

ARTICLE

PRISONERS AS HUMAN SUBJECTS: A CLOSER LOOK AT THE INSTITUTE OF MEDICINE'S RECOMMENDATIONS TO LOOSEN CURRENT RESTRICTIONS ON USING PRISONERS IN SCIENTIFIC RESEARCH

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There have been notable discussions within scientific literature, bioethics scholarship, and the popular press regarding the Institute of Medicine's (IOM) 2006 recommendations to the Department of Health and Human Services to loosen federal restrictions on using prisoners in biomedical and behavioral research. Yet there has been little dialogue among legal scholars about the recommendations' potential impact on administrative policy. Supporters point to the growing need for clinical trial participants, ethicists' changing perspectives, and greater institutional protections, while opponents point to past abuses and their likelihood to reoccur. Although certainly at odds, a common underlying theme in this debate is a focus on the possible outcomes produced by these recommendations rather than examining the argument made by the IOM Committee in proposing changes to 45 C.F.R. § 46, Subpart C. While valuable, this focus on possible outcomes might obscure a critical question that has thus far remained relatively unexamined: did the IOM come to this recommendation for a substantial shift in regulatory policy in a rigorous manner? As part of a broader effort to think about ethics' evolving relationship with administrative policy, this Article takes a closer look at the ethical framework used to justify these recommendations. Central to this inquiry is whether a proposed ethical framework that (a) is based upon a literature review of scholarship rather than an empirical examination of prison conditions, (b) treats prisoners' vulnerability to abuse as solely a product of prison conditions without broader consideration of how profit motives within the research industry might exacerbate these concerns and (c) is isolated from other relevant normative commitments (such as human rights) can appropriately inform regulatory policy. This Article argues

that it cannot. Before considering any changes to Subpart C, the Article argues that greater attention must be paid to how empirical methods can inform research ethics in prison, the different contexts that heighten prisoners' vulnerability as human subjects, and the relevance of human rights to research ethics.

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INTRODUCTION

Rapid advances in biomedical research and changing perspectives in bioethics are leading to increased calls to reform many administrative policies related to health care, drug development, and clinical trials. One critical yet underexamined¹ example of how evolving perspectives in research ethics are

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1. While the IOM's recommendations have received notable discussion in medical and bioethics circles, a LexisNexis search shows that only a handful of law review articles reference or discuss the report. *See, e.g.*, Andrea Lynn Osganian, *Limitations on Biomedical and Behavioral Research Involving Prisoners: An Argument Supporting the Institute of Medicine's Recommendations to Revise Regulations*, 34 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 429 (2008); Gerald R. Prettyman, Jr., *Ethical Reforms in Biotechnology Research Regulations*, 15 VA. J. SOC. POL'Y & L. 51 (2007); Seema Shah, *How Legal Injection Reform Constitutes Impermissible Research on Prisoners*, 45 AM. CRIM. L. REV. 1101 (2008); Keramet Reiter, Comment, *Experimentation on Prisoners: Persistent Dilemmas in Rights and Regulations*, 97 CAL. L. REV. 501 (2009); Rachel Wener, Comment, *Not Situated to Exercise Free Power of Choice: Human Subject Research in Prison Settings*,

calling for change in regulatory policy is the Institute of Medicine's (IOM) recommendations to the Department of Health and Human Services to loosen federal restrictions (45 C.F.R. §§ 46.300 et seq.²) regarding the use of prisoners as human subjects in biomedical, epidemiological, and behavioral research.³ Supporters point to the growing need for more clinical trial participants,⁴ improved institutional oversight and greater penetration of ethical values into research norms and protocols since the current restrictions were implemented in the 1970s,⁵ and prisoners' ostensible right to be included in biomedical and

26 TEMP. J. SCI. TECH. & ENVTL. L. 365 (2007). In general, the non-legal scholarly conversation on the ethics of prison research has not been particularly robust in recent years. See, e.g., Kathleen Brewer-Smyth, *Ethical, Regulatory, and Investigator Considerations in Prison Research*, 31 ADVANCES IN NURSING SCI. 119 (2008); K.C. Kalmbach and Phillip M. Lyons Jr., *Ethical and Legal Standards for Research in Prisons*, 21 BEH. SCI. & L. 671 (2003); Amy B. Smoyer et al., *Compensation for Incarcerated Research Participants: Diverse State Policies Suggest A New Research Agenda*, 99 AM. J. PUB. HEALTH 1746 (2009); Sara Wakai et. al., *Conducting Research in Corrections: Challenges and Solutions*, 27 BEH. SCI. & L. 743 (2009).

2. Research Involving Prisoners, 45 C.F.R. §§ 46.301-.306 (2009). For a list of relevant Federal Regulations, see National Institutes of Health, Regulations and Ethical Guidelines, <http://ohsr.od.nih.gov/guidelines/45cfr46.html> (last visited Nov. 11, 2009).

3. See generally COMM. ON ETHICAL CONSIDERATIONS FOR REVISIONS TO DHHS REGULATIONS FOR PROTECTION OF PRISONERS INVOLVED IN RESEARCH, INST. OF MED., ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS (Lawrence O. Gostin et al. eds., 2006) [hereinafter 2006 IOM REPORT]. While the IOM Committee's intent is for its recommendations to apply to all types of research with human subjects (biomedical, social/behavioral, and epidemiological), this Article largely discusses the recommendations in the context of biomedical research since (1) this type of research has the most significant risks and, as result, is most fraught with ethical challenges and (2) most of the discussion concerning the IOM Committee's recommendations has referenced this context.

4. The FDA "is requiring more tests and longer tests of new drug candidates" and "[b]iotechnology companies, thanks in part to the decoding of the human genome and other advancements in drug-development technology, are generating a swelling pool of new drug candidates that need to be tested." John George, *Drug Trials Cause Tribulations: Finding Volunteers is Becoming Tougher Task*, PHILA. BUS. J., Dec. 5, 2008, available at <http://philadelphia.bizjournals.com/philadelphia/stories/2008/12/08/story1.html>. Yet,

finding people . . . to test new drug products or medical devices is becoming more challenging than ever before" because "adverse events — ranging from a teenager dying in a University of Pennsylvania gene therapy study to Merck pulling its FDA-approved arthritis pain medicine Vioxx off the market because of safety concerns — have tempered people's willingness to participate in clinical trials. *Id.*

5. According to Barron Lerner,

It is often said that those who ignore history are condemned to repeat it. But a decision to retain current restrictions because of past abuses would ignore several important developments. Since 1978, a network of institutional review boards has been established at the National Institutes of Health, other governmental agencies, and research universities throughout the country. With "informed consent" now common parlance, study subjects are more aware of their rights. And, largely owing to the work of AIDS activists and breast cancer activists, sick and at-risk persons, even those from potentially vulnerable populations, now actively pursue participation in research protocols. Even though not all of these are unambiguously positive, to ignore them and the opportunities they may afford prisoners would be to regress. As the IOM report said, "Respect for prisoners also requires recognition of their autonomy."

behavioral research.⁶ Critics tend to highlight past abuses and their likelihood to repeat themselves.⁷

While at odds, this conversation's high stakes have led both sides to largely focus on the possible outcomes of this proposed shift rather than to look more carefully at how normative claims emanating from ethics discourses are being leveraged to recommend substantial changes to regulatory policy. While it would be an overstatement to say that the prison research debate has been wholly consequentialist in nature, the current framing nonetheless takes the recommendations largely at face value without examining how the Institute of Medicine reasoned to its recommendations after 265 pages of ethical deliberation. This raises a central question: What methods, approaches, and assumptions did the IOM rely upon in recommending that current restrictions should be loosened?⁸ Was the IOM's approach to research ethics—in terms of the methods used, the social contexts it identified as relevant to the issue, and the normative paradigms chosen to inform its decision-making—robust enough to justify overturning thirty years of regulatory precedent?

