JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 13, No. 3, March 2017 "Happy Trials to You"

"Ethics and Governance of Biomedical Research: Theory and Practice"

Daniel Strech and Marcel Mertz, editors, 2016, 225 pages, Springer, $79.99

Review by Norman M. Goldfarb

"Ethics and Governance of Biomedical Research: Theory and Practice" presents 15 scholarly articles on significant clinical research topics. The following three abstracts illustrate the important and interesting topics addressed by the authors:

From Altruists to Workers: What Claims Should Healthy Participants in Phase I Trials Have Against Trial Employers?

Phase I trials, which test the safety and toxicity of an investigational agent, are a vital stage of drug development. Many of these trials enroll healthy participants, and recent data suggest that some of the healthy participants treat phase I research participation as a form of work. This chapter examines three facets of the shift from research participation as a form of altruism to research participation as a form of work. First, I set out three features of trial participation that support labeling healthy participants' enrollment in phase I research as a form of work. Second, I ask: Is phase I research participation similar to risky occupations, such as firefighting or coal mining, or is phase I research participation similar to non-risky, low-wage occupations, such as janitorial work? To answer this question, I draw upon original data from a systematic review of 475 phase I trials with healthy participants that measures the risk level of the trials. Third, once I have found the appropriate "occupational bucket" for phase I work, I briefly examine the implications for contested questions within research ethics, such as the information persons need prior to consent, rights of withdrawal and compensation for injury, and efforts to increase the transparency of trial results. I argue that conceiving of phase I research as a form of work can bolster the rights of research participants in some of these areas and that bioethicists ought to be less wary of this shift in research participants' roles.

What Does the Child's Assent to Research Participation Mean to Parents? Empirical Findings in Paediatric Oncology in Germany

National law in Germany requires that, whenever possible, children must provide their assent before participating in clinical research. However, there is still academic debate about many fundamental components of assent in order to address, for example, the age or stage of development respectively, at which children should be asked for assent. Furthermore, only a few studies approach the child's assent to research participation empirically. We present empirical findings from a population-based survey in Germany on parents whose children were first diagnosed with childhood cancer in 2005. The survey's primary objective was to evaluate what the child's assent to research participation meant to parents who gave consent on behalf of their minor child. In particular, we wanted to better understand what parents think about the requirement of seeking assent, how to assess the children's competence to give assent, and who should be in charge of it. Our empirical findings indicate that parents want to give children a voice in the decision-making regarding research participation. Even though the child's competence to rationally understand

the research protocol is primarily discussed in the literature as the most important precondition for a valid assent, the surveyed parents emphasize the child's maturity instead. Given that maturity is regarded as a gradual process, parents want to have a say in assessing it. From this, it follows that parents develop and use a decision-making model that establishes appropriate roles, individual choices, and responsibilities for the children, the parents, and the physicians.

Using Patent Law to Enforce Ethical Standards: Proposal of a New Patent Requirement

Clinical trials are important instruments for achieving scientific progress within the life sciences. However, while they are of the utmost importance to our translational efforts, they are also highly expensive. To save costs, they are often relocated into developing countries, where the protection of study participants is minimal. Such relocation is not necessarily amoral, as those in charge might nevertheless adhere to high ethical standards. However, relocation is problematic if it entails the exploitation of vulnerable participants. How can such exploitation and violation of ethical standards within the life sciences be prevented? Adopting a pragmatic approach to research ethics, this paper suggests using the incentivising mechanisms of our patenting process to tackle the challenge of the prevailing unethical treatment of human subjects in life science research. By linking the granting of economic benefits via patents to the fulfilment of ethical requirements, the paper makes an important contribution to the question of how "ethical excellence" can be achieved in one of the most lucrative areas of global research.

The book includes the following 15 articles by 28 authors:

- Should Research Ethics Encourage the Production of Cost-Effective Interventions?
- From Altruists to Workers: What Claims Should Healthy Participants in Phase I Trials Have Against Trial Employers?
- Nocebo Effects: The Dilemma of Disclosing Adverse Events
- Discriminating Between Research and Care in Paediatric Oncology — Ethical Appraisal of the ALL-10 and 11 Protocols of the Dutch Childhood Oncology Group (DCOG)
- What Does the Child's Assent to Research Participation Mean to Parents? Empirical Findings in Paediatric Oncology in Germany
- Assent in Paediatric Research and Its Consequences
- Ethical Principles in Phase IV Studies
- Fate of Clinical Research Studies After Ethical Approval — Follow-Up of Study Protocols Until Publication
- Do Editorial Policies Support Ethical Research? A Thematic Text Analysis of Author Instructions in Psychiatry Journals
- Ensemble Space and the Ethics of Clinical Development
- Rethinking Risk–Benefit Evaluations in Biomedical Research
- Towards an Alternative Account for Defining Acceptable Risk in Non-Beneficial Paediatric Research
- Big Biobanks: Three Major Governance Challenges and Some Mini-Constitutional Responses
- Ethical Dimensions of Dynamic Consent in Data-Intense Biomedical Research — Paradigm Shift or Red Herring?

- Using Patent Law to Enforce Ethical Standards: Proposal of a New Patent Requirement

The book is available in bookstores.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.