



LETTER TO THE EDITORS

HUMAN SUBJECTS RESEARCH WITH PRISONERS: PUTTING THE ETHICAL QUESTION IN CONTEXT

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We write in response to the conversation initiated in Volume 24.1 of *Bioethics*, which focused on the role of prisoners in biomedical and behavioral research. As interdisciplinary legal scholars who have researched the history, ethics, and current practices of prison research in the United States, we write to encourage further dialogue about the Institute of Medicine's (IOM) recommendations to reform current standards for prisoners' participation human subjects. Specifically, we challenge three critical assumptions, which underlie several articles in the *Bioethics* special issue.

First, we challenge the idea that a risk-benefit assessment applied to prisoner participants in research is too restrictive.¹ On the contrary, we argue that it is too permissive. The IOM's risk-benefit proposal – the most significant of its five main recommendations – is designed to relax current standards that categorically restrict prisoners' participation as human subjects to four narrow situations that directly benefit prisoners.² Current policies were implemented in response to substantial abuses directly connected to prisoners' vulnerability and deplorable prison conditions; a 1976 Commission concluded that widespread research in prisons should not be reconsidered until these abuses and conditions are resolved. Yet all available evidence suggests that the situation in US prisons has only worsened, from increasing overcrowding and violence to decreasing availability of basic medical care and education.³ Thus, to suggest that the IOM's risk-benefit proposal is *too restrictive* is, at best, overly optimistic about the ability of institutional mechanisms such as institutional review boards (IRBs) – faulty

even in the best of circumstances⁴ – to mitigate the profound ethical challenges associated with such research. And at worst, the renewed enthusiasm for using prisoners as human subjects may demonstrate insensitivity to the historical and sociological contexts giving rise to current restrictions.

We are also concerned with the *methods* the IOM used to conclude that applying a risk-benefit standard in prison contexts is ethically appropriate. Our methods for assessing whether the conditions for ethical participation currently exist are as crucial as the substantive and normative questions of whether prisoners *ought* to participate.⁵ In this regard, the IOM's methodology leaves much to be desired. For example, the Committee only visited one prison and one prison medical facility – far from a robust engagement with current prison conditions. In lieu of this deeper empirical understanding, the Committee largely based its recommendations on a literature review, claiming that scholarship on research ethics has 'evolved' since the 1976 Commission's findings. What is curious, however, is that the 'evolved' literature relied upon by the IOM Committee to justify their proposal did not speak to or reference the unique challenges involved with using prisoners as human subjects. In short, the Committee privileged theory over prisoners' lived conditions.

Second, although a few articles in the *Bioethics* special issue address the importance of a human rights framework in analysing whether and how prisoners should participate in medical experimentation,⁶ we argue that this framework must be the primary lens of analysis,

¹ B. Elger & A. Spaulding. Research on Prisoners – A Comparison between the IOM Committee Recommendations (2006) and European Regulations. *Bioethics* 2010; 24: 1–13; E. Chwang. Against Risk Benefit Review of Prisoner Research. *Bioethics* 2010; 24: 14–22.

² 45 C.F.R. §46.306(a)(2)(i)-(iv).

³ *Plata v. Schwarzenegger*, No. C01-1351 TEH, 2007 U.S. Dist. LEXIS 56031 (N.D. Cal. July 23, 2007): *6; P. Wagner. 2003. *The Prison Index: Taking the Pulse of the Crime Control Industry*. Available at: <http://www.prisonpolicy.org/prisonindex/rootsofcrime.html> [Accessed 13 Aug 2010].

⁴ C. Elliott. Guinea-Pigging: Healthy Human Subjects For Drug-Safety Trials Are in Demand. *The New Yorker* Jan. 7, 2008: 36–41; J. Lenzer & S. Brownlee. 2009. Major Gaps In Oversight Of Human Medical Research. *Huffington Post* Oct. 28. Available at: http://www.huffingtonpost.com/2009/10/28/major-gaps-in-oversight-o_n_337399.html [Accessed 13 Aug 2010].

⁵ O. Obasogie. Prisoners as Human Subjects: A Closer Look at the Institute of Medicine's Recommendations to Loosen Current Restrictions on Using Prisoners in Scientific Research. *Stanford Journal of Civil Rights and Civil Liberties*, forthcoming 2010.

