Symposium Articles

6 Introduction: Vulnerability in Biomedical Research
Ana S. Iltis

Vulnerability as a Regulatory Category in Human Subject Research
Carl H. Coleman
This article examines and critiques the use of the term “vulnerability” in U.S. and international regulations and guidelines on research ethics. After concluding that the term is currently used in multiple, often inconsistent, senses, it calls on regulators to differentiate between three distinct types of vulnerability: “consent-based vulnerability,” “risk-based vulnerability,” and “justice-based vulnerability.”

19 Vulnerability in Research: Individuals with Limited Financial and/or Social Resources
Christine Grady
Individuals with limited resources are often presumed to be vulnerable in research. Concerns include the possibility of impaired decision making, susceptibility to undue inducement, and risk of exploitation. Although each of these concerns should be considered by investigators and IRBs, none justifies categorical exclusion of individuals with limited resources.

28 Limited English Proficiency and Disparities in Clinical Research
Dan Bustillos
Patients with Limited English Proficiency (LEP) are a protected class under the Civil Rights Act. However, clinical trials continue to remain largely inaccessible to this population. This article lays out the scientific, legal, and ethical rationales for the inclusion of LEP subjects in clinical research.

38 First-in-Human Trial Participants: Not a Vulnerable Population, but Vulnerable Nonetheless
Rebecca Dresser
The 21st-century translational science campaign could lead to an increase in first-in-human (FIH) trials. As tests of investigational interventions move from the laboratory to human research, scientists, officials, and review committees should address ongoing concerns about the ethics of FIH trials. In this article, I describe three ethical considerations relevant to all FIH trials: (1) the requirement for adequate preclinical research; (2) study design safeguards; and (3) choice of subject population. I also examine specific ethical considerations relevant to the three subject populations (healthy volunteers, seriously ill patients lacking standard treatment options, and stable patients) involved in FIH research. I recommend a variety of actions that could increase subject protection and the value of the information generated in FIH trials.

51 The Vulnerability of the Very Sick
Jerry Menikoff
When seriously ill patients for whom existing treatments are inadequate are invited to participate in clinical trials that offer a new treatment, should those persons be considered “vulnerable”? And if so, what additional protections should they be accorded? This article attempts to provide some answers.

59 Vulnerability in Clinical Research with Patients in Pain: A Risk Analysis
Raymond C. Tait
Some have characterized patients living with intractable pain as a vulnerable population in both clinical and research settings. Labeling the population as vulnerable, however, does not provide clarity regarding the potential risks that they face when they participate in research. Instead, research vulnerability for patients in pain is a function of an interaction between their pain conditions and elements of the research enterprise. Therefore, the identification of potential risks requires consideration not only of characteristics of patients with chronic pain, but also consideration of features of researchers, the quality of institutional oversight, and the medical/social environment within which the research is conducted. This paper provides an analysis of those risks and provides some suggestions as to how the risks might be better managed.
It also addresses broader questions of potential for stigma and risk to individuals and communities. The article concludes that the research should be permitted legally because either it does not involve human subjects, or it satisfies the requirements for waiver of consent; and that the research should also be permitted because the ethical principal of avoiding harm to individuals is fully satisfied based on a careful reading of the lessons of the tissue bank, biological property rights, and blinded seroprevalence study debates, as well as a consideration of other potential harms that might be involved.

Independent Articles

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In Defense of Bioethics

Robert Baker

Although bioethics societies are developing standards for clinical ethicists and a code of ethics, they have been castigated in this journal as "a moral, if not an ethics, disaster" for not having completed this task. Compared with the development of codes of ethics and educational standards in law and medicine, however, the pace of professionalization in bioethics appears appropriate. Assessed by this metric, none of the charges leveled against bioethics are justified. The specific charges leveled against the American Society for Bioethics and Humanities (ASBH) and its Core Competencies report are analyzed and rejected as artifacts of an ahistoric conception of the stages by which organizations professionalize. For example, the charge that the ASBH should provide definitive criteria for what counts as "medical ethics consultation" antecedent to further progress towards professionalization is assessed by comparing it with the American Medical Association's decades-long struggle to define who can legitimately claim the title "medical doctor." Historically, clarity about who is legitimately a doctor, a lawyer—or a "clinical ethicist"—is a byproduct of, and never antecedent to, the decades-long process by which a field professionalizes. The charges leveled against ASBH thus appear to be a function of impatient, ahistoric perfectionism.

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A Walk in the Park: A Case Study in Research Ethics

Zita Lazzarini, Patricia Case, and Cecil J. Thomas

Can researchers, interested in novel ways to assess HIV seroprevalence among populations which are otherwise hidden, collect condoms that have been discarded on the ground in a public sex environment and test them for HIV? Researchers, who use other types of abandoned samples, such as discarded syringes, hair or saliva samples, or excess biological samples, confront similar issues. This review evaluates whether such abandoned tissues can be studied based on U.S. Code of Federal Regulations and literature on related issues including: research involving banked tissues, blinded seroprevalence studies, and property claims that individuals might make on the samples.
Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of JLME.

Next Issue:

Pharmaceutical Regulations
A Symposium Guest Edited by Kevin Outterson

lowing: (1) overall, disparities in health care quality and access are not getting smaller; (2) progress is being made, but many of the biggest gaps in quality and access have not been reduced; and (3) the problem of persistent uninsurance is a major barrier to reducing disparities. Unless measures are taken to address this racism, unless a new sense of trust is established between the medical establishment and racial and ethnic minorities, these injustices will continue to deepen and expand, and more lives will be placed in jeopardy. What is needed is a comprehensive, multi-level, culturally relevant strategy that contains interventions that target individuals, communities, and the nation as a whole. This will entail understanding the causes of racism in the medical profession, identifying practical interventions that address racism in individuals, communities, and the nation as a whole, and forming partnerships that will work to develop a new sense of trust between the medical establishment and the minority communities.

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