Revising the Common Rule: Prospects and Challenges

Leslie Meltzer Henry

What the ANPRM Missed: Additional Needs for IRB Reform
Charles W. Lids and Suzanne Garverich

Outsourcing Ethical Obligations: Should the Revised Common Rule Address the Responsibilities of Investigators and Sponsors?
Seema K. Shah

Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects
Leslie Meltzer Henry

Take Another Little Piece of My Heart: Regulating the Research Use of Human Biospecimens
Gail H. Javitt
respect to the use of biospecimens. It argues that there is a need to distinguish between the dual roles — subject and donor — played by contributors of biospecimens.

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Biobanking, Consent, and Certificates of Confidentiality: Does the ANPRM Muddy the Water?
Brett A. Williams and Leslie E. Wolf

In its Advanced Notice of Proposed Rule Making (ANPRM), the U.S. Department of Health and Human Services proposed substantial changes to how biospecimen research is treated under the regulations governing human subjects research. Currently, much of this research can be conducted without consent because it may not be considered “human subjects” research, is considered exempt, or consent may be waived. Responding to criticisms that scientific changes have made biospecimen research riskier than contemplated when the Common Rule was last amended, the ANPRM proposes to require written consent for biospecimen research, even if they have been stripped of identifiers or initially collected for a non-research purpose.

The ANPRM’s recognition of these risks is consistent with relatively recent NIH recommendations that research projects involving genetics, genomics, or biospecimen repositories should consider getting a Certificate of Confidentiality to provide additional protections to participants where breach of confidentiality is typically the primary risk. Ironically, the ANPRM proposals may make it more difficult to provide these protections. Our paper explores the implications of the conflicting requirements of the Certificate and the ANPRM proposals and makes recommendations for achieving the dual goals of appropriate consent and adequate confidentiality protections.

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Are Changes to the Common Rule Necessary to Address Evolving Areas of Research? A Case Study Focusing on the Human Microbiome Project
Diane E. Hoffmann, J. Dennis Fortenberry, and Jacques Ravel

This article examines ways in which research conducted under the Human Microbiome Project, an effort to establish a “reference catalogue” of the micro-organisms present in the human body and determine how changes in those micro-organisms affect health and disease, raise challenging issues for regulation of human subject research. The article focuses on issues related to subject selection and recruitment, group stigma, and informational risks, and explores whether: (1) the Common Rule or proposed changes to the Rule adequately address these issues and (2) the Common Rule is the most appropriate vehicle to provide regulatory oversight and guidance on these topics.

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The Apomediated World: Regulating Research When Social Media Has Changed Research
Dan O’Connor

Social Media, like Facebook and Twitter, are having a profound effect on the way that human subjects research is being conducted. In light of the changes proposed in ANPRM, in this article I argue that traditional research ethics and regulations may not easily translate to the use of social media in human subjects research. Using the conceptual model of apomediaion, which describes the peer-to-peer way in which health information is shared via social media, I suggest that we may need to think again about the suitability of current regulations to deal with social media research.

Independent Articles

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Advance Directives, Dementia, and Physician-Assisted Death
Paul T. Menzel and Bonnie Steinbock

Physician-assisted suicide laws in Oregon and Washington require the person’s current competency and a prognosis of terminal illness. In The Netherlands voluntariness and unbearable suffering are required for euthanasia. Many people are more concerned about the loss of autonomy and independence in years of severe dementia than about pain and suffering in their last months. To address this concern, people could write advance directives for physician-assisted death in dementia. Should such directives be implemented even though, at the time, the person is no longer competent and would not be either terminally ill or suffering unbearably? We argue that in many cases they should be, and that a sliding scale which considers both autonomy and the capacity for enjoyment provides the best justification for determining when: when written by a previously well-informed and competent person, such a directive gains in authority as the later person’s capacities to generate new critical interests and to enjoy life decrease. Such an extension of legalized death assistance is grounded in the same central value of voluntariness that undergirds the current more limited legalization.

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Caring for Elder Parents: A Comparative Evaluation of Family Leave Laws
Y. Tony Yang and Gilbert Gimm

As the baby boomer generation ages, the need for laws to enhance quality of life for the elderly and meet the increasing demand for family caregivers will continue to grow. This paper reviews the national family leave laws of nine major OECD countries (Canada, Denmark, France, Germany, Italy, Japan, Netherlands, Spain, and the United Kingdom) and provides a state-by-state analysis within the U.S. We find that the U.S. has the least generous family leave laws among the nine
OECD countries. With the exception of two states (California and New Jersey), the U.S. federal Family Medical Leave Act of 1993 provides no right to paid family leave for eldercare. We survey the current evidence from the literature on how paid leave can impact family caregivers’ employment and health outcomes, gender equality, and economic arguments for and against such laws. We argue that a generous and flexible family leave law, financed through social insurance, would not only be equitable, but also financially sustainable.

Social Security Survivors Benefits: The Effects of Reproductive Pathways and Intestacy Law on Attitudes
Jason D. Hans and Martie Gillen
Most minor children are eligible for Social Security survivors benefits if a wage-earning parent dies, but eligibility of children not in utero at the time of death is more nuanced. The purpose of this study was to examine attitudes concerning access to Social Security survivors benefits in the context of posthumous reproduction. A probability sample of 540 Florida households responded to a multiple-segment factorial vignette designed to examine the effects of state intestacy laws and five reproductive pathways — normative, posthumous birth, cryopreserved embryo, cryopreserved gametes, and posthumous gamete retrieval — on attitudes toward eligibility for the Social Security survivors benefits. Broad support was found for the survivors benefits following normative and posthumous birth pathways, but attitudes were decidedly less favorable when the child was not in utero at the time of parental death. In addition, in stark contrast to the recent U.S. Supreme Court decision in Astrue v. Capoto, the vast majority of respondents did not believe state intestacy laws should determine eligibility for Social Security survivors benefits.