid.

Hume suggests that as our society increases in size, justice is quickly identified as a virtue: “We never fail to observe the prejudice we receive, either mediately (sic) or immediately, from the injustice of others” (p. chapter74.html). Such injustice displeases us and is identified as a vice. Hume continues along this line of reasoning, examines various concepts, and concludes that (a) one is obligated to keep one's promises and (b) identifying allegiance to laws and legal government, chastity, modesty, unconditional love, beauty, benevolence and goodness (evident by generosity, humanity, compassion, gratitude, friendship, fidelity, zeal, disinterestedness, liberality) as virtues.

However, one confronts dilemmas when virtuous concepts seemingly conflict. During the Nuremberg war crimes trials that followed World War II, defendants often argued that they had a duty and obligation and owed loyalty to their country—that they were simply following Germany's laws and the edicts of its leaders and courts. In following those laws, the defendants suggested that they exhibited the virtues of loyalty and fidelity. Some noted that had they not complied with those laws and edicts, they would have been removed, imprisoned, or executed

and replacements would have carried out the edicts. In contrast, prosecutors argued that by following Germany's laws and edicts, (a) the defendants had committed crimes against humanity, (b) the laws and edicts were unjust and unlawful per international treaties and norms, and (c) by failing to resist, they helped create the environment that fostered injustice, torture, and mass murder of which they were accused. The court ruled that the most defendants (a few were acquitted of the charges) had, among other things, violated the rights of citizens in occupied territories by subjecting them to "brutal treatment and tortures carried out by the most diverse methods, such as immersion in icy water, asphyxiation, torture of the limbs, and the use of instruments of torture" (*Nuremberg Trial Proceedings*, 1946/1996). Some of the tortures (e.g., immersion in icy water, exposure to high altitude) were committed as part of a government-sponsored research program so as to discover ways to reduce pilot deaths. However, the testing resulted in the deaths of subjects who were forced to participate (*Nuremberg Trial Proceedings*, 1946/1996, Volume 4, pp. 204-205). Thus, while the purpose of the research (improved survivability of pilots) might seem virtuous, the methods used (torture of unwilling subjects unto death) was not.

Four Perspectives of Ethics

As will become evident in the sections that follow, objectivity, social consciousness, and individual and societal values and perspectives affect how a given society sets moral and ethical standards. This standard-setting process involves philosophy, logic, and psychology (especially how people [a] reason, [b] make choices, [c] choose whether or not to act, and [d] take action). These processes, values, and perspectives determine (a) how apparent conflicts among virtues are reconciled, (b) what actions are deemed reasonable, and (c) what actions are deemed to

constitute obligations. Because the focus of this paper is on ethics related to research, the discussion focuses on research-related aspects.

Deontological Ethics

Blackburn (2001) notes that deontic is derived from the Greek word *deontos*, which means “duty.” Deontological notions explore who has “rights,” what “justice” requires, and what our “duty” is:

It is a question of what is *permissible* and what is *wrong*.... [These notions] have a coercive edge. They take us beyond what we admire, or regret, or prefer, or even what we want other people to prefer. They take us to thoughts about what is *due*. They take us to demands (pp. 60-61, emphasis in the original).

In lay terms, deontics express “the view that morality either forbids or permits actions; e.g., lying is wrong, even if it produces good outcomes” (Wikipedia, 2004a). Fieser and Dowden (2001) note:

A duty is a moral obligation that an agent has towards another person, such as the duty not to lie. Etymologically, duties are actions that are due to someone else, such as paying money that one owes to a creditor. In a broader sense, duties are simply actions that are morally mandatory.

Radical Academy (n.d.) clarifies this obligation by observing that deontological ethics “does not make the theory of obligation entirely dependent on the theory of value” (p. [aipphilglossary1a.htm](#), ¶ 77). In other words, deontological ethics holds that an obligation is owed regardless of the value or goodness of a given consequence or motive. In contrast, axiological ethics:

makes the theory of obligation entirely dependent on the theory of value, by making the determination of the rightness of an action wholly dependent on a consideration of the value or goodness of something, e.g. the action itself, its motive, or its consequences, actual or probable (p. aipphilglossary1.htm, ¶ 52).

Thus, a deontological ethicist probably would argue that Hammurabi's law wherein punishment for incompetent medical practice varied according to the social status of the individual killed, and laws and norms that permit slavery and/or killing of slaves both are immoral and unjust.

Feiser (2001) reports that there are four central duty theories. First, 17th century German philosopher Samuel Pufendorf classified dozens of duties into three broader classes: duties to God, duties to oneself, and duties to others. Some of these duties are theoretical (e.g., a theoretical duty to know the existence and nature of God), some practical (e.g., duties to worship God, develop one's skills and talents, and not harm our bodies), some universally binding (e.g., to avoid wronging others, treat people as equals, and promote the good of others), and some are conditional (e.g., agreements such as contracts and treaties, the duty is to keep one's promises).

