Essays in Philosophy
A Biannual Journal
Vol. 4 No. 2, June 2003

Medical Research Ethics: Introduction

Medical Research Ethics is a rapidly developing area in both the philosophical and public policy arenas. And as should be expected, the discipline is suffering from a number of growing pains. First, there are the perennial problems associated with the field which still require a great deal of time and effort to examine. Questions, such as, How much information is required to obtain informed consent? What does it mean to freely consent for informed consent? How do we ethically incorporate groups that have been excluded from medical testing, such as woman, as well as groups that have been historically exploited by researchers, such as black men, the mentally disabled, and prisoners? have been wrestled with since the middle of the 19th century when scientists began to pay serious consideration to how research affected human subjects. Although progress has been made in defining and developing ethical codes for conduct in research, especially after the Nazi atrocities were discovered, it is obvious there is a long way to go before the codes are complete. The fundamental concept of autonomy, for example, is still not as clear as it needs to be for evaluating moral claims, even though the basic requirements of autonomy have been recognized by a number of people.

Furthermore, as we discover that the set of moral considerations for ethical decision making is greater than we perceived previously, we find new complexities for the perennials. For example, the developed world’s researchers and policy makers often have very little insight into the developing world’s practices and customs. What might count as informed consent in the developed world would be insufficient in some areas outside of it. In one case, researchers for a study conducted in an African community in which the tribal leaders have enormous power in setting the community’s goals sought informed consent from both the leaders and the human subjects. The study used a higher standard than that found in the developed world, in which community leaders are not asked for their informed consent to participate in the research. With the greater awareness of moral considerations in research situations, the definition of informed consent might have to be modified accordingly. The remaining perennial issues are likely to be effected in a similar manner, which sets the stage for an extensive re-examination of currently accepted standards and practices.

The introduction of new technology causes a second growing pain for Medical Research Ethics: New technology creates new moral problems. Medical Research Ethics tries to address future issues, such as the alteration of hog DNA to make the species a viable source for human transplants, but because of the speed of technological advancements, the field is often struggling merely to keep pace with developments as they occur. The work done so far on the perennial questions is useful but insufficient to solve the problem. The difficulty is that although the new problems might be similar to the perennials, the former have unique moral features that require a great deal of additional evaluation. For example, the moral issues involved with pharmaceutical transgenic organisms, in which DNA from one species is “spliced” into that of another to create new
pharmaceutical products, have only recently begun to receive the attention that they deserve. The available literature on the perennial issues lays some groundwork for answering the old questions of morality, such as the duties to make the products available to all citizens, animals, and the environment, but it does not say anything about the morality of this type of transgenics. Some of the transgenic issues are distinctive in that they require the evaluation of technology that was thought to be science fiction a mere twenty years ago. New questions about the intrinsic moral value of pharmaceutical organisms, for instance, need to be fully addressed before we can make decisions about whether or not to introduce such products into the marketplace. Medical Research Ethics’ growing pain becomes especially acute as the number of developments outpaces the resources of those trained properly in the field.

A third growing pain can be found in the struggle of social and political policymakers to catch up to medical research developments and relationships. Due to the increase in conflicts of interests, for example, the federal government is beginning the process of formulating rules for Institutional Review Boards\(^4\) (IRBs) to manage conflicts.\(^5\) University researchers have recently developed ties to corporations, which provide funding for their research and sometimes expect the researchers to fully support conclusions that benefit the company, or at least finesse results in its favor. Even without the illicit pressure to alter results, the fiscal relationship between researchers and corporations might be in conflict with the interests of the university or the public it serves. The university and public expect unbiased research, which can be used to make good decisions. In these situations, researchers might not be able to serve their three masters well.

Another questionable financial relationship is the relatively new phenomenon of university researchers forming corporations of their own to profit from the results of their research. This sets up conflicts of interests between the universities, researchers, and everyone else involved in the process. Researchers have a financial interest in the success of their corporation, which might be in conflict with the interests of the university to produce unbiased research. Furthermore, the university, itself, might be unduly influenced to relax its strive for objective research by the possibility of financial gain through the corporation, a part of which the university might own. In these situations, the duty of the university to the students or the public might be subverted for the profit that could be made.

Finally, IRB members might have conflicts of interests of their own. Since experts in the research areas are needed to evaluate research protocols for scientific validity as well as ethical legitimacy, the experts tend to come from the same department as the researchers. Hence, there are at least apparent conflicts between the interests of the department, university, and human subjects, which need to be addressed. To complicate matters further, if the IRB member has an unequal power relationship with the researcher, e.g., one will be making tenure decisions for the other, there is an even greater probability that the conflict will produce unethical results.

IRBs are in a bad situation. It has been clear for some time that IRBs need rules to help them do the right thing in all conflict of interest situations, but policymakers have not provided it. However, even though official rules are not in place, it would be unethical to stop research that has conflicts until the rules have been codified. IRBs will have to continue to try to do what is ethical without much outside guidance.

