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Letters to the Editors: Comments on articles in the Journal should be addressed to the Editor at the editorial office or emailed to thutchinson@aslme.org.

Submission Guidelines: For submission guidelines, please contact the editorial office at thutchinson@aslme.org. Submission guidelines are also available online at <http://journals.sagepub.com/home/lme>.

The Journal of Law, Medicine & Ethics (ISSN 1073-1105 (J812)) is published quarterly—in March, June, September and December—by SAGE Publishing, 2455 Teller Road, Thousand Oaks, CA 91320 in association with the American Society of Law, Medicine & Ethics. Send address changes to the Journal of Law, Medicine & Ethics, c/o SAGE Publishing, 2455 Teller Road, Thousand Oaks, CA 91320.

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Introduction

Carl H. Coleman

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**The Reasonable Person Standard for
Research Disclosure: A Reasonable
Addition to the Common Rule**

Rebecca Dresser

The revised Common Rule adopts the reasonable person standard to guide research disclosure. Some members of the research community contend that the standard is confusing and ill-suited to the research oversight system. Yet the revised rule is not as radical as it might seem. During the 1970s, judges started using the standard to evaluate negligence claims brought by injured patients who said doctors had failed to obtain informed consent to the harmful procedures. In its influential *Belmont Report*, the National Commission recommended application of a “reasonable volunteer standard” to guide IRBs evaluating research disclosures. Evidence also suggests that IRBs often invoke the reasonable person standard in deliberations about consent forms. But past application of the standard has been informal and uneven. Robust application of the reasonable person standard will require researchers and IRBs to learn more about what ordinary people want and need to know about the studies they are invited to join. Input from people with personal experience as study participants could be particularly useful to this effort.

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**Key Information in the New Common
Rule: Can It Save Research Consent?**

Nancy M. P. King

Informed consent in clinical research is widely regarded as broken, but essential nonetheless. The most recent attempt to reform it comes as part of the first revisions to the Common Rule since it became truly “common” in 1991. This change, the addition of a “key information” requirement for most consent forms, is intended to support and promote a reasoned decision-making process by potential subjects. The key information requirement is both promising and problematic. It is promising because it encourages clarity and honesty about research partici-

pation, creativity in information disclosure, and mutual learning through the investigator-subject relationship. It is problematic because those goals — which have remained aspirational since the beginning — may be difficult to achieve in what has become an excessively compliance-oriented regulatory regime.

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**Implementing Regulatory Broad
Consent Under the Revised Common
Rule: Clarifying Key Points and the
Need for Evidence**

*Holly Fernandez Lynch, Leslie E. Wolf,
and Mark Barnes*

The revised Common Rule includes a new option for the conduct of secondary research with identifiable data and biospecimens: regulatory broad consent. Motivated by concerns regarding autonomy and trust in the research enterprise, regulators had initially proposed broad consent in a manner that would have rendered it the exclusive approach to secondary research with all biospecimens, regardless of identifiability. Based on public comments from both researchers and patients concerned that this approach would hinder important medical advances, however, regulators decided to largely preserve the status quo approach to secondary research with biospecimens and data. The Final Rule therefore allows such research to proceed without specific informed consent in a number of circumstances, but it also offers regulatory broad consent as a new, optional pathway for secondary research with identifiable data and biospecimens. In this article, we describe the parameters of regulatory broad consent under the new rule, explain why researchers and research institutions are unlikely to utilize it, outline recommendations for regulatory broad consent issued by the Secretary's Advisory Committee on Human Research Protections (SACHRP), and sketch an empirical research agenda for the sorts of questions about regulatory broad consent that remain to be answered as the research community embarks on Final Rule implementation.

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Public Health Data Collection and Implementation of the Revised Common Rule

Lisa M. Lee

For the first time, the revised Common Rule specifies that public health surveillance activities are not research. This article reviews the historical development of the public health surveillance exclusion and implications for other foundational public health practices.

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Learning Health Systems and the Revised Common Rule

Joshua A. Rolnick

Quality improvement (QI) is an important function of learning health systems, and public policy should promote QI activities. Use of systematic methodologies in QI has prompted substantial confusion regarding when QI is human subjects research under the Common Rule, and this confusion persists with the revised Rule. Difficulty distinguishing research from QI imposes costs on the quality improvement process. I offer guidance to IRBs to mitigate these costs and suggest a new regulatory exclusion for minimal risk quality improvement activities.

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Rethinking the Regulatory Triggers for Prospective Ethics Review

Carl H. Coleman

Under the Common Rule, federally-supported activities involving human participants are presumptively required to undergo prospective ethics review if they are “designed to develop or contribute to generalizable knowledge.” However, the “generalizable knowledge” standard is inherently ambiguous; moreover, it is both over- and under-inclusive of the type of activities that warrant prospective ethical oversight. Rather than conditioning prospective ethics review on an ethically irrelevant criterion like the generalizable knowledge standard, this article proposes that prior ethics review should be required when some individuals are exposed to greater-than-minimal risks for the potential benefit of others, at least when the activity in question is conducted or supported by federal agencies. Under such an approach, the fact that an activity constitutes research would be neither necessary nor sufficient to trigger prospective ethical oversight.