The second theory involves rights—justified claims against another person's behavior. For example, one person has a right not to be harmed by another. These rights imply a corresponding duty. For example, Hammurabi's law spelled out correlative rights regarding payment and medical services. If one pays a physician, one has a right to competent service; if the physician accepts payment, he has a duty to provide competent service. Also, if the physician delivers competent service, he has a right to payment; and if the patient receives competent service, he has a duty to adequately compensate the physician. Rights to life, health, liberty, and possessions are deemed foundational rights, or natural rights as they are not invented or created by governments (Feiser, ¶ 17).

The third theory centers on Kant's (1785/1934/n.d.) concept of the *categorical imperative*. Using the concept of a *maxim*—an internal rule for what action to take in a given set of circumstances—Kant theorized that morally permissible behavior is determined by the universalization of the maxim via a question such as: What would happen if everyone were to behave in the same way, given this set of circumstances? In essence, if everyone could behave in the same way without bringing an end to civilized culture, then the behavior is morally permissible. Inversely, if no one behaved that way and that inaction brought about the destruction of civilization, the behavior is morally obligatory (a duty or moral *ought*). Furthermore, Kant suggests that “moral laws ought to hold good for every rational creature” (§ 53) as legislated laws must apply to all members of society (except, possibly, sovereigns). Because every rational human wants to preserve or further himself/herself, the only way that all may be satisfied is the live by a categorical imperative: “So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as means only” (§ 99), or “Act on maxims which can at the same time have for their object themselves as universal laws of nature” (§ 130). This principle, Kant suggests, “is the formula for an absolutely good will” (§ 130).

The fourth duty-based theory, developed by W. D. Ross, emphasizes *prima facie* duties—actual moral convictions:

1. Fidelity: the duty to keep promises;
2. Reparation: the duty to compensate others when we harm them;
3. Gratitude: the duty to thank those who help us;
4. Justice: the duty to recognize merit;
5. Beneficence: the duty to improve the conditions of others;

6. Self-improvement: the duty to improve our virtue and intelligence;
7. Nonmaleficence: the duty to not injure others (Fieser, 2001, ¶ 19).

Austrian philosopher Ernst Mally is credited with developing the first deontic logic in 1926 (Stanford University Metaphysics Research Lab, n.d.; Lokhorst, 2002), attempting to lay the foundation for “an exact system of pure ethics” (Lokhorst, ¶ 4, after Mally, 1926). Mally’s logic uses a language that is similar to classical propositional calculus and is comprised of five axioms or principles from which he derived 35 theorems. Karl Menger subsequently reviewed Mally’s work, determined that it was flawed, and exposed the flaws, prompting most philosophers to disregard it. Lokhorst, however, believes that a slightly modified version of Mally’s work has value.

During the past two decades, behavioral psychologists have begun to contribute to deontics as they experimentally explore how and why people make specific choices. For example, Over, Manktelow, and Hadjichristidis (2004) explore the effect of deontic conditionals (such as “If you use a lot of salt on your food, then you must try to cut down”)—rules for guiding behavior that are used in the hope of preventing or altering certain matters of fact—to determine why doctors use and, why patients either accept or reject, such rules. Such studies examine the deontic modals—should, ought to, and must (which all express obligation) and may (which expresses permission). One of their examples illustrates deontic logic. Consider the rule,

(Rule 1) If the fire alarm goes off, then you *must* leave the building.

Deontic logic explores the possible alternative outcomes and the impact of altering the rule. In this case, there are four possible outcomes:

1. the alarm goes off and people leave the building;
2. the alarm goes off and people do not leave the building;

3. the alarm does not go off and people leave the building; and,
4. the alarm does not go off and people do not leave the building.

Deontics addresses which of the above options is preferred when a fire occurs. Obviously, for health, safety, and liability reasons, “1” is the preferred choice.

Deontic logic also explores the impact of changing operators. That is, would the rule be more or less effective if it instead read:

(Rule 2) If the fire alarm goes off, then you *may* leave the building.

Obviously one may infer Rule 2 (you have permission to leave the building if the alarm sounds) from Rule 1; however, some individuals may interpret Rule 2 as not obligating them to leave the building when the alarm sounds. From a health, safety, and liability perspective, Rule 1 is preferable. It is the interpretation of these semantic differences (among other things) by individuals that behavioral psychologists explore.

Deontic philosophers also explore logical premises. If, for example, Joe did something morally wrong, then one might argue that (a) he ought to have done something else instead and (b) if he ought (obligation) to have done something else instead, then he could (permission) have done something else. Some philosophers debating the concept of causal determination (the idea that every event is necessitated by antecedent events and conditions together with the laws of nature) argue that if causal determination is true, then Joe could not have done something else instead. However, Fischer (2003) suggests that Joe could simply have deliberately refrained from acting instead of taking a different action. That is, doing something else should be broadly construed to include refraining or deliberately not doing.