This Article argues that it was not. Biomedical and research ethics offer many contributions for thinking through the proper relationship between doctors and patients as well as governments' role in protecting human subjects in scientific research.⁹ While ethics certainly has a place in policy discussions,

Barron H. Lerner, *Subjects or Objects? Prisoners and Human Experimentation*, 356 NEW ENG. J. MED. 1806, 1807 (2007).

6. The exclusion of seriously ill prisoners from clinical trials through which they may receive potentially life-saving treatment is constitutionally dubious and morally troubling. It is arguable that prisoners have a right to participation under the Eighth Amendment, the Due Process Clause, and the promise of Equal Protection. In addition, moral considerations impel the allowance of prisoner enrollment in therapeutic biomedical research.

Sharona Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 IND. L. REV. 475, 515 (2000). See generally David L. Thomas, *Prisoner Research: Looking Back or Looking Forward?*, 24 BIOETHICS 23 (2010).

7. The United States has a lengthy history of abusing prisoners in the name of medical research. It was this well-documented history that led to the near prohibition of federally funded prisoner medical experimentation by the 1970s. The Institute of Medicine's proposal to loosen these recommendations is ill-advised and shows a poor understanding of the modern American prison system.

Paul Wright, Op-Ed., *Look Elsewhere For Subjects*, USA TODAY, Aug. 22, 2006, at 10A.

8. While the IOM characterizes its recommendation as strengthening oversight mechanisms for research with prisoners, I use the term "loosen" to specifically describe the IOM's proposed shift from prisoners' categorical restriction to a risk/benefit approach. Compared to current regulations, this shift would likely lead to a substantial increase in the number of prisoners participating in scientific research. See *infra* Part II.C.

9. For example, Kuhse and Singer note that bioethics "is a more overtly critical and reflective enterprise" that is distinguished in three different ways:

First, its goal is not the development of, or adherence to, a code or set of precepts, but a better understanding of the issues. Second, it is prepared to ask deep philosophical questions about the nature of ethics, the value of life, what it is to be a person, the significance of being human. Third, it embraces issues of public policy and the direction and control of science.

Helga Kuhse & Peter Singer, *What is Bioethics? A Historical Introduction*, in A COMPANION TO BIOETHICS 4 (Helga Kuhse & Peter Singer eds., Blackwell 2001) (1998).

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this Article argues that it is not in and of itself a sufficient basis from which to develop public policy. This is where the IOM Committee's report misses the mark. The IOM Committee largely treats its report as a scholarly exercise in ethics that should be adopted as regulatory policy rather than embracing its role as an independent government advisor that can provide the necessary bridgework to bring ethical inquiries into public policymaking in a robust and credible manner. This shortcoming is evident in at least three ways. First, from a *methodological* standpoint, the IOM Committee forgoes taking a serious empirical assessment (i.e. collecting primary data) of modern prison conditions and instead bases its updated ethical framework on a literature review of scholarly papers. Second, in terms of having an appropriate *context* from which to understand the ethics of prison research, the IOM Committee only situates its ethical inquiries into prisoners' vulnerability by looking at prisons' shifting demographics (racial disparities, health inequalities, etc.) without examining how shifting market conditions may lead researchers to treat vulnerable human subjects in a less than virtuous manner. Lastly, the IOM Committee does not meaningfully acknowledge other *substantive* sources that inform normative commitments to human subject protection outside of research ethics or biomedical ethics—namely human rights. Taken together, these methodological, contextual, and substantive critiques suggest that the IOM's recommendations leave too much to be desired before they can meaningfully inform regulatory policy.

This Article's critique is broken into three parts. Part I briefly describes the Institute of Medicine in terms of its history, organization, and modern influence on health policy. After outlining the history of prisoners' participation in scientific research in the twentieth century and the regulations implemented in the 1970s to oversee this practice, Part II describes the recommendations put forth by the Institute of Medicine as well as the updated ethical framework used to reach this conclusion. Part III then provides an extended discussion of the methodological, contextual, and substantive shortcomings of the Institute of Medicine's ethical framework and recommendations. While these three critiques overlap at points, they nonetheless provide a useful analytic mechanism to think through the report's limitations. This Article concludes by discussing how ethical inquiries can best serve future public policymaking endeavors.

I. THE INSTITUTE OF MEDICINE: ORGANIZATION, STRUCTURE, AND INFLUENCE

Positions taken by the Institute of Medicine carry significant weight as recommended public policy due to the IOM's unique history and organizational structure. The IOM is one of four organizations that constitute the National Academies.¹⁰ The first of these organizations—the National Academy of

10. The other organizations are the National Academy of Sciences, the National

Sciences (NAS)—was established after the Civil War for the specific purpose of advising the nation on matters of science. President Lincoln signed the Act of Incorporation on March 3, 1863. Section 3 of the Act lays out the basic parameters of the NAS:

The Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science or art, the actual expense of such investigations, examinations, experiments, and reports to be paid from appropriations which may be made for the purpose, but the Academy shall receive no compensation whatever for any services to the Government of the United States.¹¹

The National Academy of Sciences broadened its scope throughout the twentieth century at the request of several presidents to provide additional scientific advice to government. Under the original charter, the National Research Council was created in 1916 to “improve government decision making and public policy, increase public education and understanding, and promote the acquisition and dissemination of knowledge in matters involving science, engineering, technology, and health.”¹² Also under the same charter signed by Lincoln, the National Academy of Engineering was founded in 1964 to “provide[] engineering leadership in service to the nation.”¹³ It is comprised of over 2000 peer-elected members who provide expert research and analysis to many levels of government.

Membership in the Institute of Medicine, which was founded in 1970, is highly selective and quite prestigious. As both an honorific society and a non-profit organization charged with providing guidance to government on biomedical science, health, and medicine, the IOM has a strong reputation as an independent consultant to government. Indeed, the Institute of Medicine’s stated mission is to “serve[] as adviser to the nation to improve health,” which it does by providing “unbiased and authoritative advice to decision makers and the public.”¹⁴

The Institute of Medicine is organized in a manner that emphasizes impartiality and objectivity in its recommendations. It is a private, non-governmental organization that does not receive any direct federal money for its services. The majority of its studies are conducted at the request of government agencies who then fund the work out of the federal appropriations

Academy of Engineering, and the National Research Council. *See* The National Academies, <http://www.nationalacademies.org/about/> (last visited Jan. 25, 2010).

11. *See* National Academies of Science, About the NAS: Incorporation, http://www.nasonline.org/site/PageServer?pagename=ABOUT_incorporation (last visited Jan. 25, 2010).

12. National Research Council, <http://sites.nationalacademies.org/NRC/> (last visited Nov. 20, 2009).

13. National Academy of Engineering, About the NAE, <http://www.nae.edu/About.aspx> (last visited Jan. 23, 2010).

14. Institute of Medicine, About the IOM, <http://www.iom.edu/About-IOM.aspx> (last visited Jan. 24, 2010).

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made available to them.¹⁵ State and local governments, foundations, and other independent organizations also suggest and provide support for studies.¹⁶ IOM members are elected by their peers based upon their scientific accomplishments and serve without compensation.¹⁷

Much of the IOM's influence and credibility comes from the rigorous study process behind each of its reports.¹⁸ This careful scholarly approach to its research along with its organizational structure allows the IOM's reports and recommendations to have widespread influence among policymakers. Indeed, this influence is precisely why the federal government established the IOM and why their opinion is so highly sought: to affect policymaking.¹⁹

Examples of this policy influence abound. The IOM's *Dietary Reference Intake*²⁰ provided "the scientific basis for the 2005 *Dietary Guidelines for Americans*—the government's primary nutrition policy document . . . [and is] also credited with contributing to the removal of trans fats from foods."²¹ *Saving Lives Buying Time*,²² an IOM study on malaria drugs and their economics, is largely credited with "convinc[ing] a coalition of organizations, including the World Health Organization and the World Bank, to develop a worldwide subsidy program to make antimalarial drugs more affordable and available."²³ The Institute of Medicine engaged in a study on the quality of health care with its 2001 report entitled *Crossing the Quality Chasm*.²⁴ Part of this series entailed a report on medical errors, which "inspired the creation of patient safety centers in several states to track and analyze data on hospital errors."²⁵ And an IOM Study entitled *Injury in America*²⁶ "was a major

15. See generally THE NATIONAL ACADEMIES, OUR STUDY PROCESS, available at <http://www.nationalacademies.org/studycommitteeprocess.pdf>.

