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Review of “Responsible Conduct of Research”

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Book Review


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Introduction:

With the increased interest in various areas of professional ethics, there has been a corresponding rise in the number of texts devoted to the teaching of ethics to students and professionals. The style of these texts can be broken down into two separate and unequal groups. First, the large majority of authors take “A Little Dab Will Do You” approach, which entails an introductory chapter or two at most on the historical theories of ethics before proceeding to applied issues. Since time and space is limited, the overview is often of only the briefest sort. For each moral theory and principle, there is a very short introduction, which lists several of the major proponents of the theory, one or two of the theory’s main ideas, generally an unsophisticated version of its moral principle, and one or two of the main problems the theory or principle encounters, (Biomedical Ethics by Thomas A Mappes and David DeGrazia offers one of the most thoughtful introductions to the various theories.) In many cases, the result is that readers only get the driest taste of some of the most influential and compelling moral theories that have influenced human behavior and the field of ethics for over two thousand years, which were created by
some of the greatest minds to have ever existed.

In the minuscule second category are those authors, such as Beauchamp, Childress and Engelhardt, who attempt to formulate their own theory of ethics for readers to use in evaluating moral issues. As do those in the “Little Dab” canon, these texts start off with very brief introductions to classical ethics, and then proceed to offer the author’s theory and principles, which he believes better captures morality than any individual historical theory. One of the greatest benefits from this approach is the vivacity of the writing, since the author is developing a theory that he believes in rather than merely introducing another person’s work. The result is that readers are more likely to see the importance of professional ethics, rather than merely something to cover in a course that they must take to satisfy some regulatory or academic requirement. Moreover, the theories and principles that are expostulated are more likely to be practical because they have been used by the author, who is an expert in the various areas in which he is writing. The theories, hence, have been field tested in the very conditions in which they will be utilized by the reader.

Adil E. Shammoo and David B. Resnik’s otherwise excellent book, *Responsible Conduct of Research*, seems to want to follow the latter approach, but unfortunately cannot quite take the final step. Although the authors present a nuanced and very complex decision making procedure, which includes almost every conceivable element of ethics, they merely hint at what their actual principle is rather than telling the reader in explicit terms. The result is that readers must ultimately rely upon their intuitions and the moral principles their biases draw them to, tempered only by the ambiguous moral rules the authors provide.

In order to better understand the need for a practical ethical theory in research ethics and other professional ethics texts, I will first exposit Shamoo and Resnik’s decision procedure and the moral guidelines it incorporates. In the second section, I will develop several arguments that show the decision method the authors employ is too general to afford accurate guidance in scores of relevant cases.

**Section 1: The Decision-Making Procedure**

Many professional ethics textbooks lack a simple decision procedure that readers can utilize to make decisions about moral issues raised in their professional lives. The result is that people who are relatively unfamiliar with formal critical reasoning in ethics are at a loss to determine how to use the formal moral theories and principles to arrive at a morally acceptable conclusion.

Shamoo and Resnik do not make this mistake. Instead they provide a plausible step method of evaluation, which is listed below:

- **Step 1:** State or define the problem.
- **Step 2:** Gather relevant information.
- **Step 3:** Delineate or construct different options.
- **Step 4:** Relate the different options to the different values or principles that are at stake.
- **Step 5:** Evaluate the different options in light of different values or principles as well as the relevant facts. (17)

By allowing some variation in the ordering of steps, the authors rightly acknowledge that people
have to make decisions about real world situations, which might not allow a rigid approach. (18) Gathering the relevant information, for instance, might overlap the delineation of options because of the fact that many issues in research are constantly evolving or gaining new information from among other sources, new trial data or regulations.

Several benefits of the authors’ decision-making method are that it is simply written and follows common sense for the most part. For example, in order to know what information is relevant, it is necessary to first know what the problem is.

However, since the authors’ values and principles have not yet been revealed at the moment, it is impossible to evaluate the legitimacy or practicality of steps 4 and 5, much less the usefulness of the overall decision procedure. Hence, at this time, it will be useful to examine what I call Shamoo and Resnik’s Three Order Theory (TOT).

On the first order or most fundamental level are seven of the standard moral theories. The basics of Kantianism, Utilitarianism-act and rule, Natural Law, Virtue Ethics, Natural Rights, Social Contract Theory, and Divine Command Theory are covered in approximately four pages. (12-15) The section on Kantianism, for example, includes the dates for Kant’s life, a mention that his main theory is the Categorical Imperative, and two versions of the Categorical Imperative. Furthermore, it is stated that the “basic insight of Kantianism is that ethical conduct is a matter of choosing to live one’s life according to the moral principles or rules.” (12) Living according to the moral principles or rules requires each agent to act according to the Categorical Imperative.