With respect to ethics related to research, Nozick (2001) appears to offer a useful perspective. He asserts that:

The function of ethics is to protect and promote voluntary cooperation and coordination between people, to guide this cooperation (through norms of division of benefits) and to demarcate the domain of such cooperation (which people are to be the participants); also, to specify what is to be done when the above rules, norms, etc. are *not* followed . . . ; and to guide or mandate character virtues relevant to cooperation, and to people's response to noncooperators (pp. 266-267).

He suggests that there are four layers of ethics:

1. Ethics of respect: rules and principles mandating respect for another person's life and autonomy.
2. Ethics of responsibility: founded on the notion of inherent value of all individuals; mandates that we act in ways that are responsive to people's value, enhancing and supporting it, and enabling it to flourish.
3. Ethics of caring: ranges from concern to compassion to love; mandates nonharm and love to all people, and, perhaps, to all creatures.
4. Ethics of Light: encompasses truth, beauty, goodness, and holiness as directed by Socrates, Buddha, Jesus, deities, philosophers, and sages (p. 280).

There is no universal agreement regarding which of these ethical layers should be imposed worldwide. Nozick believes that the core principle—the ethics of respect—is the one and only layer that should be mandatory across all societies; the other layers, he believes, involve personal choice and should not be imposed by governments (p. 281). However, theocracies clearly exist (Iran, for example) and are advocated by some religious groups; also, the principle of nonharm which is a foundational ethic of the medical profession, appears to have been

endorsed (and possibly enforced) by several governments (a topic will be discussed further below).

In summary, the philosophical debates about deontical ethics appears to focus on (a) developing a set of infallible guidelines or rules that one can follow to assure moral outcomes, (b) what those rules should be, and (c) what the proper sources are for those rules. Most philosophical discussions appear to be attempts to construct internally consistent theories or justifications wherein one selects a starting point (or initial postulate) and uses reason to explore related concepts and issues. If, after a through examination, upon arriving back at the starting point, the initial postulate appears consistent with the concepts and issues explored, the philosopher in essence declares apparent victory. However, the fact that such exercises are based on individual and societal values makes derivation of a single, truly universal, deontic system difficult.

Utilitarian Ethics

Utilitarian ethics holds “that the rightness of an action entirely depends on the value of its consequences, and that the usefulness can be rationally estimated” (Wikipedia, 2004c). Fieser (2001) notes that consequentialism is based on the premise that “An action is morally right if the consequences of that action are more favorable than unfavorable” (§ 21). In essence, consequentialists argue that moral choices should only be made based on cost-benefit analyses wherein good and bad consequences are tallied to determine which outweighs the other. In contrast, deontic theories are nonconsequentialist (that is, the obligations exist regardless of consequences).

Fieser notes that utilitarian theories became popular because (a) one could base decisions on experience instead of intuitions or long lists of duties and (b) “it appeals to publicly

observable consequences of actions” (§ 23). Competing consequentialist theories, distinguished by the groups or parties who are impacted, exist:

1. Ethical Egoism: an action is morally right if the consequences of that action are more favorable than unfavorable *only to the agent* performing the action.
2. Ethical Altruism: an action is morally right if the consequences of that action are more favorable than unfavorable *to everyone except the agent*.
3. Utilitarianism: an action is morally right if the consequences of that action are more favorable than unfavorable *to everyone* (Feiser, § 23, emphasis in the original).

These three theories may yield different moral conclusions. Consider the case involving an accident victim in a country where those who assist might be held responsible and jailed should the victim die. Given there is a possibility that the person who gives aid to the victim could be jailed, the ethical egoism view would hold that it is morally proper for someone to refuse to give aid. However, given the magnitude of the consequences (death for one versus jail for the other), the utilitarian view might debatably hold that giving aid is morally proper, while the ethical altruist view would hold that giving aid is the only available moral course of action.

There are two other issues within utilitarian theory. The first involves whether to measure the costs and benefits derived from (a) a sequence of acts or (b) individual acts. The latter view (act-utilitarianism) holds that we should tally costs and benefits for each individual act. However, under act-utilitarianism, some acts, e.g., torture or slavery, would be morally permissible if the social benefits outweigh the costs—e.g., the benefits to the many outweigh the cost to the one. Sometimes such views are combined with rules, e.g., prohibitions against theft and murder, to yield outcomes that are more widely regarded as moral (Feiser, §§ 25-26).