⁶ Elger & Spaulding, *op. cit.* note 1, pp. 1–13; D. Thomas. Prisoner Research – Looking Back or Forward. *Bioethics* 2010; 24: 23–26.

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especially in the United States where human rights violations are particularly prevalent in prisons. The US prison system is not only large, as mentioned in the introduction to Vol. 24.1. But it is also overcrowded and under-resourced. It is not uncommon for prisons to function at 200 percent of capacity, and judges have declared health-care provisions so inadequate as to be unconstitutional.⁷ US prisoners are especially vulnerable because their access to courts – an informal mechanism to protect their legal rights as potential experimental subjects – is severely limited. Not only do American prisoners suffer from extraordinarily low literacy rates⁸ that make it difficult for them to document and articulate problems when filing legal claims, but federal legislation explicitly limits prisoners' ability to bring lawsuits to challenge prison conditions and prisoner treatment.⁹

Finally, we have documented the frequency of experimentation on prisoners currently taking place in the United States, challenging the inaccurate assumption that existing regulations severely curtail such experimentation.¹⁰ For instance, in the late 1990s, the University of Miami enrolled prisoners in an HIV/AIDS experimental treatment trial. The *St. Petersburg Times* reported on several illegal aspects of this study: the prisoner participants in the allegedly therapeutic trial did not understand the meaning of a 'placebo', were incentivized inappropriately by receiving better healthcare treatment in the experimental program than was otherwise available in the prison, and experienced better day-to-day living conditions while participating in the study, including more comfortable clothing and housing with air conditioning.¹¹ The Florida study was one of the few prison studies that was actually subject to existing federal guidelines.

⁷ H. Mintz. 2009. Prison on the Brink: California Facilities are Overcrowded, Dangerous. *Sacramento Bee* Sep. 16; S. Moore. 2009. Prison Overcrowding Fix. *New York Times* Feb. 10. Available at: <http://www.nytimes.com/2009/02/11/us/11prisons.html> [Accessed Aug 13 2010].

⁸ Wagner, *op. cit.* note 3.

⁹ J. Boston. 2004. The Prison Litigation Reform Act. Available at: <http://www.wnyc.net/pb/docs/plra2cir04.pdf> [Accessed Aug 13 2010].

¹⁰ K. Reiter. Experimentation on Prisoners: Persistent Dilemmas in Rights and Regulations. *California Law Review* April 2009; 97: 501–566.

¹¹ S. Freedberg. 2000. Questions Raised over AIDS Research on Inmates. *The St. Petersburg Times* Mar. 19: 1A. Available from: http://www.sptimes.com/News/031900/State/Questions_raised_over.shtml [Accessed Aug 13 2010].

But human subjects research on prisoners that does not fall within the regulatory scope of US federal law is similarly disturbing. For example, between 2006 and 2008, a drug company called Hythian contracted with jurisdictions in at least five different states to enroll criminal defendants in an experimental drug addiction treatment program.¹² As part of this program, state judges 'divert' drug court participants, who have been found in possession of drugs, into an experimental treatment program called Prometa. The program involves thirty days of treatment, with three different drugs, none of which has been approved for use in addiction treatment by the US Food and Drug Administration (FDA). Hythian bills the state \$15,000 per person for this experimental 'treatment' program.¹³

Those who advocate relaxed standards for using prisoners as human subjects (such as the IOM's proposed risk-benefit approach) often do so as part of a laudable effort to give prisoners access to new and cutting edge treatments. While we certainly want prisoners to have access to potentially beneficial treatments, we think this concern is necessarily secondary to our primary concerns with ensuring that basic healthcare needs in prisons are met, facilities improved, and resources expanded. Offering prisoners an opportunity to participate in experimental research that may or may not lead to treatments that may or may not benefit them in their current context of severe healthcare deficiencies may itself function as a form of coercion. Put simply, such compromised conditions may lead prisoners to agree to things they might not otherwise.

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¹² G. Dober. Cheaper than Chimpanzees: Expanding the Use of Prisoners in Medical Experiments. *Prison Legal News* Mar. 2008: 5.

¹³ L. Weinstein et al. 2007. Scientific Basis of the Prometa Treatment Program. Available at: www.stayontrak.com/images/ScientificBasisPTP.pdf [Accessed Aug 13 2010].