Although there are far more issues in Medical Research Ethics that can be addressed, including but
not limited to stem cell research, human cloning, and genetic therapies, the enormous complexity and challenges of this developing field should now be apparent. The main question that we in the field should be considering is how to ethically proceed with developing Medical Research Ethics. My suggestion is to make an effort to see if we have set the groundwork needed to make useful progress in field. That requires going back to the basics of philosophical study.

Relatively early in their careers, philosophers learn by heart an old adage: Questions of meaning come before questions of truth. Basically, if the definitions of words or terms are unclear in the propositions in which they appear, then it is impossible to evaluate the truth of the propositions, or the principles, arguments, or theories that contain the propositions. In the abortion debate, for example, the pro-choice side often defines the unborn as fetuses, while the pro-life side claims that the unborn are babies or children. Regardless of who is truly right or wrong, arguments using the word “unborn” cannot be evaluated until it is clear which definition, if either, is intended. Philosophical reasoning, hence, is judged adequate or inadequate based in part upon how well the words and terms employed are defined.

The two papers and my book review in this issue of *Essays in Philosophy* take the adage seriously. First, Richard Miller’s paper takes on what is one of the most influential works in Medical Research Ethics: The Belmont Report. The Belmont Report’s three rules of morality have been the basis of most of the various codes of conduct formulated by public and private agencies involved in research ethics. The National Institutes of Health’s Office for Human Subjects Research, among others, has it listed on their website. Furthermore, there is not one textbook in bioethics or medical ethics that does not refer to the Report as an important component in the literature.

Unfortunately, as Miller convincingly argues, the Report’s guidelines give little assistance in making ethical decisions. In the first case, the guidelines are full of terms that are so vague or ambiguous, that the resulting rules cannot be understood. Second, in many instances, when the terms are sufficiently defined, the guidelines are internally and externally inconsistent. The justice principle, for example, lists five distributive justice principles, including socialism, egalitarianism, and capitalism, but provides no guidance in selecting which of the theories to use for any situation, even though they cannot each be satisfied at the same time. Using the Principle of Charity, the best that can be said about the Belmont Report is that it recognizes that justice, beneficence, and respect for persons are good things and necessary features of right actions, although it remains unclear exactly what role the three play in ethical decision making.

Second, in “Do Unknown Risks Preclude Informed Consent?,” David Rudge argues that Allen Buchanan and Daniel Brock make an unwarranted presumption that the riskier a therapy is, then the higher the level of cognitive competence the patient/human subject must have for an informed decision. Rudge contends that the presumption entails one of two implausible results for experimental therapies. First, if the competency standard is higher than merely making a reasonable choice, then most human subjects can never give informed consent because they do not truly understand the nature of experimental therapies and the risks involved. Second, if the competency standard is merely making a reasonable choice, then a much lower standard for experimental therapies is implied. Rudge argues that making a reasonable choice in the face of uncertain odds, such as when a fiscally naïve person invests successfully in the stock market, is not an informed decision, due to the lack of relevant information. Hence, instead of having a higher standard of
competency for human subjects in experimental therapy clinical trials, the competency standard is lower than that used for the normal or benchmark treatments.

In my review of Adil E. Shamoo and David B. Resnik’s *Responsible Conduct of Research*, I use much the same process that Miller employs to such great effect against the Belmont Report. Although the authors’ moral theory, principles, and guidelines are important ethical considerations when it comes to making moral decisions, it is not clear how practical their decision making procedure is. Many terms are left inadequately defined, and some of the rules are contradictory, e.g., the justice principle is the same as that of the Belmont Report. The result is that researchers are more likely to be able to identify the moral considerations situations have, but there is no clear method to help them make decisions in difficult situations in which those moral considerations are at odds with each other. In the end, although otherwise an excellent addition to the literature, *Responsible Conduct of Research* needs a more practical decision procedure with understandable components.

What all three articles show is the need to carefully evaluate the literature that has become part of the foundations of thinking in Medical Research Ethics, instead of trying to formulate policy or ideas for new developments as they come. Although this method will necessarily impose a hiatus on some work on newer issues, the additional clarity achieved will be useful in the long run for formulating the best arguments and preventing a great deal of wasted effort that arises only because those doing it are ignorant about the emptiness of the terms.

**Useful resources on Medical Ethics Research:**

- Association of American Medical Colleges (AAMC): http://www.aamc.org/
- Food and Drug Administration (United States) www.fda.gov/oc/gcp/default/htm
- Indian Council of Medical Research http://www.icmr.nic.in/ethical.pdf.


- National Institutes of Health: http://www.nih.gov/sigs/bioethics/
  - Web resources on conflicts of interest: (http://www.nih.gov/sigs/bioethics/conflict.html),
  - International research ethics in developing countries: (http://www.nih.gov/sigs/bioethics/internationalresthics.html)


- World Medical Association (WMA): http://www.wma.net/e/policy/17-c_e.html

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Notes:

1. See Bernard, C. 1865 [1957]. An Introduction to the Study of Experimental Medicine, H. Green (trans). Dover, NY.


4. IRBs govern human subject research at various institutions.

5. Other examples include human and non-human cloning and stem cell research.