The second issue involves how to measure costs and benefits. Jeremy Betham first suggested that pleasure and pain are the only consequences that truly matter (Feiser, ¶25). Blackburn (2001) notes that utilitarianism focuses on general well-wishing or benevolence, pleasures or pain, or welfare of people as a whole. The principle of utility, generally stated, is to advance the good, “identified with the greatest happiness of the greatest number of people” (p. 86). However, this also might lead to situations where a few are harmed so that many may benefit. Hedonistic utilitarianism holds that pleasurable consequences are the only ones that matter, morally speaking, but such a view ignores consequences that are painful or not pleasing (Feiser, ¶ 27). Blackburn promotes the concept of “freedom from the bad”—that each person should be free from various evils (pp. 93-97). Such a view holds that no individual should suffer pain, disease, misery, pity, disrespect, etc. Under such a view, costs and benefits should be calculated for each individual and deemed moral only if benefits outweigh the costs for *each and everyone* involved. Doing so (especially if calculated for each specific act) should eliminate the possibility that slavery or torture might be deemed a moral act.

In summary, utilitarian ethics is based on perceived value of the consequences. While the desire is to improve well-being or increase happiness, when more than one or two individuals are involved, the potential exists for burdens or costs potentially may be distributed inequitably, e.g., harming a few to benefit many.

Relational Ethics

Relational ethics emphasizes the maintenance and propriety of relationships. Simply put, relational ethics asserts that to be ethical, one should do what one’s relationships require (Wikipedia, 2004b). Relational ethics, also referred to as situational ethics, holds that you owe those close to you (e.g., your parents) much (everything) and those distant from you (e.g., people

you don't know) less (perhaps nothing). Confucianism is a form of relational or situational ethics. Confucianism holds that only rarely are laws or principles universal or absolutely true. Confucianism asserts that ideal leaders are humane and lead by example rather than attempting to force everyone to be good—that the ideal ruler fosters harmony rather than laws.

Through a variety of quotes from personal interviews, Bergum (1998) described the role that relational ethics plays in healthcare:

"Ethical behaviour is not the display of one's moral rectitude in times of crisis," says nurse Myra Levine, "It is the day-to-day expression of one's commitment to other persons and the ways in which human beings relate to one another in their daily interactions."

"The Chinese character for acupuncture means golden needles. For me," says physician Dr. Steven Aung, "this symbolizes that the needle is only a bridge between myself and my patients. It is a bridge built on compassion and the cultivations of physical, mental and spiritual energy. This is what does the healing—not the needle. The really important thing is the relationship of trust and respect between healer and patient." It is the business of caregivers to explore the reasons, and even argue, with patients about the decisions they wish to make because, says lawyer Robert Burt, people are connected to each other. Caregivers (doctors, nurses, and others) are human beings who are necessarily involved in another's life, so, "we have to negotiate together what our shared meanings are about, what it is that you want me to do or not to do." (¶¶ 1-2)

The common threads in these perspectives are trust, respect, caring, and interaction on a daily basis—a process of continually striving to make connections with people. During this process, one need not necessarily remain docile; Burt (in Bergum) notes that it is permissible to question and argue during the process of developing and clarifying shared meanings.

Bergum believes that relational ethics involves four central concepts:

1. How we treat each other;
2. Reciprocity;
3. Autonomy;
4. Asking for input about preferences instead of rather than prescribing or dictating.

Regarding the latter, Bergum suggests that medical practitioners ask “what should I do now?” instead of stating “this is what you should do.” She notes, “As action ethics, relational ethics looks to the way we are with each other as doctors, patients, nurses, families, or chaplains. We are participants by being with rather than merely spectators who only observe, advise, or treat” (¶ 4).

Relational ethics is a shared experience. Ethical practice requires a general knowledge of ethics, but situations may arise wherein such knowledge alone is not sufficient for ethical practice. For example, if a physician values life above all else, he might choose to prolong life at all costs. However, relational ethics considers the choice from the view of the patient and the physician, sometimes by asking whether the quality of life warrants terminating treatment or even euthanasia.

Clearly the reach of relational ethics extends beyond the medical field, into education (teacher-student, student-student relationships), the workplace, the family, and the local community. Jensen (2002) suggests that a community-developed narrative helps individuals understand how they personally are formed by, live through relations with, and share beliefs with others in that community. Kosmicki (2002) suggests that relationships are a primary source of happiness and well-being and that relational ethics “refers to the balance of trustworthiness, loyalty, merit, and entitlement within relationships” (p. 6). In relationships, people seek to have

their own needs met and, in exchange, help meet the needs of others. “Relational ethics require that individuals assume responsibility for the consequences of their behaviors in relationships and strive for fairness and equity in relationship processes” (p. 6). Kosmicki notes that relational ethics assumes that “individuals have an innate sense of fairness, justice, and inequity in relationships” (p. 7) and that such relationships early in life help individuals develop trust, loyalty, and commitment.