16. See *id.*

17. INST. OF MED., INFORMING THE FUTURE: CRITICAL ISSUES IN HEALTH 2 (5th Ed. 2009), available at <http://www.iom.edu/~media/Files/Informing%20the%20Future%202009.ashx>.

18. See generally THE NATIONAL ACADEMIES, OUR STUDY PROCESS, *supra* note 15.

19. The IOM's work is organized into seventeen topic areas, including mental health, child health, public policy, public health and prevention, and minority health. See, e.g., National Information Center on Health Services and Health Care Technology, Introduction to Health Services Research: A Self-Study Course, available at <http://www.nlm.nih.gov/nichsr/ihtm/03players/players16.html> (last visited Jan. 25, 2010).

20. PANEL ON DIETARY REFERENCE INTAKES FOR ELECTROLYTES AND WATER, INSTITUTE OF MEDICINE, DIETARY REFERENCE INTAKES FOR WATER, POTASSIUM, SODIUM, CHLORIDE, AND SULFATE (2004).

21. INST. OF MED., ABOUT THE INSTITUTE OF MEDICINE: ADVISING THE NATION. IMPROVING HEALTH (on file with author) [hereinafter ADVISING THE NATION].

22. COMM. ON THE ECONOMICS OF ANTIMALARIAL DRUGS, INST. OF MED., SAVING LIVES, BUYING TIME: ECONOMICS OF MALARIA DRUGS IN AN AGE OF RESISTANCE (Kenneth J. Arrow, et al. eds., 2004).

23. ADVISING THE NATION, *supra* note 21.

24. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (6th prtng. 2005).

25. ADVISING THE NATION, *supra* note 21.

contributor to the development of the injury control and prevention field.”²⁷ To be sure,

soon after *Injury in America* was released, Congress appropriated funds for a pilot program for injury control at CDC, and two years later, a new IOM-NRC [National Research Council] committee reviewed its progress. In *Injury Control* (NRC, 1988), the committee concluded that the program had been sufficiently successful to warrant permanent support. It commended the CDC program for establishing five interdisciplinary research centers; sponsoring a new program of extramural research; and building staff expertise for intramural research, database development, coordination, and technical assistance.²⁸

While the Institute of Medicine’s effect on policymaking is not easily quantifiable, this anecdotal evidence along with its organizational mandate and structure suggests that it continues to have a significant influence on government decision-making. This also suggests that the Institute of Medicine’s recommendations concerning the loosening of restrictions on using prisoners in scientific research should be taken seriously; a long line of evidence implies that there is a strong likelihood that the federal government will give these recommendations careful consideration.²⁹

II. THE INSTITUTE OF MEDICINE AND ITS RECOMMENDATION TO LOOSEN CURRENT RESTRICTIONS ON PRISON RESEARCH

In 2004, the Department of Health and Human Services’ (DHHS) Office for Human Research Protections commissioned the Institute of Medicine to “review the ethics regarding research involving prisoners.”³⁰ In particular, the Institute of Medicine was charged with “examin[ing] whether the conclusions reached in 1976 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [1976 Commission] remain appropriate today.”³¹ The 1976 Commission was convened following the revelation of significant abuses in scientific research as a way to improve government oversight and human subject protection. To the extent that it is widely acknowledged that the 1976 Commission’s report “was the basis for 45

26. COMM. ON TRAUMA RESEARCH, INST. OF MED., *INJURY IN AMERICA: A CONTINUING PUBLIC HEALTH PROBLEM* (1985).

27. *ADVISING THE NATION*, *supra* note 21.

28. COMM. ON INJURY PREVENTION AND CONTROL, INST. OF MED., *REDUCING THE BURDEN OF INJURY: ADVANCING PREVENTION AND TREATMENT* 20 (Richard J. Bonnie et al. eds., 1999).

29. In a personal communication with Julia Gorey, Subpart C coordinator at the Office for Human Research Protections, she noted that no changes have been made to federal regulations based upon the IOM report but that changes to Subpart C are still under consideration. Communication with Julia Gorey, Office of Human Research Protections (Oct. 15, 2010) (on file with author).

30. 2006 IOM REPORT, *supra* note 3, at ix.

31. *Id.* at 22.

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C.F.R. § 46³²—which provides federal regulations for human subjects research—and that the agency commissioning the report (DHHS) is the regulatory body that oversees and enforces these regulations,³³ the IOM report has been largely seen as a serious attempt to rethink current restrictions on using prisoners in human subjects research.³⁴

The IOM report is the most recent chapter in a much longer conversation on using prisoners as human subjects. Before engaging in a detailed critique of the report, it is first necessary to (1) have a brief yet careful understanding of the history of conducting scientific research in American prisons and (2) engage in a close reading of the 1976 Commission's report to appreciate the sensibilities leading to the current regulatory framework found at 45 C.F.R. § 46, Subpart C.

A. Background to the Current Regulatory Restrictions: Past Abuses with Using Prisoners as Human Subjects

Prisoners' participation in biomedical and behavioral research was common in the United States throughout most of the twentieth century. Today, we largely associate unethical practices such as not obtaining subjects' consent and coercion with Nazi medicine's ghastly horrors.³⁵ But these practices were

32. *Id.* at 22-23.

33. The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.

U.S. DEP'T OF HEALTH AND HUMAN SERVICES, OFFICE FOR HUMAN RESEARCH PROTECTIONS FACT SHEET, *available at* <http://www.hhs.gov/ohrp/about/ohrfactsheet.htm> (last visited May 2, 2010).

34. The Institute of Medicine provides the following background to the commissioning of this report:

The OHRP's responsibilities include implementation of the DHHS Regulations for the Protection of Human Subjects . . . and the provision of guidance on ethical issues in biomedical and behavioral research. OHRP has oversight and educational responsibilities wherever DHHS funds are used to conduct research involving human participants. The Secretary's Advisory Committee for Human Research Protections (SACHRP), the advisory committee to OHRP, has asked OHRP to rewrite Subpart C, taking into consideration the current prison environment.

OHRP recommended that, before such an effort is undertaken, there should be a thorough review of the ethical considerations in research involving prisoners, which could serve as the basis for developing new regulations. Beyond its importance regarding revisions to Subpart C, such a review would be instructive for developing ethical bases for making future changes to the DHHS Regulations for the Protection of Human Subjects and the Common Rule.

2006 IOM REPORT, *supra* note 3, at 24.

35. *See generally* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION (George J. Annas & Michael A. Grodin eds., 1992) (discussing the implications of the Nuremberg trial and the subsequent impact of the Nuremberg Code on research ethics and international human rights). Annas and Grodin write,

far from unique to the Holocaust;³⁶ ethical lapses led popular drugs such as Retin-A to be developed literally on prisoners' backs before being mainstreamed into many Americans' drug cabinets.³⁷ To be sure, the questionable practices giving rise to the dramatic postwar increase in American prisoners' human subject participation predated the Nuremberg trials by nearly half a century.

As early as 1906, Dr. Richard P. Strong—director of the Biological Laboratory of the Philippine Bureau of Science who later became a professor of tropical medicine at Harvard—gave a cholera vaccine to twenty-four Filipino inmates without their consent in order to learn about the disease; thirteen died.³⁸ Though this provides an early modern example of using prisoners as human subjects, it certainly was not the last. Twelve inmates from Mississippi's Rankin Farm prison became test subjects in 1915 to study pellagra—a disfiguring and deadly disease characterized by skin rashes and diarrhea. Though common wisdom at the time suggested that pellagra was a disease caused by germs, Dr. Joseph Goldberger—a physician in the federal government's Hygienic Laboratory, predecessor to the National Institutes of Health—thought it was linked to malnutrition characteristic of Southern rural poverty. After Mississippi Governor Earl Brewer promised pardons to all participants—an inducement to participate in research that would be intolerable today—Goldberger tried to prove his theory that poor diet caused pellagra by subjecting inmates to what many called a “hellish experiment”: eating exclusively high-starch foods such as “corn bread, mush, collards, sweet

[t]he most important historical forum for questioning the permissible limits of human experimentation was the trial of Nazi physicians in post-World War II Nuremberg, Germany. The trial provided the occasion for a substantive analysis of ethical standards. The physicians and professors prosecuted at Nuremberg represent a frightening example of medicine gone wrong. The extent of human experimentation, atrocities, and murders that were recorded during the trials is inescapable.

