

"Human Medical Research: Ethical, Legal and Socio-Cultural Aspects"

Jan Schildmann, Verena Sandow, Oliver Rauprich, and Jochen Vollmann, editors, 2012, 188 pages, Springer, \$189

Review by Norman M. Goldfarb

"Human Medical Research: Ethical, Legal and Socio-Cultural Aspects" provides important insights into the ethics and social aspects of clinical research in a time of globalization and rapidly advancing technology. Both trends challenge the clinical research industry to come to grips with complex issues that have no easy answers. Nevertheless, good answers — or, at least, good questions — must be found if clinical research is to continue its vital role in medical progress.

The book includes diverse perspectives, such as the following:

Schmidt is correct to remind the reader that the ethical standards of today were not enshrined in law in the Allied countries either. In the United States, forced sterilization had been legal in some states since 1907, something the eugenicist Ernst Rudin was keen to point out while under house arrest (Weindling 2004). However, the medical crimes of the Nazis had to be compared against some ethical premise, and that yardstick was Allied ethics. Therefore, forced sterilization performed on the German population outside the concentration camps, although the most widespread Nazi crime, would have no part in a Nazi Doctors' Trial conducted by the United States (Sofair and Kaldjian 2000). This admission was a regrettable consequence of the Americans taking control of the Doctors' Trial.

Those supporting a restrictive disclosure policy disagree that showing respect for a participant's autonomy necessarily requires disclosure. Respect for participants means treating human beings capable of self-determination as autonomous agents. It also requires researchers to provide all the information about the trial, allow people to enroll and withdraw, etc. According to this argument, however, it does not require them to actively disclose individual research results to the participants (Melzer 2006).

Actually, whether showing respect for a participant's autonomy indeed supports disclosure depends on how one understands autonomy (Bredenoord et al. 2011a). Autonomy, in a negative interpretation, is most commonly understood as the individual's right to make their own decision without interference or coercion from others (Berlin 1969). From this perspective, researchers can deploy a very restrictive disclosure policy (i.e., only returning life-saving data) and, at the same time, respect a participant's autonomy, as long as participants are well informed about the restrictive disclosure policy, have an adequate understanding, and no coercion or undue influence has occurred. In a positive account, autonomy entails the ability to take control of one's life and to live according to one's values and beliefs (Berlin 1969). From this perspective, autonomy also entails maintaining or fostering people's capacity for autonomy (Feinberg 1987). If we interpret the duty to respect autonomy in a positive account, then this indeed forms a ground to support disclosure of genetic research results. After all, people may use information about their genetic make-up to take control of their lives and realize or adjust their life-plans.

In this paper, we hypothesize that the current paradigm for research ethics, underlying our positive and negative obligations, is changing. We claim that in the new paradigm, human subjects research is regarded as an “ordinary rather than an extraordinary practice in our society.” If our claim is correct, it may influence a future theory of research ethics. This theory may concentrate on the question of how we may encourage people to participate in clinical research rather than on the best way to protect them against incremental risks and burdens.

The book includes 15 essays by 28 contributors from nine countries:

- Introduction
- British Responses to Nazi Medical War Crimes
- History and its Relevance in the Development and Teaching of Research Ethics
- Human Embryo Research and Islamic Bioethics: A View from Iran
- From Farming to Pharming: Transcending of Bodily Existence as a Question of Medical Ethics in an Intercultural Context
- Rethinking the Therapeutic Obligation in Clinical Research
- Biomedical Research in Developing Countries and International Human Rights Law
- Research Involving Human Subjects and Human Biological Material from a European Patent Law Perspective. Autonomy, Commodification, Patentability
- The Development and Validation of a Guide for Peruvian Research Ethics Committees to Assist in the Review of Ethical-Scientific Aspects of Clinical Trials
- Conflicts of Interest in Medical Research: What can Ethics Contribute?
- Research Ethics in Genomics Research: Feedback of Individual Genetic Data to Research Participants
- Regulating “Higher Risk, No Direct Benefit” Studies with Children: Challenging the U.S. Federal Regulations
- A Paradigm Change in Research Ethics
- Translation of Cancer Molecular Biomarkers: Ethical and Epistemological Issues
- Rethinking the Ethics of Human Biomedical Non-Interventional Research

The book is available in bookstores.

Reviewer

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