Ecological Ethics

Ecological ethics is both ancient and new. It is ancient in that native peoples observed the wild things in their original state, became sensitive to seasonal and other changes, and learned to cope with those changes. In essence, those native peoples recognized that they were a part of the ecology.

Ecological ethics is ancient in that farmers also became sensitive to the land and its capacity to grow food. When the land’s capacity was exceeded, farmers had to adjust. Sometimes they adjusted by moving on to new locations in search of land with better capacity. Sometimes they adjusted by reducing the number of cattle grazing on the land. Sometimes they adjusted by adding nutrients to the soil or rotating the types of crops that they grew. Sometimes, such as during the great Irish potato famine, they sent their young people off to a New World, thereby downward adjusting the number of people that the land had to support. In this sense, too, farmers were a part of the ecology.

But ecological ethics is new in that the first writings that juxtaposed the term ecology and ethics were published fewer than seven decades ago. In 1948, Aldo Leopold wrote “There is as yet no ethic dealing with man's relation to land and to the animals and plants which grow upon it” (Leopold, 2002/1949). He also stated, “That land is a community is the basic concept of

ecology, but that land is to be loved and respected is an extension of ethics” (Leopold, 1977/1949, p. ix). Furthermore,

Conservation is getting nowhere because it is incompatible with our Abrahamic concept of land. We abuse the land because we regard it as a commodity belonging to us. When we see land as a community to which we belong, we may begin to use it with love and respect (p. ix).

Leopold argued that industrialized humans have lost touch with the land and need to remind themselves where heat and food really comes from. He suggested that by cutting our own firewood, growing a garden, and reflecting upon those activities, we would begin to realize that it takes time to grow a tree, and seeds, water, and good land to grow the garden. *Sand County Almanac* reflects on these things, but mostly it describes and reflects on nature—the wild animals, the trees, the diseases that render the trees homes and food for the animals, the marshes, and much more. “The extension of ethics to this third element in human environment is, if I read the evidence correctly, an evolutionary possibility and an ecological necessity” (Leopold, 2002, ¶ 8).

All ethics so far evolved rest upon a single premise: that the individual is a member of a community of interdependent parts. His instincts prompt him to compete for his place in that community, but his ethics prompt him also to co-operate (perhaps in order that there may be a place to compete for).

The land ethic simply enlarges the boundaries of the community to include soils, waters, plants, and animals, or collectively: the land (Leopold, 2002, ¶¶ 11-12).

Some philosophers, such as J. Baird Callicott, believe that the environment has intrinsic value—value in itself or for its own sake (Ouder Kirk, 2002). Callicott (n.d.) notes that Leopold's work is most popular among conservationists and least popular among philosophers:

Conservationists are concerned about such things as the anthropogenic pollution of air and water by industrial and municipal wastes, the anthropogenic reduction in numbers of species populations, the outright anthropogenic extinction of species, and the invasive anthropogenic introduction of other species into places not their places of evolutionary origin. Conservationists as such are not concerned about the injury, pain, or death of nonhuman specimens—that is, of individual animals and plants—except in those rare cases in which a species's populations are so reduced in number that the conservation of every specimen is vital to the conservation of the species. On the other hand, professional philosophers, most of them schooled in and intellectually committed to the Modern classical theories of ethics, are ill-prepared to comprehend morally such "holistic" concerns. Professional philosophers are inclined to dismiss holistic concerns as non-moral or to reduce them to concerns about either human welfare or the welfare of non-human organisms severally. And they are mystified by the land ethic, unable to grasp its philosophical foundations and pedigree (§ 1).

Thus, in Leopold we have an interesting juxtaposition of two views—one holistic and one intrinsic, for it is clear in reading *Sand County Almanac* that Leopold was enamored with the daily wildlife activity, saw value individual birds and trees, and understood the intricate workings of ecological systems. Yet he also saw man as part of that system. He recognized that man potentially could destroy that system and, thereby, mankind. But as a professional forester,

he also understood the utilitarian views. He argued not for setting *all* areas aside for nature preserves, but for setting *some* areas aside.

In essence, Callicott states that philosophers have difficulty justifying a system that alleges it is ethical to injure some plants and animals. How do we overcome the individualistic aspect of ethics? How can it be acceptable to harm some flora and fauna if it is not also acceptable to harm some humans? Does not such a system seem internally inconsistent? Leopold recognized that ecosystems are about energy—for plants and animals to grow, some have to die. “Indeed, one might say further, that the life of one member is premised squarely on the death of another” (Callicott, n.d., ¶ 6). Ecologically this fact is reflected in the food chain. Callicott suggests that this dilemma might be resolved by slightly modifying Leopold’s prose: “A thing is right when it tends to disturb the biotic community only at normal spatial and temporal scales. It is wrong when it tends otherwise” (Callicott, n.d., ¶ 21).