Id. at 3.

36. [T]he Nazis were not the only ones to involve doctors in evil. One need only look at the role of Soviet psychiatrists in diagnosing dissenters as mentally ill and incarcerating them in mental hospitals; of doctors in Chile (as documented by Amnesty International) serving as torturers; of Japanese doctors performing medical experiments and vivisection on prisoners during the Second World War; of white South African doctors falsifying medical reports of blacks tortured or killed in prison; of American physicians and psychologists employed by the Central Intelligence Agency in the recent past for unethical medical and psychological experiments involving drugs and mind manipulation; and of the “idealistic” young physician-member of the People's Temple cult in Guyana preparing the poison (a mixture of cyanide and Kool-Aid) for the combined murder-suicide in 1978 of almost a thousand people. Doctors in general, it would seem, can all too readily take part in the efforts of fanatical, demagogic, or surreptitious groups to control matters of thought and feeling, and of living and dying.

ROBERT JAY LIFTON, *THE NAZI DOCTORS: MEDICAL KILLING AND THE PSYCHOLOGY OF GENOCIDE* xii (1986).

37. See generally ALLEN M. HORNBLUM, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* 211-31 (1998).

38. See generally Eli Chernin, *Richard Pearson Strong and the Iatrogenic Plague Disaster in Bilibid Prison, Manila, 1906*, 11 REV. INFECTIOUS DISEASES 996, 996 (1989).

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potatoes, grits and rice” that caused considerable pain, lethargy, and dizziness.³⁹ Despite their pleadings to end the study, prisoners were not allowed to withdraw.⁴⁰ And, in an early 1920s experiment that was as bizarre as it was gratuitous, 500 inmates at California’s San Quentin prison had testicular glands from rams, boars, and goats implanted into their scrotums to see if their lost sexual potency could be rejuvenated.⁴¹

Though rare in the early twentieth century, these experiments highlight basic breaches in human subject protections that would be unconscionable under modern rules: the cholera test subjects had no idea what they were being infected with, the prisoners in the pellagra study were not allowed to stop their participation despite enduring substantial pain, and the San Quentin study’s purpose and mechanism were questionable. In all, prisoners were used during the early 1900s as convenience populations that had little control over their own health and welfare.

World War II turned these small-scale endeavors into “considerably larger[,] broad-scale investigations that were adequately funded and well-staffed.”⁴² The war played a central role in giving legitimacy to unbridled human experimentation in prisons.⁴³ One infamous study was the Stateville Prison Experiments, where researchers deliberately infected over 400 state inmates with malaria in order to test treatments that were considered urgent for

39. HORNBLUM, *supra* note 37, at 78.

40. HORNBLUM, *supra* note 37, at 78-79. Hornblum writes, Goldberger would not allow [the prisoners to be returned to the general prison population]. They had volunteered; they would have to stay the course regardless of the physical consequences. [Soon] the first skin lesions began to appear and by the end of the month all of the men showed signs of a rash on their hands, faces, and scrotums, the typical markings of pellagra.

Id., at 78.

41. In 1918,

Leo Stanley, resident physician of San Quentin prison in California . . . began transplanting testes removed from recently executed prisoners into older inmates, who in most cases testified to the recovery of sexual potency and the alleviation of many other illnesses. In 1920 the “scarcity of human material” prompted him to substitute goat, deer and boar testes, which appeared to work equally well.

E.J. Barten & D.W.W. Newling, *Transplantation of the Testis; From the Past to the Present*, 19 INT’L J. OF ANDROLOGY 205, 206 (1996).

42. HORNBLUM, *supra* note 37, at 80.

43. Hornblum writes,

The war years had become the transforming moment for human experimentation in America and particularly for penal institutions as a site of such scientific endeavors. What had once been a small, underfunded, unsophisticated cottage industry had blossomed into a well financed, broad clinical research programme investigating avant garde procedures, cures, and treatments. Human experimentation had been legitimised and prisoners had become the guinea pigs of choice for scores of inspired researchers. Public opposition to such medical initiatives was scant. The overriding goal was to win the war in Europe and Asia; everything else was secondary, including research ethics and the issue of consent. Millions of American fighters were risking life and limb daily; at the very least, lawbreakers could contribute to the war effort with similar commitment. And they did.

Allen M. Hornblum, *They Were Cheap and Available: Prisoners as Research Subjects in Twentieth Century America*, 315 BRIT. MED. J. 1437, 1440 (1997).

aiding the war effort. The Stateville Experiments were troubling for many reasons. For example, investigators—led by the University of Chicago’s Dr. Alf S. Alving—used confusing consent forms to coax inmates into being injected with a life-threatening disease. Participation was also rewarded; 317 of the 432 inmates, including twenty-four murderers and one rapist, had their sentences commuted after participating.⁴⁴

Other wartime human subject research involving prisoners included efforts to find treatments for gonorrhea, gangrene, and influenza in addition to testing ultraviolet radiation’s effectiveness in killing airborne germs. The apparent patriotism and selflessness surrounding prisoners’ wartime volunteering not only led human experimentation to go unquestioned, but also led it to be seen as an affirmative good.⁴⁵

Prisoner experiments skyrocketed in the post-war era. Despite the horrific stories that came out of the Nuremberg trials and other narratives detailing Nazi research practices, medical researchers in the United States continued to go about their business without giving much thought to the Nuremberg Code or other emerging ethical principles.⁴⁶ American exceptionalism and the increasing profit motive stemming from rapidly expanding research industries clouded opportunities for self-reflection, leading to inmates’ continued exposure to dangerous research.⁴⁷ This included radioactive blood tests, live

44. HORNBLUM, *supra* note 37, at 83.

45. For example,

[t]he U.S. Penitentiary at Atlanta, Georgia, played a critical role in the fight to conquer malaria and approached the challenge as if it were ‘a major military engagement.’ . . . [Inmates were informed by government authorities] that malaria infection was taking a toll on American soldiers far in excess of Japanese soldiers.

Approximately 600 of Atlanta’s 2,000 inmates volunteered to become ‘human guinea pigs and undergo malarial infection and treatment with new drugs that were untried on the human system.’

...

. . . Nearing the end of the experiment a reporter trumpeted the prison’s malaria project as ‘another shining light in the galaxy of wartime achievements at Atlanta.’

Id. at 83-84.

46. “The Nuremberg Code was widely regarded as ‘a good code for barbarians but an unnecessary code for ordinary physicians.’ . . . In general, there appeared to be a broad refusal among American medical scientists to draw lessons regarding their own actions from the Nuremberg medical trial.” Bruce Gordon & Ernest Prentice, *Protection of Human Subjects in the United States*, 6 J. PUB. HEALTH MGMT. 1, 3 (2000).