The four second order principles are identical to those found in the Belmont Report and other documents and regulations dealing with medical research ethics, and are supported by one or more of the moral theories from level one. Shamoo and Resnik stipulate the definitions of each, which I will list here in turn, although the sequential order of the four do not play a role in any sort of principle ranking for the authors. First, the principle of Nonmaleficence is the rule to “not inflict unjustified harm to ourselves or other people.” (16) The principle of Beneficence states, “Promote one’s own well-being and benefit others.” (16) The third principle, that of Autonomy, commands agents to “Allow rational individuals to make their own decisions and act on them.” (16) Finally, although Justice is a principle, the authors never stipulate its definition. Instead, they merely acknowledge that there are formal and material principles of justice, and give examples of a few distributive justice principles.

Finally, the seventeen third order guidelines are those that particularly govern morally responsible conduct in research. As the second order principles depended in part upon the underlying order to support them, so to do the third order guidelines rely upon the two preceding levels. (19-20) Since it would take a great deal of space to present each of the authors’ seventeen guidelines themselves, I will merely list the names, and then the *prima facie* rule for three of them. The seventeen guidelines are Honesty, Objectivity, Integrity, Carefulness, Openness, Confidentiality, Respect for Colleagues, Respect for Intellectual Property, Freedom, Social Responsibility, Efficiency, Education, Competence, Equality of Opportunity, Legality, Animal Care, and Human Subjects Protection. The rule for Integrity is to “Act with integrity in all aspects of the research process.” (20) Respect for Colleagues requires researchers to “Respect your colleagues and students; avoid harming them and promote their well-being. Treat your colleagues fairly.” (20) Finally, for Animal Care, researchers are to “Show the proper respect and care for animals when using them in research. Do not conduct
unnecessary or poorly designed animal experiments. (21)

Although the authors do not explicitly state it, it seems that under normal conditions researchers will be able to follow each of the seventeen guidelines, without a conflict arising between them, or lower order principles, or theories. However, in cases in which “the principles conflict in a practical decision, [agents are to] use the decision-making method described above to settle conflicts.” (19) Nothing is said about what to do if a guideline has an internal conflict, such as if an action promotes freedom for some, while taking freedom from others. For example, a rule that allows more freedom for research subjects could very well entail less freedom for researchers to use the subjects for trials. However, for consistency’s sake, let these conflicts be resolved in the same manner as those between rules of the same order or rules of different orders, viz., by resorting to Shamoo and Resnik’s decision procedure.

Section 2: Questions of Meaning and Questions of Truth

Given the lack of specifics in the decision-making method and the operation of the various rules of conduct, two problems should now be apparent. First, the guidelines’ generality greatly reduces the number of conflicts between principles, but hinders an adequate understanding of what is morally required of each researcher. Second, even though the authors take great pains to avoid relativism, the gaps in their theory lead to a form of individual relativism, and hence, to incorrect moral classifications of research. I will consider each problem in turn.

First, there is an old saying in philosophy that questions of meaning come before questions of truth. In other words, no one can determine if a rule, for example, is correct until she can understand what the rule means. The same problem arises in each of the three orders of Shamoo and Resnik’s theory. The third order’s prima facie rule of Integrity, for example, prescribes researchers to “act with integrity in all aspects of the research process.” (19) The question arises as to what exactly is entailed by this particular rule. Does it mean that all of our overt actions must be done with integrity, but that acts of omission do not fall under the guideline? Using the Principle of Charity, it seems safer to assume that the rule covers both acts of omission and commission.

What cannot be so easily resolved is what “integrity” itself means in the guideline. Many of the readers of the text are attempting to learn how to conduct ethical research. If they do not know what the terms in the rule mean, then they have a greatly reduced chance of satisfying the guideline. Sending the readers to the dictionary merely allows them to struggle with an unhelpful definition of integrity, such as “soundness of and adherence to moral principle and character; uprightness; honesty.” (Webster’s, 738) If the intention of a text is to teach people to be more ethical researchers, then it is necessary to make sure that all readers are familiar with what the rules entail. Defining terms clearly is one of the first necessary steps to accomplish this end.