In contrast to the land ethic, animal rights groups argue that all creatures have intrinsic rights and that we should harm none, even for our own benefit—animals should have autonomy, these groups argue. Proponents of animal rights often become vegans, thereby attesting to their belief. Utilitarians, in contrast, hold that plants and animals exist to provide food for other creatures, including man. According to Taylor (2002), Callicott rejected both views—that “extending to wild animals the same consideration that we rightly have for members of our [human] community would be inappropriate—indeed, ecologically disastrous” (Taylor, pp. 229-230). Regan (1983) tries to separate domestic animals from wild creatures, arguing that only wild creatures should have a right to self-determination and be free from man’s interference. Midgley (1983) recognizes that different organisms have different needs and drives and concludes that different creatures merit different treatment. She suggests that sentience is important because it

potentially gives other creatures experiences that would enable them to relate to moral and ethical perspectives (e.g., the Golden Rule). Callicott asserts that we have an “unspoken social contract” with farm animals that includes our killing them (Taylor, p. 233). Others, Taylor asserts, believe that animals do not consent to being killed and that no such contract exists.

One could argue that an unspoken agreement exists to care for them in exchange for their good behavior, perhaps, or for allowing themselves to be milked or shorn. But to imagine that they agree to suffer or to be killed is to indulge in a convenient fantasy. And it will not do to claim that because certain creatures have been bred to be abusively exploited, it is in their nature to be abusively exploited, and we therefore do no wrong when we abusively exploit them (Taylor, p. 234).

If we examine animal rights from the perspective of pain and pleasure, it is clear that some animals feel pain when they die. One only need listen to the squeals of a pig as s/he is slaughtered by a farmer that the animal feels pain. Also, research by Harry Harlow and others on affection demonstrates that animals value a mother’s love and become socially dysfunctional when such love is removed for long periods of time (Blum, 2002).

Based on such readings, it appears that ecological ethics is still in the early stages of formation and debate. There is no consensus among humankind regarding whether to extend rights to some or all creatures, plants, rocks, soil, water, and other objects; yet many governments and persons recognize that humans are a part of a broader ecological community and that our survival depends on the well-being of that community as a whole. Even if mankind could reach a consensus, we will be left to ponder (a) whether the other beings in our ecosystem are willing participants in such a consensus and (b) what such a consensus would look like could they fully participate in the consensus-building process.

Comparisons, Contrasts, and Ethical Dilemmas that Result

As noted earlier, Nozick (2001) suggests that ethics helps coordinate the actions of individuals to one another, thereby aiding each to achieve mutually beneficial action (p. 243). He identifies four types of coordinated actions that lead to mutual benefits:

1. Action toward a joint goal that the parties share and desire.
2. Complementary actions towards separate goals (e.g., voluntary exchange of goods and services).
3. Wanting to pursue separate goals without diverting energy and attention to protecting the activity, our person, or property from predation by the other.
4. Coordination of interactive behavior with those who act on the same norms and principles of interactive behavior (p. 245).

One can use these four types of actions as a framework for comparing and contrasting the four perspectives or types of ethics (Table 1). Deontological ethics appears to offer norms that address all four types of coordinated action, from prohibitions about murder and theft to allocation of benefits that result from mutual cooperation. Utilitarian ethics also offers norms that address all four types of coordinated action; however, some modes of comparing costs and benefits might lead to determination that slavery or other predation is morally justifiable.

The primary focus of relational ethics is on addressing joint goals and actions. Relational ethics guides the formulation of joint goals, selection of actions to be taken, ongoing feedback, reexamination processes, adjustment, and abandonment or replacement of such goals. Relational ethics helps defend against predation (e.g., a doctor forcing treatment on a patient solely for the physician's financial gain). However, relational ethics does not address coordination among persons who have similar norms and needs but who have no contact with one another.

Table 1

Types of coordinated actions addressed by these four ethical perspectives

	Deontological Ethics	Utilitarian Ethics	Relational Ethics	Environmental Ethics
Addresses coordinated actions toward joint goals	Yes	Yes	Primary focus	Yes (as qualified below)
Addresses complementary actions toward separate goals	Yes	Yes	Possibly	Yes (as qualified below)
Defends against predation	Yes	In some forms	Yes	Yes (as qualified below)
Coordinates interactive behavior among persons with similar behavioral norms	Yes	Yes	No	Yes (as qualified below)