47. Hornblum writes,

[O]nce the war was over, there was no decline of medical experimentation in prisons. Battlefield victories were replaced by medical triumphs as the focus of governmental concern, and prisoners were once again the subjects of choice for research. The eradication of disease had become the enemy, and postwar budgetary priorities supported this societal mission. For example, in the last year of the war, the National Institute of Health received about \$700,000, which had climbed to \$36 million by 1955, and over 10 times that just 10 years later. In 1970, \$1.5 billion was awarded to some 11,000 grant applicants, nearly a third of them performing experimentation. Called “the gilded age of research” by Professor David Rothman, this new era of laissez-faire attitudes in the laboratory ushered in a frenzy for research on prisoners that lasted for over a quarter century. Rothman argues that a “utilitarian ethic” was able to dominate the field of human experimentation because “the benefits seemed

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cancer cell injections, and even behavioral and mind control experiments. It was not uncommon for inmates to be either purposely given a disease or kept from safer alternatives in order to test experimental drugs or procedures. This quickly became standard fare: according to some reports, ninety percent of all new pharmaceuticals were tested on prisoners until the 1970s.⁴⁸

B. Mounting Concerns and Current Regulatory Framework

Sensibilities began to shift in the 1970s with a number of revelations regarding the unethical treatment of vulnerable communities—both prisoners and non-prisoners. The growing criticism of human subjects research among the general population was ushered in by a number of events,⁴⁹ but none so striking as the Tuskegee experiment where rural Black men with syphilis were deliberately left untreated so that researchers could study the course of the disease.⁵⁰ However, public exposure of what was happening within prisons also played a key role. For example, it was during this period that the Holmesburg Prison experiments became public—where an array of human subjects studies coordinated in large part by the University of Pennsylvania used prisoners to explore everything from shampoo and deodorants to dioxin and chemical warfare materials. Major pharmaceutical companies were involved, such as Dow Chemical and RJ Reynolds, not to mention the United States Army.⁵¹

With these revelations came the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was created by the National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974),

so much greater than the costs” and because “there were no groups or individuals prominently opposing such an ethic.

Hornblum, *supra* note 43, at 1439.

48. Ian Urbina, *Panel Suggests Using Inmates in Drug Trials*, N.Y. TIMES, Aug. 13, 2006, § 1, at 1.

49. By the early 1970s, social and political indifference to human experimentation had begun to shift. Events as disparate as drug scares (thalidomide), hospital embarrassments (the use of 22 senile patients for live cancer cell studies at the Jewish Chronic Disease Hospital in New York City), alarming articles in professional journals (Dr Henry Beecher’s analysis of unethical medical studies), and popular books (Jessica Mitford’s *Kind and Usual Punishment*) contributed to a growing repugnance towards scientific experiments on unwitting and institutionalized populations.

Hornblum, *supra* note 43, 1440.

50. Susan M. Reverby writes,

In the counties surrounding [Tuskegee, Alabama], the U.S. Public Health Service ran a forty-year study, from 1932 to 1972, of “untreated syphilis in the male Negro,” while telling the men in the study that they were being “treated” for their “bad blood.” The outcry over the study, which affected approximately 399 African-American men with the disease and 201 controls, led to a lawsuit, Senate hearings, a federal investigation, and new rules about informed consent. It provided a powerful metaphor for racism, ethical mistakes, and the danger of state-run medical research.

Susan M. Reverby, *More Than Fact and Fiction: Cultural Memory and the Tuskegee Syphilis Study*, 31 THE HASTINGS CTR. REP. 22 (2001).

51. See generally HORNBLUM, *supra* note 37.

to “develop ethical guidelines for the conduct of research involving human subjects and to make recommendations for the application of such guidelines to research conducted or supported by [what is now called the Department of Health and Human Services.]”⁵² The Commission based its recommendations, published in 1976, on an examination of “the conditions under which such research is conducted, and the possible grounds for continuation, restriction or termination of such research.”⁵³ To do this, “members and staff made site visits to four prisons and two research facilities outside prisons that use prisoners, in order to obtain first-hand information on the conduct of biomedical research and the operation of behavioral programs in these settings.”⁵⁴ These visits included interviews with prisoners who had participated in research while incarcerated as well as with non-participants.⁵⁵

For the Commission, the task of developing ethical practices was as much of an empirical investigation⁵⁶ as a principled one.⁵⁷ These site visits provided a grounded assessment⁵⁸ for what the Commission considered to be the key ethical consideration regarding prisoners’ human subject participation: “(1) whether prisoners bear a fair share of the burdens and receive a fair share of the benefits of research; and (2) whether prisoners are, in the words of the Nuremberg Code, ‘so situated as to be able to exercise free power of choice’ — that is, whether prisoners can give truly voluntary consent to participate in

52. NAT’L COMM’N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REP. AND RECOMMENDATIONS: RESEARCH INVOLVING PRISONERS vii (1976) [hereinafter 1976 COMMISSION REPORT].

53. *Id.* at viii.

54. *Id.*

55. *Id.*

56. The Commission took pains to visit and survey different types of prisons across the country so that its recommendations would be informed by prisoners’ diverse experiences and institutional situations. They visited the State Prison of Southern Michigan at Jackson, which at the time was the largest prison in the United States with over 5000 inmates. To have a sense of behavioral programs operating in a prison setting, the Commission visited a unit of the Washington State Penitentiary at Walla Walla and the Michigan Intensive Program Center at Marquette. They also visited the California Medical Facility at Vacaville, which mostly held prisoners referred there for medical or psychiatric reasons. *Id.*, at 33, 39.

57. In their influential text on biomedical ethics, Tom Beauchamp and James Childress identify respect for autonomy, non-maleficence, beneficence, and justice as the four principles approach to biomedical ethics, which has become known as ‘principlism.’ They note that “the four principles derive from considered judgments in the common morality and medical traditions.” TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 23 (5th ed. 2001).

58. In the 1976 Commission report,

[T]he Commission has noted and cannot ignore serious deficiencies in living conditions and health care that generally prevail in prisons. Nor can the Commission ignore the potential for arbitrary exercise of authority by prison officials and for unreasonable restriction of communication to and from prisoners. The Commission, although acknowledging that it has neither the expertise nor the mandate for prison reform, nevertheless urges that unjust and inhumane conditions be eliminated from all prisons, whether or not research activities are conducted or contemplated.

1976 COMMISSION REPORT, *supra* note 52, at 5.

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research.”⁵⁹ By explicitly referencing the Nuremburg Code, the Commission implied that the abuses conducted by American physicians and researchers raised concerns similar to those raised by scientists put on trial after World War II. To the extent that the American research industry did not see itself in this manner, drawing upon the Nuremburg Code to ground recommendations for American physicians’ behavior was a profound paradigm shift. To be sure, the Commission notes, “it is within the context of a concern to implement these principles that the Commission has deliberated the question of use of prisoners as research subjects.”⁶⁰

This sensibility led the Commission to take a protectionist approach in providing recommendations regarding prisoners’ participation in biomedical and behavioral research.⁶¹ In applying the basic ethical principles of justice (“that persons and groups be treated fairly”)⁶² and respect for persons (“that the autonomy of persons be promoted and protected”)⁶³ the Commission forwent other interpretations and favored the protection of prisoners from abuse and exploitation:

When persons seem regularly to engage in activities which, were they stronger or in better circumstances, they would avoid, respect dictates that they be protected against those forces that appear to compel their choices. *It has become evident to the Commission that, although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom.* The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation. Hence it calls for certain safeguards intended to reduce the elements of constraint under which prisoners give consent and suggests that certain kinds of research would not be permitted where such safeguards cannot be assured.

Further, a concern for justice raises the question whether social institutions are so arranged that particular persons or groups are burdened with marked disadvantages or deprived of certain benefits for reasons unrelated to their merit, contribution, deserts or need. . . . To the extent that participation in research may be a burden, the Commission is concerned to ensure that this burden not be unduly visited upon prisoners simply because of their captive status and administrative availability.⁶⁴

59. *Id.*

60. *Id.* at 6.

61. The Commission notes,

[r]eflection upon [the principles of justice and respect for persons] and upon the actual conditions of imprisonment in our society has led the Commission to believe that prisoners are, as a consequence of being prisoners, more subject to coerced choice and more readily available for the imposition of burdens which others will not willingly bear. Thus, it has inclined toward protection as the most appropriate expression of respect for prisoners as persons and toward redistribution of those burdens of risk and inconvenience which are presently concentrated upon prisoners.

Id. at 8.

62. *Id.* at 5.

63. *Id.* at 5-6.

