



EDITORIAL

Mention the name ‘Tuskegee’ in a room full of bioethicists and expect a host of reactions. The name – poetic as it rolls off the tongue but unsettling as it hangs in the air – evokes a maelstrom of emotions, concerns, questions, and objections. Long since it first made news in the early 1970s, long after the experiment ended, discussions around the infamous Tuskegee Syphilis Study persist as a mainstay of bioethics conferences, journal articles, and curricula. Among other things, the Tuskegee Study stands as an example of the perils of reducing humans to objects of research. It encapsulates almost every topic that bioethicists and medical and clinical researchers continue to grapple with – undue inducement, consent, psychiatric wellbeing, distribution of costs and benefits, controlled studies, institutional review boards, public and researcher perceptions on race, class, gender, capability . . . the list goes on. The Study is a compelling cautionary tale against the use of vulnerable populations for medical research, a practice that has been strictly regulated and closely observed since the Tuskegee Study made national headlines in the early 1970s.

A well-publicized awareness of the dangers of undertaking research studies on vulnerable populations contributed to the sense of shock when, in August of 2006, the Institute of Medicine (IOM) released a report titled ‘Ethical Considerations for Research Involving Prisoners’.¹ The committee recommended five central changes to current practice. First, the panel recommended expanding the definition of ‘prisoner’ ‘to include a much larger population of persons whose liberty is restricted by virtue of sentence, probation, parole, or community placement’ (IOM Report, xiii). Secondly, the panel argued that prisoners should be assured of universal and standard protections no matter what the source of research funding. Thirdly, the panel suggested that prison research be evaluated on a risk-benefit approach, as opposed to a categorical ruling in or out of experiments or populations of prisoners. Fourthly, they suggested that the prisoners be involved collaboratively in their research. And finally, they suggested that stronger and more rigorous oversight be put in place.

These recommendations raise many ethical considerations. They include concerns about interracial justice (as the incarcerated are disproportionately composed of racialized groups), about individual and public health (as

accurate medical research on human subjects could provide valuable insight into cures and solutions to our most vexing maladies), about rights (as the incarcerated have lost some legal rights), about freedom (as the options available to the incarcerated are sharply constrained), and even about autonomy (as it’s difficult to see how prisoners are in a position to participate genuinely in the research).

Such concerns are both philosophical and political, reflecting strong convictions, underlying values, and social forces, while directly affecting people’s lives in significant ways. This is why the Philosophy Department at the University of Colorado at Boulder, under the auspices of the Center for Values and Social Policy (CVSP), approached the issue in a 2008 symposium on the Use of Prisoners for Medical Research. With financial support from the Ford Foundation, the University of Colorado’s Law School, and the Bioethics Center at CU-Denver, CVSP hosted a series of public events addressing issues revolving around medical research on prisoners and other vulnerable populations. The essays collected in this volume follow up on those events.

In this special issue of *Bioethics*, the authors revisit the findings of the report. We have collected some essays from participants at the Colorado conference, but also solicited wider feedback from the academic community. Given the length restrictions of an academic journal, we have had to make some difficult decisions about what to include and what to exclude. The essays collected here have been selected in part because they focus on a wide range of issues stimulated by the report. The first essays address concerns that are specifically about the IOM report, while the remaining essays cover broader questions related to experimentation on prisoners and vulnerable populations. Many issues remain to be explored, and we hope that this volume will inspire further investigation.

The first piece, by Drs. Bernice Elger and Anne Spalding, offers a comparative analysis of the differences between the recommendations contained in the IOM report and various regulations currently guiding policy in Europe. The authors focus explicitly on the differences between the IOM report and related European regulations, with a particular emphasis on the use of risk-benefit analysis in the IOM report. They note several important differences between the two approaches. In Europe, for instance, there is no suggested limit for the percentage of prisoners who should be involved in a biomedical study. The IOM report, by contrast, recommends limiting any such study to 50% prisoner participation. In this respect, the IOM report is more restrictive than current European practice. Current European regulations require that any

¹ L.O. Gostin, C.Vanchieri & A. Pope, eds. 2006. *Ethical Considerations for Research Involving Prisoners: Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research*. Washington DC: Institute of Medicine of the National Academies. Available at: <http://www.iom.edu/CMS/3740/24594/35792.aspx> [Accessed 25 Aug 2009].

experimentation offer some potential for benefit to the experimental subject, and that risks should be minimal if there is no direct expected benefit but only a benefit for prisoners as a group. Similar stipulations are also in the IOM report, though what constitutes a 'minimal risk' varies between the two. In this respect, the IOM report is more permissive than current European regulations. Elger and Spalding also comment on the extent to which the IOM report offers several helpful suggestions for ensuring the safety and fairness of prisoner research, but note that the European context also offers several insightful pragmatic solutions to some of the most controversial questions. In the end, they suggest that US regulators consult the European model for more ideas before instituting any such policies.