Attempting to include environmental ethics in Table 1 is problematic. First, there is no apparent consensus regarding the appropriate perspectives that comprise environmental ethics. Environmental ethics might involve deontics (e.g., such as never killing another creature unless

attacked by it), utilitarian processes (cost-benefit analyses), and relational perspectives (e.g., we have greater obligations to our own pets than to wild creatures). Second, the very essence environmental processes is based on a cycle of predation and decomposition—animals (including humans) eat plants and other animals, then animals produce waste that is eaten or decomposes to provide nutrients for plants and small creatures, and eventually animals die and, in turn, are eaten or decompose to provide more nutrients. Thus, the nature of ecology includes predation. Third, ecological ethics, thus far, appears to be a one-sided affair. That is, mankind is discussing ethics and deciding upon a proper course without true input from the other participants in the ecosystem. We cannot, therefore, be certain that we are embarked on a course with which apes, elephants, lions, dogs, cats, and other creatures would agree is ethical assuming they understood the concept. [Social researchers might agree that some creatures exhibit a relational ethic—e.g., lions tend to protect their own offspring or pride; pets sometimes will defend human masters]. However, environmental ethics does help coordinate *human* activities towards joint and complementary environmental goals, even among those who have no contact with one another. And, some modes of environmental ethics (e.g., some animal rights groups) promote an ethic that protects against all predation while others (a conservation ethic) protects against wasteful or unnecessary predation. Of course, once again this raises the issue that different societies define *wasteful* and *unnecessary* in different ways.

The IRB Process

Historical Perspective

The war crimes trials following World War II has been noted above. During a subsequent doctors trial (*USA vs. Karl Brandt et. al.*), the German defendants demonstrated that no international law or informal statement existed that differentiated legal from illegal human

experimentation. Two American doctors developed an outline entitled “Permissible Medical Experiments” that the American military tribunal modified and included in the verdict of August 19, 1947. Curiously none of the specific findings in the verdicts mentioned any of the ten points in this “Nuremberg code.” As a result, the legal force of the document was uncertain until it informed several international codes of ethics (e.g., the World Medical Association Declaration of Helsinki, 1964 and as subsequently revised).

The Nuremberg code’s ten points made it clear that (1) voluntary consent of human subjects was essential; (2) experiments should yield fruitful results for the good of society; (3) design should be based on already gathered scientific knowledge; (4) unnecessary suffering and injury was to be avoided; (5) experiments that might result in death or permanent disability were to be avoided except in cases where the physicians themselves were the subjects; (6) risks taken should never exceed the humanitarian purpose of the experiment; (7) precautions must be in place to guard against “even remote possibilities of injury, disability, or death;” (8) only scientifically qualified personnel were to conduct the experiment and they were to exercise the “highest degree of skill and care;” (9) test subjects should always have an option to halt the experiment at any time of their own choosing; and (10) the scientist in charge must be prepared to terminate the experiment when he determines that injury, disability, or death is likely if it is continued.

The Nuremberg code never became law in the United States or Germany (U.S. Holocaust Memorial Museum, 2001); however, U.S. Department of Health and Human Services includes the code within Appendix 6 of its *IRB guidebook* (Penslar, 1993).

On July 28, 1974, the National Research Act (Pub. L. 93348) created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. That

act directed the Commission to identify basic ethical principles that should guide biomedical and behavioral research and develop guidelines for such research. Specifically, the Commission was directed to consider:

(i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings. (Department of Health, Education, and Welfare, 1979)

Not surprisingly, the Commission referred to the Nuremberg code. Noting that situations occasionally arise wherein parts of the code seem to conflict or are difficult to interpret, the Commission nonetheless believed that three principles within the code were essential: (a) respect for persons, (b) beneficence, and, (c) justice.

The Commission recognized that respect for persons incorporated two ethical convictions: “first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection” (National Commission, ¶ 10). It defined beneficence as making efforts to secure the well being of test subjects, opining that researchers were *obligated* to (a) do no harm and (b) maximize possible benefits and minimize possible harms. However, the Commission also recognized that difficult choices may arise when research subjects may not themselves benefit from the research. The Commission recognized that justice involves “fairness in distribution” and “what is deserved” (¶ 19). It noted that the burdens of serving as research subjects during the 19th and early 20th centuries often fell on the poor while private patients largely benefited. The Commission also cited the experiments that

occurred in Nazi concentration camps and the Tuskegee syphilis study of the 1940's as examples of particularly flagrant injustices (§ 20). Finally, the Commission recommended procedures to assure (a) informed consent, (b) assessment of risks and benefits, and (c) proper selection of research subjects.

The World Medical Association (1964) Declaration of Helsinki was earlier cited as an example of an international code of ethics that drew from and expanded upon the Nuremberg code. The declaration was revised in 1975, 1983, 1989, 1995, and 2002. In its current form, the declaration primarily focuses on the protection of human patients and test subjects, but also notes that “Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.” (World Medical Association, 2002, principle 12).

In addition to the ten principles relating to human research that are contained in the Nuremberg code, the declaration adds, among other things, (a) obligations to preserve the accuracy of results; publish negative as well as positive results; and not accept research for publication when WMA principles are violated, (b) a recommendation to avoid dependent relationships where duress may become a factor in decisions made by potential tests subjects, (c) an obligation to provide test subjects—including control groups at the conclusion of every study—with access to the best proven diagnostic and therapeutic care, and (d) an obligation to avoid retaliation against patients who refuse to participate in a study. WMA also specifies that “Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research” (principle 19). In sum, WMA concludes that “In medical research on human subjects, considerations related to

the well-being of the human subject should take precedence over the interests of science and society” (principle 4).