64. *Id.* at 6-7 (emphasis added).

While the Commission's definitions of "justice" and "respect for persons" as motivating ethical principles may seem vague, they nonetheless gave substance to its protectionist approach that, in turn, led to five key recommendations.⁶⁵

The Belmont Report⁶⁶ informed new rules in the Code of Federal Regulations that strengthened all human subject protections.⁶⁷ Additional subparts were added to provide specific protections for research involving vulnerable subjects—pregnant women, human fetuses, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). Established in 1978, Subpart C reflects many of the recommendations put forth by the 1976 Commission. It permits research with prisoners only when it falls within one of

65. *See generally id.*, ch. 2. The commission's recommendations can be summarized as follows: (1) Studies of the possible causes, effects, and processes of incarceration and prisons as institutions may be conducted if they only present minimal risk or inconvenience to subjects. (2) Research on practices that are intended to improve prisoners' health or well-being are permitted. (3) Other studies that fall outside of the aforementioned parameters should not be permitted unless (a) they fulfill an important need and there are compelling reasons to use prisoners; (b) conditions of equity support the use of prisoners; and (c) there is a high degree of voluntariness among participants and openness by the institution. (4) The head of the responsible federal department should determine the investigators' competency and the adequacy of the research facilities. Moreover, all research proposals involving prisoners should be approved by an Institutional Review Board (IRB). (5) Ongoing research projects that fall underneath the third recommendation shall continue until one year from the recommendations' publication or their completion, whichever comes first.

66. On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by [sic] creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. . . .

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy.

NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS (1979), *available at* <http://ohsr.od.nih.gov/guidelines/belmont.html> [hereinafter BELMONT REPORT].

67. 45 C.F.R. § 46 (2009).

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four categories:

1. Studying the possible causes, effects, and processes of incarceration and/or criminal behavior,
2. Studying prisons as institutional structures or prisoners as incarcerated persons
3. Research on conditions that particularly affect prisoners as a class, and
4. Research developed to improve subjects' health and well-being.

Minimal risk, or that the potential harm does not exceed what one might encounter in daily life or routine medical examination, is this subpart's general standard. Under this framework (which only applies to research funded or conducted by the Department of Health and Human Services, Social Security Administration, CIA, or voluntarily compliant institutions⁶⁸), "the default position is that no such research should occur, and the four or five categories of research allowed under the regulations are essentially exceptions to that general rule."⁶⁹

C. The 2006 IOM Report and Its "Evolved" Ethical Framework for Evaluating Prison Research

The Institute of Medicine's 2006 report, *Ethical Considerations for Research Involving Prisoners*, was commissioned by the Department of Health and Human Services, whereby the charge of the Committee "was to explore whether the conclusions reached in 1976 . . . remain appropriate today."⁷⁰ Weighing in at 265 pages, the report takes what appears to be an exhaustive look at all of the issues involved. Concluding that current restrictions should be loosened while boosting overall oversight, the IOM makes five major recommendations:

1. Expand the definition of prisoner
2. Ensure universal, consistent ethical protection
3. Shift from a category-based to a risk benefit approach to research review
4. Update the framework to include collaborative responsibility (e.g. developing research in collaboration with prisoners and prison staff)
5. Enhancing oversight of research involving prisoners

The first and last two recommendations are largely uncontroversial if not unequivocally beneficial in and of themselves. The first two, expanding oversight by including persons under any aspect of criminal justice supervision and ensuring universal ethical guidelines are surely an improvement over today's patchwork of federal, state, and local rules. The last two, bringing

68. Lawrence O. Gostin, *Biomedical Research Involving Prisoners: Ethical Values and Legal Regulation*, 297 JAMA 737 (2007).

69. 2006 IOM REPORT, *supra* note 3, at 73.

70. *Id.* at ix.

prisoners into the research process as collaborators and strengthening IRB oversight, will similarly find few opponents. The third recommendation—shifting from prisoners’ almost categorical exclusion from research to a more permissive risk/benefit analysis—is where the ethical road meets the legal rubber. As such, this recommendation will be the focus of this Section.

In describing how the 1976 Commission developed the current restrictions, the IOM report acknowledges the “commission’s emphasis on limiting research involving prisoners was guided by its choice of ethical framework.”⁷¹ Although the 2006 IOM Committee uses the term “ethical framework” throughout the report to both define core aspects of the 1976 Commission’s work and recommend substantial changes through an alternative approach, the IOM Committee does not define this concept precisely. A fair and plain reading of the IOM Committee’s usage of the term suggests that “ethical framework” is used to denote the ethical principles that guide each panels’ decision making with regards to the normative claims made about prisoner participation in scientific research.

As discussed earlier, current regulations (informed by the 1976 Commission’s ethical framework and findings) prioritize justice—defined here as whether prisoners are treated fairly and whether they bear a fair share of the research benefits and burdens—and respect for persons, which questions whether prisoners have enough personal autonomy to give voluntary consent. In short, the 1976 Commission felt that prison was no place to conduct widespread scientific research. The 2006 IOM Committee starts by creating “an updated ethical framework” based upon its conclusion that “ideas about justice and respect for persons have evolved over the past three decades.”⁷² Put differently, the 2006 Committee sidesteps the threshold issue concerning prison conditions presented by the 1976 Commission and instead asks whether *ideas* about ethical principles have changed. Its first evolutionary update is to “question[] the myopia caused by . . . a narrow focus”⁷³ on informed consent. After reviewing a handful of articles, the Committee notes, “[m]ore attention needs to be paid to risks and risk-benefit analysis rather than the formalities of an informed consent document.”⁷⁴ This shapes the major recommendation to stop thinking of prisoners as a category of individuals who, by default, should not be human subjects. Instead, the Committee recommends looking at each research proposal on a case-by-case basis to assess its potential risks and benefits.⁷⁵ The Committee’s second evolutionary update is to expand justice

71. *Id.* at 115.

72. 2006 IOM REPORT, *supra* note 3, at 113, 116.

73. *Id.* at 117.

74. *Id.* at 118. While a risk/benefit approach is a new proposal in the context of prison research, such analyses are not uncommon in other aspects of human subjects research. *See* CARL H. COLEMAN ET AL., THE ETHICS OF REGULATION OF RESEARCH WITH HUMAN SUBJECTS ch. 6 (2005).

75. The IOM Committee argues, “The risks and benefits of human subjects research

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from its original meaning in 1976 to now include collaborative responsibility, or that prisoners be able to give input on research design.

This shift from a *substantive* approach to justice and respect for persons (emphasizing protection, fairness, and burden-sharing) to a more *procedural* mechanism (emphasizing representation, along with the noncategorical risk/benefit analysis) constitutes the IOM Committee's "evolved" or "updated" ethical framework. These changes represent the revised first principles from which the Committee recommends loosening current human subject restrictions for prisoners. The Committee believes that prisoners' participation should no longer be highly restricted simply because they are prisoners, which runs directly against the 1976 Commission's concern with prisoners as a category of human subjects to the extent "that the status of being a prisoner makes possible the perpetration of certain systemic injustices."⁷⁶ The 2006 IOM Committee suggests changing regulatory policies to cut in a different, more permissive direction: the benefits and risks of research should be weighed independently before a decision is made.

Before moving on to a critique of this shift away from prisoners' categorical restrictions to a risk/benefit approach, it is important to note that the IOM Committee recognizes the concerns that may stem from its recommendations. Not only does it dedicate an entire chapter of the report to discussing oversight mechanisms and safeguards to accompany the recommendations, but it also provides specific guidance for conducting biomedical research with prisoners, which potentially carries the most risks.⁷⁷ Here, the IOM Committee recommends that in applying the risk/benefit framework in prison contexts, there should already be evidence of safety and efficacy (e.g., Phase III testing) and the ratio of prisoners to non-prisoners used in the study should not exceed fifty percent.⁷⁸ (The Committee notes that these rules can be disregarded "in exceptional circumstances" and with additional safeguards.⁷⁹) The IOM Committee emphasizes that biomedical research in prisons should only be done to benefit individual prisoners; inmates should not be used as a convenience population. While these additional protections are notable, this Article's focus is on how the IOM Committee reasoned to the ethical propriety of its proposed risk/benefit approach to displace longstanding categorical restrictions, not the procedural mechanisms and limitations developed afterwards.

are the ethically relevant issues, not the category of the research." 2006 IOM REPORT, *supra* note 3, at 123. The Committee acknowledges that "weighing risks against benefits is inherently subjective," but that such analysis should be based upon data to identify "the types of potential harms and benefits, their probability of occurrence, and their long term consequences." *Id.* at 118.