There are a considerable number of instances in which a guideline, principle, or moral theory’s meaning is so murky that it is rendered almost useless for the decision-making procedure. Of these, the principle of justice is the worst case. The authors write that:

“Justice” is a complex concept that we will not analyze here. We will simply note that there are formal as well as material principles of justice. Formal principles, such as “Treat equals equally, unequals, unequally,” and “Give people what they deserve,”
merely set logical conditions for applying principles that have more definite content, such as, “Allocate resources fairly.” Some of the approaches to resource distribution include equality…need…merit…chance…and utility (16)

Given that the decision-making procedure sometimes uses the second order principles to resolve conflicts between the third order guidelines, not explaining what is meant by the formal principles gives readers little hope of resolving moral dilemmas.

Moreover, by not analyzing the concept at all, the justice principle either becomes irrelevant because it cannot be understood, or may be open to whatever idiosyncratic interpretation the researcher has. A rabid libertarian researcher, for example, would read the justice principle as a libertarian negative rights theory. Since there is nothing offered in the text to contradict the researcher’s interpretation, he must be justified in his interpretation. Of course, this could lead to him conducting clinical trials that benefit the rich, while ignoring research that would help only populations with whom he does not want to contract, e.g., poor people who cannot pay for the products being tested. Under the researcher’s libertarian interpretation of justice and the authors’ justice principle—which is counter to what most people think of as justice-his exclusionary action would be just.

Further problems can be found within the various guidelines themselves. For example, what happens if we are able to satisfy either one or another, but not both, of a guideline’s conjoined prescriptions? Logically, we might have failed to follow the guideline, but that does not give even prima facie evidence that we have done something wrong. Guidelines with disjunctions are also problematic. Is it permissible for the researcher to pick and choose which of the disjuncts he wishes to fulfill?

The second major problem with Shamoo and Resnik’s overall theory, also arises from the lack of detail in the guidelines, but is considerably more serious than the vagueness problem. No one would disagree that good moral guidelines generally correctly classify actions as right or wrong. It follows that one way of testing a set of guidelines for adequacy is by running obvious examples through the set to see if it generally classifies the actions correctly. The mere fact that the set fails to produce the correct results in each instance is insufficient evidence to justify the claim that the guidelines are defective. After all, the guidelines are only prima facie, not absolute. Hence, in order to call into the question a set of prima facie rules’ adequacy, it is necessary to show that the guidelines generally do not classify actions when they should, make the wrong classifications, or make contradictory classifications.

In order to show the problem of not stipulating and explaining a moral theory in adequate depth-or at least stating that there will be gaps in the theory that will require the individual to consult a trained ethicist-and how that leads to contradictory classifications, I will use three common conflict situations to illustrate why clear mechanisms for resolving conflicts are required in any useful moral theory.

First, at times, there are situations in which an agent must choose between actions, all of which have negative utility. One of the most common examples of this state of affairs is that which occurs when a funding decision on research for severe diseases is made. Since there are limited grant resources, some very important research will not be funded, in favor of more promising work.
While it is clear that even if the research produces a medical product that will eliminate suffering, for example, which it usually does not, the fact that so many other people suffer from so many other diseases, which could have been researched, entails that there will always be more negative value than positive produced by any funding decision for research in this area. For example, if the money is used for HIV research, clinical trials for heart disease or diseases which affect a very small number of people are prevented from being funded.

The general common sense rule that most people employ for resolving these dilemmas is to minimize the negative utility by performing the best of the negative alternatives. However, since none of Shamoo and Resnik’s seventeen guidelines requires the agent to do the best he can or to minimize harms, they can be satisfied even though the agent is performing the worst alternative open to him.

Second, on the opposite side of the spectrum is when the agent must choose between alternatives with positive utility, with one alternative being far better than the rest. For example, a researcher could choose to conduct research that will result in a small positive utility¾perhaps working on ways to brighten teeth to their whitest¾or research that will have enormous positive utility, such as creating transgenic organisms that increase crop yield and lower pesticide use. In either case, the researcher can satisfy the seventeen guidelines. However, it is clear to most people that a researcher, who chooses to spend her time finding new ways to make teeth look better rather than the alternative, has done something morally wrong. In this case, she should have performed the best action.

