

8-1-1982

## [Book Review of] *Ethics and Regulation of Clinical Research*, by Robert J. Levine

Robert L. Barry

Follow this and additional works at: <http://epublications.marquette.edu/lnq>

 Part of the [Ethics and Political Philosophy Commons](#), and the [Medicine and Health Sciences Commons](#)

---

### Recommended Citation

Barry, Robert L. (1982) "[Book Review of] *Ethics and Regulation of Clinical Research*, by Robert J. Levine," *The Linacre Quarterly*: Vol. 49: No. 3, Article 13.

Available at: <http://epublications.marquette.edu/lnq/vol49/iss3/13>

the profession. With the sick person as the major concern, no professional has the option of avoiding the religious dimension of that person.

One other point can be made about the kind of religion or ethics to be taught. If the ethics treated is strictly philosophical, it is not sufficient for religious believers. For them, the theology of suffering is a means of grace, of reconciliation. A naturalistic ethics falls far short of this meaning and scarcely touches on the fact of suffering. We might conclude with a quote of Dr. Edmund Pellegrino, former president of the Catholic University of America:

What are the duties imposed on us by virtue of the volunteer act we take as professional healers? It's high time we disclose to the public what we stand for (*Denver Catholic Register*, Sept. 9, 1981, p. 3).

— F. J. Malecek, S.J.

Bellarmino House of Studies, St. Louis, Mo.

---

## *Ethics and Regulation of Clinical Research*

Robert J. Levine

*Urban & Schwarzenberg, Baltimore, 1981, xvii + 299 pp.*

This book is filled with minor mistakes and glaring deficiencies. The title of the work seems to need a definite article somewhere. The book begins with a misspelled nominalist quote: "*Entia non sunt multiplicanda prater* [sic] *necessitatem*." The most quoted source in the work is the author himself.

The work appears to be a summary and critique of the DHEW and DHHS regulations of clinical research on human subjects. As a summary it is helpful, but as a critique, it is quite weak. The weakness stems from the author's superficial grasp of the ethical principles which ground the federal regulations. The brief discussions of the principles of justice, beneficence and respect of persons indicates that the author does not understand a great deal of moral philosophy, and this is borne out in the criticisms the author makes. Not only is Levine's understanding of these principles inadequate, but his understanding of consent, human acts, conscience and human goods is also faulty. He argues that informed consent is gained through a process of negotiation between the researcher and the client. This view implies an adversary relationship, rather than one in which cooperation is the keynote. In the researcher-client relationship, the client offers consent in order to promote goods and values for the community without violating values of his own health and well-being. The researcher promotes these values through his work, while also acting to limit any harm to the client, and compensating the client for any harm that comes about through the experiment. Informed consent is not "negotiated" into being, as much as it is brought about by the client understanding the facts of the situation and intuiting or apprehending the values involved in it.

Levine approves of non-therapeutic experimentation on children, the mentally infirm and fetuses within certain limits, on account of his inadequate understanding of the relationship of acts of conscience to acts promoting one's health and well-being. Decisions concerning one's health are moral decisions in that one is determining how to promote the moral value of one's physical health and well-

being. As such, they are prudential judgments of conscience, and for them to be attributable to the agent, the conditions required to satisfy an ordinary judgment of conscience are applicable here. As it is not ethically permissible to impose the harms of war on a conscientious objector, so also is it not permissible to impose harms involved in research on patients who object to them. As a society cannot demand of children that they agree to risk harms for the good of society, so also medical research cannot demand of children that they risk harms for the purpose of advancing medical knowledge. This is so because children lack the conceptual wherewithal to formulate responsible prudential judgments of conscience. And what applies to children applies even more forcefully to the unborn. The duty to receive informed consent is grounded only generically on the principle of respect of persons, for its specific foundation is the principle that decisions concerning one's health and physical well-being must be made by someone — either the person himself or one charged with the care of the person — who is capable of making this type of judgment.

The author makes the very fine point that all arrangements between the researcher and client should include the stipulation that compensation will be provided to the client for any harms whatsoever incurred on account of the research, irrespective of the liabilities of the researcher.

This work was written with the express purpose of modifying and streamlining regulations and procedures employed by Institutional Review Boards. It is unlikely that the modifications suggested by the author would be as cost-effective as he suggests, and in all probability the modified procedures would be less ethically acceptable than the ones presently in use.

This book is of value for the summary and review of current DHEW and DHHS regulations, but it is seriously deficient as an ethical critique of these policies and regulations.

— Robert L. Barry, O.P.

---

## *New Religions and Mental Health: Understanding the Issues*

Herbert Richardson, Editor

*Edwin Mellen Press, Lewiston, N.Y. 14092, LII + 172 pp.*

In the book *New Religions and Mental Health*, Herbert Richardson has brought together in a single volume a series of articles which delineate the salient issues of what, for some, seems to be a modern, perplexing problem — the conversion of many of our intelligent young people to forms of religious belief and practice which are perceived as new and inimical to established religious beliefs and practice and even to the good of society itself. The editor selects articles by authors who present a wide variety of viewpoints on this controversial issue and integrates them into a manageable whole, through an introduction which summarizes the issues raised in the articles.

The first set of articles is used to define the problem by presenting a case against the cults and then showing what is involved in the process of “deprogramming.” A discussion of “mental health” as a social weapon and various proposals