76. 1976 COMMISSION REPORT, *supra* note 52, at 7.

77. See generally 2006 IOM REPORT, *supra* note 3, ch. 6.

78. *Id.* at 126.

79. *Id.*

III. BEYOND CONSEQUENCES: A CRITIQUE OF THE INSTITUTE OF MEDICINE'S RECOMMENDATIONS

In an effort to assess the prevailing level of discourse and criticism, this Part begins by examining some of the commentaries published in scientific and public outlets in reaction to the Institute of Medicine's recommendations. After highlighting the largely consequentialist nature of this commentary, this Part offers a critical assessment that draws attention to significant shortcomings in the IOM's approach that have yet to be discussed.

A. Existing Commentaries on the IOM Report

The Institute of Medicine's updated ethical framework and recommendations have not been discussed widely in legal literature, and the attention they have received in the scientific community,⁸⁰ ethics scholarship,⁸¹ and the popular press⁸² has been limited. While perspectives have been mixed, there has not been a robust scholarly critique of the reasoning and methodology behind the IOM's proposed ethical stance on prisoners' participation as human subjects. Georgetown Law Professor Lawrence Gostin, who chaired the 2006 IOM Committee, wrote in the *Journal of the American Medical Association* (JAMA) that despite valid concerns, "[t]he opening of otherwise closed institutions to outside health professionals . . . could increase transparency and public accountability. Research can help society better understand how to improve prisoners' chances to succeed."⁸³ Since the current regulations only apply to research supported or conducted by a handful of federal agencies and voluntary compliant organizations, the vast majority of prison-related research occurs with little oversight. Therefore, Gostin argues, the 2006 IOM Committee's recommendations actually expand regulation by bringing all research involving incarcerated persons under the same framework. Barron H. Lerner agreed with the IOM Committee's assessment in the *New England Journal of Medicine*, writing, "[t]he panel's decision makes sense for several reasons."⁸⁴ Lerner notes that "despite the findings at Nuremberg and occasional other warnings, human experimentation was largely seen as a 'good,'

80. See, e.g., Samuel Loewenberg, *US Advisory Panel Revisits Prison Research Rules*, 368 *THE LANCET* 1143 (2006); Emily Waltz, *US Ponders Unlocking the Gates to Prisoner Research*, 12 *NATURE MEDICINE* 3 (2006).

81. See, e.g., Eric Chwang, *Against Risk-Benefit Review of Prisoner Research*, 24 *BIOETHICS* 14 (2010); Bernice S. Elger & Anne Spaulding, *Research on Prisoners: A Comparison Between the IOM Committee Recommendations (2006) and European Regulations*, 24 *BIOETHICS* 1 (2010); Thomas, *supra* note 6.

82. See, e.g., Jeffrey Brainard, *Report Calls for Easing Rules on Research Involving Prisoners*, 52 *CHRON. HIGHER EDUC.*, July 28, 2006, at A16; Urbina, *supra* note 48, at 1.

83. Gostin, *supra* note 68, at 739.

84. Barron H. Lerner, *Subjects or Objects? Prisoners and Human Experimentation*, 356 *NEW ENG. J. MED.* 1806, 1807 (2007).

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something that would advance science and benefit health.”⁸⁵ To the extent that abuses took place during previous periods, Lerner argues that the advent of Institutional Review Boards in the late 1970s provides sufficient protection to prevent their reoccurrence. Moreover, Lerner argues that the idea that prisons are coercive environments that mitigate ideals such as informed consent “is a theory that can and should be investigated empirically,” and coercive elements are present in all research regardless of subjects’ imprisonment.⁸⁶ Therefore, as another commentator notes, it is not uncommon within the research literature for people to conclude that the “type[s] of oversight described [by Lerner and Gostin], as well as in the Institute of Medicine Report, are likely to yield the benefits to incarcerated persons and minimize the risks of abuse.”⁸⁷

At first blush, it is striking that two prominent medical journals published articles strongly supporting a more permissive approach to using prisoners in scientific research. This type of support can also be seen in the bioethics literature. For example, David Thomas makes a familiar argument in the journal *Bioethics* that access to clinical trials give prisoners access to cutting edge therapies; denying this access simply because they are incarcerated may itself be unethical.⁸⁸ Other commentators, however, have taken a more sober approach. Paul Wright, founder and editor of *Prison Legal News*, writes, “the key element to any ethical system of human subject testing is informed, voluntary consent. Prisons and jails fail on all counts. All 50 states and the federal government have banned sex among prisoners and staff because detention facilities are inherently coercive, and prisoners cannot give ‘consent’ in any meaningful sense of the word.”⁸⁹ As the editor for a magazine that takes a human rights approach to incarceration, Wright is noticeably concerned that looser restrictions will result in abuses similar to those that occurred in the past. Investigative journalist Sonia Shah, an expert on the outsourcing of clinical trials to the developing world, argues that the Institute of Medicine’s recommendations have less to do with improving prisoners’ health or giving them access to cutting edge research and more to do with giving pharmaceutical companies access to human subjects when other volunteers are scarce. Moreover, Shah is not convinced that the IOM’s proposal for increased oversight for biomedical research in prison settings—such as limiting prisoner participation to Phase III trials and requiring that prisoners make up no more than half of all trial participants—are meaningful in light of broader

85. *Id.*

86. *Id.*

87. Josiah D. Rich, *Health Issues in Prisons and Jails*, 84 J. URB. HEALTH 740, 741 (2007).

88. “[I]t is the feeling of many practitioners that the only way cutting edge therapy can be given to the incarcerated is through offering clinical trials in the prison setting. Likewise, denying them the advantages of cutting-edge treatments would be tantamount to abridging their rights only because of their incarcerated situation.” Thomas, *supra* note 6, at 25.

89. Wright, *supra* note 7, at 10A.

dynamics.⁹⁰

B. Three Critiques of the IOM's Updated Ethical Framework

While the possible outcomes of the Institute of Medicine's recommendations have received considerable attention, there has been little, if any, critique of the evolved or updated ethical framework developed by the Institute of Medicine to justify its more permissive approach. Put differently, how did the Committee come to its decision? What were the Committee's reasons for supplanting the 1976 Commission's ethical framework? How do they justify recommending a substantial departure from thirty years of regulatory policies regarding prisoners' participation as human subjects? Are the reasons and ethical principles behind these justifications persuasive? Are there any limitations with the logic behind the IOM Committee's new ethical framework? The Institute of Medicine report is certainly laudable in attempting to provide better oversight for prisoners' participation as human subjects and reviewing whether the ethical commitments made three decades ago still serve prisoners' best interest. Yet, there are at least three key critiques of the committee's approach—spanning its methods, context, and substance—that raise serious questions about the Institute of Medicine's more permissive ethical framework.

1. Methodological Critique

How we come to a particular decision is often as important as the decision itself. Thus, what is meant by critiquing the methods behind the Institute of Medicine's report is to investigate the data, assumptions, conclusions, and arguments that inform the ethical choices that are made. What *process* did the

90. For example, Shah discusses the difficulty of recruitment:

The bottleneck for drugmakers is in recruiting warm bodies for late-phase trials that establish a new product's effectiveness with statistical certainty. These "Phase 3" trials can require tens of thousands of patients to complete, and most drug-saturated Americans are reluctant to take part. Eighty percent of trials fail to meet recruitment deadlines, bleeding drugmakers of \$1 million a day while their blockbuster wannabes remain locked up in development.