Third, the most common situation in which agents must use decision-making procedures are those in which the agent must choose between actions that will benefit some and harm others. Suppose that Mary is a researcher employed by a drug company to conduct clinical trials on HIV vaccines. One vaccine she is asked to collect data on by her supervisor is unnecessarily risky, according to Mary. However, if she refuses to perform the trial, she will be fired and replaced with someone else. The result of the replacement will be that her colleagues are harmed because they are upset over her departure and their work is delayed, while a new team leader becomes acclimated. On the other hand, if Mary conducts the trials, her fears are realized and the human subjects are injured. Her colleagues’ reputations suffer in this alternative because of the notoriety gained by the flawed experiment. In this example, the seventeen guidelines proscribed Mary from acting in either way. If we further plausibly assume that there are no alternatives open to Mary in which her colleagues are not harmed in some manner, then there is nothing that she can do that is morally right.

Resorting to the second order principles in any of the three common situations encountered by researchers affords no assistance in resolving these problem cases. Although Shamoo and Resnik claim that the second order principles will settle moral conflicts, the rules do not provide adequate guidance. The authors state that “Although we should follow these [second order] principles, they may conflict, and we may have to choose between them sometimes.” (15-6) However, the authors do not provide the reader with a mechanism-other than his own intuitions-to choose between the principles in conflict cases or, for that matter, for the three common situations.

Consider what occurs in the example of Mary’s research dilemma from above. If, for example,
Mary proceeds with her experiment, then she violates the principle of Nonmaleficence, since the trial harms the human subjects and Mary’s colleagues. However, at the same time, the trial promotes Mary’s well being because she keeps her job. If Mary refuses her supervisor’s request, and then is fired, she again violates the principle of Nonmaleficence. Mary’s actions have harmed her colleagues’ reputations. If the authors’ term “unjustified harm”-which is used to help explain the Nonmaleficence principle--means that the costs of the action are outweighed by the long term benefits, then Mary’s action clearly fails to satisfy the principle. The amount of harm is too great without a sufficient amount of benefits.

For the other two dilemma situations, i.e. selection of the least worst or the far better alternative, respectively, the principles are unhelpful. First, Nonmaleficence does not say that an agent is obligated to select the least worst action, if all he has are negative alternatives from which to select. The fact of the matter is requiring the benefits to outweigh the harms will always lead to irresolvable problems for circumstances in which it is a choice between the least worst of all the alternatives open to the individual.

Moreover,Beneficence does not have a utility calculation in it. All that an agent has to do to satisfy this rule is to promote his or her own well-being and benefit others. Even if the meaning of “well-being” and “benefit” were more clearly developed, the rule is rather simple to fulfill. Even though I could easily give a large amount of food to a lot of starving people, without sacrificing anything of comparable moral worth, if I give a lunch to one starving person, I have satisfied the rule of Beneficence.

Any attempt to resort to the first order moral theories to find an answer to the dilemmas posed by the three situations is also doomed to fail, since the authors, once again, provide us with no mechanism for choosing between the theories. In fact, Shamoo and Resnik state that “No theory, in our opinion, is the ‘single true theory,’ although different theories capture important moral insights and intuitions.” (12) Do the authors mean that one merely has to make a guess based on his intuitions as to which theory or set of theories will classify correctly the alternatives open to an agent? If so, then personal bias will in all likelihood interfere in the decision-making procedure. Hence, Judith Jarvis Thomson’s famous Trolley examples would pose a problem for Shamoo and Resnik’s decision-making procedure. (Thomson, 176-202)

Unless there is a clearly stated mechanism that allows readers to correctly select the moral theories which govern the situation, inter and intra-order conflicts cannot be resolved. The result is that the authors’ decision-making procedure devolves into a form of limited relativism. Limited in that not every action that a person believes to be morally right or morally wrong has that moral feature merely because the person believes it. After all the seventeen guidelines, four principles, and seven moral theories do provide some objective standards about morality. However, within that framework, the missing mechanism(s) for resolving conflicts allows agents great leeway to pick and choose which theories and principles she cares to follow. Furthermore, the manner in which she interprets each theory, principle, or guideline may be idiosyncratic, but just as legitimate, as any other interpretation. I will address the latter problem first.