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Vexed Again: Social Scientists and the Revision of the Common Rule, 2011-2018

Zachary M. Schrag

In revising the Federal Policy for the Protection of Human Subjects (Common Rule) between 2009 and 2018, regulators devoted the vast bulk of their attention to debates over biomedical research. They lacked both expertise in and concern about the social sciences and humanities, yet they imposed their will on experts in those fields. The revision process was secretive, spasmodic, and unrepresentative, especially compared to rulemaking in Canada, where social scientists participate in the process, and revisions take place every few years. The result was a final rule that offers some wins for social science and the humanities, but that fails to solve the problems identified by Ezekiel Emanuel and in the 2011 advance notice of proposed rulemaking.

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Requiring a Single IRB for Cooperative Research in the Revised Common Rule: What Lessons Can Be Learned from the UK and Elsewhere?

Edward S. Dove

This article argues in general support of the sIRB rule, but also draws on recent empirical research to highlight several residual weaknesses in the US regulatory structure for research ethics review, and suggests ways in which these weaknesses might be addressed in future regulatory reforms to improve upon the sIRB rule.

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Local All-Age Bicycle Helmet Ordinances in the United States: A Review and Analysis

Molly Merrill-Francis, Jon S. Vernick, and Keshia M. Pollack Porter

Bicycle helmets protect against head injury. Mandatory helmet laws likely increase their use. Although 21 states and Washington, DC have mandatory helmet laws for youth (variously defined) bicyclists, no U.S. state has a mandatory helmet law that applies to all ages; however, some localities have all-age helmet laws for bicyclists. This study abstracted local helmet laws applicable to all-ages to examine their elements.

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**Considering Quality of Life while
Repudiating Disability Injustice: A
Pathways Approach to Setting Priorities**
Govind Persad

This article proposes a novel strategy, one that draws on insights from antidiscrimination law, for addressing a persistent challenge in medical ethics and the philosophy of disability: whether health systems can consider quality of life without unjustly discriminating against individuals with disabilities. It argues that rather than uniformly considering or ignoring quality of life, health systems should take a more nuanced approach. Under the article's proposal, health systems should treat cases where (1) quality of life suffers because of disability-focused exclusion or injustice differently from cases where (2) lower quality of life results from laws of nature, resource scarcity, or appropriate tradeoffs. Decisionmakers should ignore quality-of-life losses that result from injustice or exclusion when ignoring them would improve the prospects of individuals with disabilities; in contrast, they should consider quality-of-life losses that are unavoidable or stem from resource scarcity or permissible tradeoffs. On this proposal, while health systems should not amplify existing injustice against individuals with disabilities, they are not required to altogether ignore the potential effects of disability on quality of life.

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**Geographic Location and Moral
Arbitrariness in the Allocation of
Donated Livers**
Douglas MacKay and Samuel Fitz

The federal system for allocating donated livers in the United States is often criticized for allowing geographic disparities in access to livers. Critics argue that such disparities are unfair on the grounds that where one lives is morally arbitrary and so should not influence one's access to donated livers. They argue instead that livers should be allocated in accordance with the *equal opportunity principle*, according to which US residents who are equally sick should have the same opportunity to receive a liver, regardless of where they live. In this paper, we examine a central premise of the argument for the equal opportunity principle, namely, that geographic location is a morally arbitrary basis for allocating livers. We raise some serious doubts regarding the truth of this premise, arguing that under certain conditions, factors closely associated with geographic location are relevant to the allocation of livers, and so that candidates' geographic location is sometimes a morally non-arbitrary basis for allocating livers. Geographic location is morally non-arbitrary, we suggest, since by taking it into account, the UNOS may better fulfill its central goals of facilitating the effective and efficient placement of organs for transplantation and increasing organ donation.

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**Appraising Harm in Phase I Trials:
Healthy Volunteers' Accounts of Adverse
Events**

*Lisa McManus, Arlene Davis, Rebecca L.
Forcier, and Jill A. Fisher*

While risk of harm is an important focus for whether clinical research on humans can and should proceed, there is uncertainty about what constitutes harm to a trial participant. In Phase I trials on healthy volunteers, the purpose of the research is to document and measure safety concerns associated with investigational drugs, and participants are financially compensated for their enrollment in these studies. In this article, we investigate how characterizations of harm are narrated by healthy volunteers in the context of the adverse events (AEs) they experience during clinical trials. Drawing upon qualitative research, we find that participants largely minimize, deny, or re-attribute the cause of these AEs. We illustrate how participants' interpretations of AEs may be shaped both by the clinical trial environment and their economic motivation to participate. While these narratives are emblematic of the larger ambiguity surrounding harm in the context of clinical trial participation, we argue that these interpretations also problematically maintain the narrative of the safety of clinical trials, the ethics of testing investigational drugs on healthy people, and the rigor of data collected in the specter of such ambiguity.

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*Karolina Strzebonska and
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