Prof. Eric Chwang takes a more fine-grained look at one provision of the IOM report. He argues that the report is wrong to suggest adding risk-benefit constraints, reasoning that such additional risk-benefit constraints are unnecessary, as the current 'Common Rule' regulations, in conjunction with the other IOM report recommendations, are enough to secure the permissibility of prisoner research. He begins his argument by claiming that the comparison between children and prisoners is a false one. Provisions that protect children ought not to be the same as those that protect prisoners, since prisoners are not only competent but also not in situations that undermine their rational decision-making. Chwang then proceeds to examine and reject several possible contenders to justify risk-benefit constraints. The analogy to children is the first contender, but there are others: coercion, undue inducement, exploitation, and paternalism. Chwang's is a controversial position, which conflicts with intuitions that many hold regarding the problems with prisoner research. Nevertheless, his argument reflects an interpretation of freedom and consent that cannot be overlooked in this discussion.

Dr. Thomas concludes that the IOM Report overreaches in its attempt to protect prisoners as human subjects. He even challenges the constitutionality of some of the Report's provisions. For example, where the Federal government does not provide funding for research, Thomas argues that a prisoner's right to participate in research takes priority over any interest in providing governmental oversight. Dr. Thomas challenges notions of collaboration by committees and academics to protect prisoners, by emphasizing the importance of their voluntary participation in studies. Dr. Thomas terms this the 'right to research' and encourages vigorous discussion on moral, ethical and legal grounds.

Dr. Laura Calkins' piece diverges somewhat from the other papers. It offers an historical investigation of pharmaceutical use in the interrogation of suspects, prisoners, patients, and POWs in the United States. Clearly this

is an extraordinarily important and timely question. Calkins contextualizes her piece in relation to the controversial 2003 'Yoo memo'. The Yoo memo states that the US 'Constitution is not in play' with regard to prisoners at Guantanamo Bay, thereby authorizing the Justice Department to employ a range of interrogation techniques, including the use of mind-altering pharmaceuticals. Appealing to several cases of prisoner interrogation since WWII, Calkins explores the extent to which the memorandum may have had spill-over consequences affecting US policy toward prisoners.

By raising concerns related to forensic psychiatric research, Prof. Christian Munthe's paper introduces yet further questions about the scope of the IOM report. Munthe et al. address the problem of a 'dual role' dilemma in forensic psychiatry – the idea that the forensic psychiatrist is in the business not only of caring for the patient, but also in working for the public good. They point out that this dual role dilemma emerges with special acuteness in research involving prisoners. Munthe et al. seek to establish a reasonable balance between risk and consent, reasoning that in some cases, as when direct risks to patients are slight, informed consent from the patient can be overridden by other considerations.

Given that there are roughly 2.3 million people in prison and jail in the United States at any time, or about one in every 135 citizens, the prison population is sizable (Prison Statistics, USDJ).² It is both the largest per capita and the largest overall population of incarcerated people in the world (Walmsley, 2007).³ This population is at once controlled, ripe for most any scientific study, and a population under control, primed for exploitation and abuse. There are many ethical and moral considerations related to almost all prisoners, young and old, violent and nonviolent, male and female, mentally ill and of sound mind. Essentially these concerns remind us of the disproportionate number of African Americans in US penal institutions and how they might be affected by recommendations in the IOM report. The issues in the IOM report go well beyond the questions raised initially by the Tuskegee Study. The essays collected here touch only a small fraction of these considerations, but we hope that their authors' analyses and commentary regarding the IOM report will encourage greater scrutiny of the IOM report whose publication inspired our colloquium in 2008.

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² Bureau of Justice Statistics. *Prison Statistics*. US Department of Justice. June 30, 2008.

³ R. Walmsley. 2007. *World Prison Population List*. 7th edn. London: International Centre for Prison Studies. School of Law, King's College. Available at: <http://www.kcl.ac.uk/depsta/law/research/icps/downloads/world-prison-pop-seventh.pdf> [Accessed 25 Aug 2009].