As was previously stated for the second order Justice principle, since Shamoo and Resnik leave the interpretation of rules open to the individuals by not providing clear and useful principles, different people may permissibly interpret the rules in different ways. For example, a libertarian would
permissibly evaluate alternatives using the distributive justice theory of libertarianism, while a socialist would evaluate differently based upon her theory of distributive justice. Because there is no mechanism for determining who is objectively correct, if either, it follows that both of them are right in their classifications. As a result, contradictions are generated. For example, some people have condemned several clinical trials in Africa because the latter do not follow a socialist principle of distributing goods according to need, while libertarians see no moral proscription from conducting a trial which will net none of the human subjects or their communities any benefits other than those directly related to the trial itself, such as better medical care within the trial. It follows from both distributive justice principles that it is morally right to conduct the trials and it is morally wrong to conduct the trials. Since Resnik and Shamoo’s theory leads to a contradiction, it should be rejected, until that time when it has been clarified in the proper way, (of course, I am assuming that the theory generates contradictions because of its lack of definition, rather than it having an inherent defect.)

What makes matters graver is that the same conclusion follows for individual selection of rules from the first and second order. Since there is no mechanism in place for which rules apply in particular situation, the individual may choose whichever theory strikes her fancy, bound only by whatever intuitions she has and the seventeen guidelines. If there is a conflict between Beneficence and Nonmaleficence, for instance, the agent can legitimately select according to her personal preferences. Furthermore, if a conflict requires resolution at the first-order, then there is little to prevent her from selecting a theory based upon personal bias. If she is a Nazi, then her interpretation of Kantianism, for example, would be as legitimate as that of a morally decent researcher. Once again, each person would classify actions correctly even if the result leads to a contradiction, which is likely to occur given the fact that people hold such different views of morality.

There is one final puzzle that I will address with the decision-making procedure. The general step order is to gather relevant information and then relate it to the different values and principles that are at stake. The question arises, however, as to how to gather relevant information without first knowing what values and principles are at stake in the situation. For example, I might search and gather an incredible amount of information on the social contract that I think is relevant without realizing that Divine Command Theory governs the particular situation. By the time that I arrive at the fourth step, I find that I have wasted a considerable amount of resources pursuing irrelevant material. In order to be able to effectively make decisions, hence, it seems as if we must have a good idea of the theory that is to be used prior to the information gathering stage so that we can limit our search to the relevant and exclude the irrelevant.

The puzzle offers some insight into one of the main problems with the chapter on ethics: by trying to be too inclusive of all moral intuitions, theories, and so on, and too general to avoid problems that simple theories regularly encounter, Shamoo and Resnik have produced an impractical theory.

Now I do not intend to impugn excessively the authors’ theory, but it is missing a critical feature, viz. a mechanism for determining priority of the various rules or which one(s) actually apply in a situation and which ones do not. It is not enough to state merely that everyone intuitively knows which theory, principle, or guideline to use and how to use it because if that were truly the case, there would be no need for training in ethics. Everyone would already intuitively know the answers to moral dilemmas.
In order to rectify the problem, I suggest something much simpler and straightforward than the three level method the authors have developed. What is needed is a much less complex theory that incorporates as many of the main insights that are listed as possible, while at the same time being practical to use. Since many of the guidelines talk about well-being and harm, it seems that a form of utilitarianism should be a component of the overall theory. Furthermore, the requirement to respect people in the proper ways requires a form of Kantianism be included. In order to act morally, perhaps the overall rule would be to satisfy both principles. In order to make a moral decision using the two part moral theory, Shamoo and Resnik’s second and third order guidelines must be considered by the agent as part of the utility calculations and as part of what it means to respect the individuals affected by the action. The result of the process might not always be a correct classification, but it will generally work. For the most part, maximizing utility, while respect all persons affected by the action in the proper manner, will not generally lead to a wrong action.

Furthermore, the four principles and seventeen guidelines are valuable tools for moral decision making. Given the practical theory, the twenty-one rules can help researchers to find the relevant information and weigh it correctly. Each of the twenty-one rules, although not sufficient on its own, reminds researchers what is important and help them to not overlook any information that should be used in making an ethical decision. If these rules are combined with a practical moral theory, then *Responsible Conduct of Research* would arguably be the best work on research ethics to date.

**Conclusion:**

Although it might be crass for highly trained ethicists to give people what they want, it might be the right thing to do. People who want to be good researchers or professionals have so much other work to do that they do not have an enormous amount of time or energy to receive the ethics’ education that one usually obtains only through doctoral study at a good university. What professionals require is a practical theory that is readily understandable to them and which almost always gives the correct answers to their normative questions on ethical conduct. Granted that it would arguably be a better world if all professionals underwent much more rigorous ethics training, the real world situation is not conducive to efforts to bring this world about. Even though *Responsible Conduct in Research* is a valuable addition to the texts in research ethics, it could be improved by being made clearer and more practical to use.

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**References:**


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