Laws

The primary law governing human research is 56 FR 28003 which (a) requires any organization engaged in human research to create an Institutional Review Board (IRB), (b) describes the composition and responsibilities of those boards, (c) exempts certain types of research from the IRB requirements, and (d) standardizes IRB requirements across federal agencies. This standardized rule (actually a federal policy) is codified (transformed into law) in the codes of 15 federal agencies (U.S. Department for Health and Human Services, 1991/2004).

An institutional review board (IRB) is a group, formally designated by an organization, whose function is to review and monitor research to assure the protection of the rights and welfare of the human subjects (U.S. Food and Drug Administration, 1998b, question 1, ¶ 2). 56 FR 28003 defines several terms, mandates informed consent and record-keeping requirements, and stipulates the findings that every IRB must make for each project that it authorizes. In essence, these requirements transform several key recommendations of the Belmont report into federal policy and enforceable law: (a) minimization of risks to test subjects, (b) requiring risks to be reasonable in relation to anticipated benefits, (c) equitable selection of test subjects, (d) informed consent requirements, (e) related required documentation, and (f) continuous monitoring to assure safety of test subjects during the research. In addition, the policy/law requires adequate provisions to protect privacy of test subjects and maintain confidentiality of data.

Related Guidelines

At least two agencies—U.S. Department for Health and Human Services [HHS] (Penslar, 1993) and U.S. Food and Drug Administration [FDA] (1998a)—have published extensive guidelines to aid IRBs in understanding their responsibilities and, to some extent, guide board members towards standardized decisions. FDA includes the 1983 and 1989 versions of World Medical Association’s Helsinki declaration and the Belmont report as appendices to their guide. HHS (Penslar) includes these same two documents and the Nuremberg code as part of an appendix. Both guides provide details on the regulatory requirements of their respective agencies. And both guides provide guidance regarding risk-benefit analysis, informed consent, selection of subjects, monitoring, safeguards, incentives for participation by subjects, and continuing review.

Chapter 6 of Penslar addresses issues surrounding the potential involvement of special classes of research subjects (e.g., terminally ill patients; comatose patients). In so doing, he address problematic issues such as whether it is appropriate to test medical devices, such as artificial hearts, that might prolong life but that will eventually end in the death of the test subject.

Role of Ethical Theories in the IRB Process

The laws, regulations, and guidelines that require or inform the IRB process in essence transformed the Nuremberg code, Belmont report, and parts of the Helsinki declaration into enforceable law, while adding confidentiality provisions. Thus, all of these documents, laws, and guidelines have ethics as their foundation.

Most of the IRB-related laws and guidelines clearly have a deontic root—focusing on assuring equity, justice, autonomy, and the well-being (physiological and psychological) of

individuals. By so doing, federal law clarifies that the rights of test subjects are paramount and eliminates debates that might arise from other ethical perspectives. For example, if a utilitarian perspective were deemed legal, an IRB could decide that it is acceptable to harm a few test subjects to benefit many individuals. The current laws and guidelines make it clear that such a conclusion would be in error.

The IRB does not explicitly address relational ethics. However, relational ethics could conceivably play a role in the informed consent process. That is, it is possible that a physician and a patient could use a relational approach during the informing, initial decision-making, monitoring, and review processes, and during any deliberations regarding whether to terminate participation in an experiment. However, the laws and guidelines make clear that a physician is obligated to terminate an experiment if the patient is likely to suffer injury (including psychological harm) or death, even though the patient might wish to continue.

None of the IRB-related laws or guidelines reviewed mention animal research or environmental issues; thus, it appears that review boards do not currently have to grapple with environmental ethics. However, some institutions may have equivalent processes governing animal research, guided by state or local laws, the Helsinki declaration, or other appropriate codes of ethics.

Summary and Conclusions

At least four types of ethics—deontological, ecological, relational, and utilitarian—provide a basis for identifying, examining, and resolving ethical issues. These four ethical perspectives sometimes value outcomes differently and potentially yield conflicting results regarding whether specific actions are moral or ethical.

The federally mandated institutional review board (IRB) process, informed by laws and guidelines, largely uses a deontic approach. The associated laws and guidelines (a) specify that certain types of actions are illegal (and thereby presumed unethical or immoral), (b) declare that the physical and mental health and safety of test subjects is highest importance, (c) establish requirements to assure that test subjects adequately understand the nature of the research and any and all risks, and (d) specify methods to assure autonomy.

The IRB process does not currently address issues related to animal research, environmental impacts, or environmental ethics.

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