To solve the dilemma, many drugmakers have rushed overseas, to places like India and Poland, where sick, desperate patients are abundant. Now, if the institute's recommendations hold sway, they'll be able to access the 7 million souls captive to the US correctional system as well. The institute's proposed caveat that prisoner experiments include subjects from outside prison walls as well will make little practical difference in such trials. Few, if any, drugmakers would want to restrict these huge trials to prisoners anyway.

Sonia Shah, Op-Ed., *Testing Drugs on Prisoners: The Easy Out*, BOSTON GLOBE, Aug. 17, 2006, at A13. See also Leda M. Perez & Henrie M. Treadwell, *Determining What We Stand For Will Guide What We Do: Community Priorities, Ethical Research Paradigms, and Research With Vulnerable Communities*, 99 AM. J. PUB. HEALTH 201 (2009) (arguing that "until the question of adequate health care for prisoners is resolved, human experimentation should not be allowed.").

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Institute of Medicine Committee engage in to identify, collect, and analyze the data that informs its recommendations? And was this process robust enough to form the basis for a new ethical framework that suggests significant policy changes?

The first methodological issue concerning the Institute of Medicine's updated ethical framework stems from the fact that the Committee "visited one prison and one prison medical facility to discuss experimentation with current prisoners and peer educators."⁹¹ This rather cursory first-hand look at the modern conditions of prison life is a stark contrast to the more in-depth examination made by the 1976 Commission, which based its recommendations on conditions observed during four site visits made to different types of prisons across the country. The 1976 Commission based its assessment on an empirical investigation into prisoners' lived conditions and developed an ethical framework of protectionism that evolved out of its grounded assessment that basic ethical norms of justice and respect for persons would be difficult to achieve in a prison setting.⁹² Not only did the Institute of Medicine Committee not replicate the methodological rigor behind this approach, they also did not fully engage the *conditional* nature of the 1976 Commission's sense of when these restrictions should be lifted: "should coercions be lessened and more equitable systems for the sharing of burdens and benefits be devised, respect for persons and concern for justice would suggest that prisoners not be deprived of the opportunity to participate in research."⁹³

The 2006 IOM Commission's lack of engagement with this conditional statement is notable. As a matter of precedent, that is where the 1976 Committee left the conversation. Ethic's engagement with precedent—not unlike precedent's role in legal reasoning—can promote stability, consistency, and predictability that ultimately protect the most vulnerable parties involved. Many of the 2006 Committee's recommendations can be read as providing a more equitable system of burdens and benefits sharing. But the issue of whether coercion has been lessened is an *empirical question* that is difficult to answer with one site visit. Moreover, it is also difficult to come to any *policy recommendation*—ethical in nature or otherwise—without committee members taking a more serious first-hand look at the conditions shaping modern prison life. This imperative is even more compelling if the committee's leanings are to contravene three decades of ethical and administrative precedent to loosen restrictions initially developed to protect prisoners from exploitation. To the IOM Committee's credit, it did collect information from six state corrections departments regarding their policies and practices pertaining to research with prisoners.⁹⁴ But, there is a strong argument—particularly when judged by the

91. 2006 IOM REPORT, *supra* note 3, at 122.

92. *See generally* 1976 COMMISSION REPORT, *supra* note 52.

93. *Id.* at 8.

94. 2006 IOM REPORT, *supra* note 3, at 59.

standard set by the 1976 Commission—that this is insufficient for the Committee to gain an adequate appreciation for the unique challenges posed by conducting scientific research in a prison setting. This issue becomes even more relevant once one takes into consideration that all available evidence suggests that the conditions of prison life that might lead to coercion are unlikely to have improved and are most likely to have worsened since 1976.⁹⁵

This first critique concerning the Institute of Medicine’s cursory assessment of modern prison life is inextricably intertwined with a second methodological critique. Rather than engaging in an empirical understanding of prison conditions and how this may affect prisoners’ participation in scientific research, the Institute of Medicine relies heavily on shifting academic perspectives to form its ethical framework. What is remarkable, however, is that the Institute of Medicine Committee bases this new framework—which drives its policy recommendation to loosen restrictions—*not* on a substantial shift in the literature documenting prison experiences, but rather on what it calls an evolution in the ethics literature:

Ideas about justice and respect for persons have evolved over the past three decades. To construct a comprehensive ethical framework for thinking about research in prisons, [we] explore[] recent research ethics scholarship. Changes in the way these principles have been conceptualized have influenced the shape of our recommendations.⁹⁶

Put another way, *the committee bases its recommendations largely on a literature review*. For example, the IOM Committee’s expanded view of respect for persons was informed by “recent scholarship [that] has questioned the myopia caused by such a narrow focus”⁹⁷ on informed consent. They reference Kahn, Mastroianni, and Sugarman’s edited volume *Beyond Consent: Seeking Justice in Research* for the proposition that “[t]here seems to be agreement from a variety of perspectives that informed consent forms have consumed too much time and energy.”⁹⁸ This leads the IOM Committee to question “whether too much weight has been placed on informed consent in the framework of research ethics and research regulation,”⁹⁹ which ultimately leads them to state that “questions about an undue focus on informed consent influence [its] recommendations.”¹⁰⁰ It is this literature review based critique of informed consent that shapes the Committee’s most significant recommendation to change current regulatory policy: the shift from treating prisoners as a

95. For discussions of prison ethnographies that provide a close analytical look at the lived experiences of prisoners in today’s penal system, see, e.g., Jonathan Simon, *The Society of Captives in the Era of Hyper-Incarceration*, 4 THEORETICAL CRIMINOLOGY 285 (2000); Loic Wacquant, *The Curious Eclipse of Prison Ethnography in the Age of Mass Incarceration*, 3 ETHNOGRAPHY 371 (2002).

96. 2006 IOM REPORT, *supra* note 3, at 116.

97. *Id.* at 117.

98. *Id.*

99. *Id.* at 118.

100. *Id.*

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categorically excluded group (with few exceptions) to a more permissive risk/benefit assessment.¹⁰¹ Similarly, the IOM committee bases its recommendation to shift from a strong protectionist model (which was highly preferred by the 1976 Commission) to a moderate protectionist approach on the notion that “[a]dvances in ethical thinking about protectionism suggest a new regulatory model.”¹⁰² As a side note, it is interesting to point out that the IOM Committee provides additional justification for its more moderate approach to protectionism (and its ultimate recommendation to loosen restrictions) by pointing to empirical data gathered by the 1976 Commission in which several interviewed prisoners said that they appreciated the opportunity to participate in research¹⁰³—a sentiment corroborated by other prisoners during the IOM Committee’s singular site visit. But what the IOM Committee fails to disclose is the extent to which the 1976 Committee found prisoners’ apparent willingness to participate irrelevant to the broader question of the ethics of using prisoners in research given their particular circumstances. The 1976 Commission notes that it “did not find in prisons the conditions requisite for a sufficiently high degree of voluntariness and openness, notwithstanding that prisoners currently participating in research consider, in nearly all circumstances, that they do so voluntarily and want the research to continue.”¹⁰⁴

This methodological approach of using literature reviews as a basis for developing regulatory policy also informs the IOM Committee’s approach to its “evolved” understanding of justice. The first aspect of this evolution—collaborative responsibility—stems from the Committee’s assessment that the “conceptualization of justice has expanded since the original [1976] commission’s work. They primarily thought of justice in terms of the distribution of risks and benefits.”¹⁰⁵ The IOM Committee shifts this take on justice to include a concept of collaborative responsibility, which means that multiple stakeholders such as prisoners and representatives from outside community groups should participate in the conduct and design of research

101. “More attention needs to be paid to risks and risk-benefit analysis rather than the formalities of an informed consent document.” *Id.*

102. *Id.* at 121.

103. The Institute of Medicine Committee notes that in 1975, commission members spoke,

with a representative sample of research participants and nonparticipants selected by commission staff from a master list of all prisoners [in Jackson State Prison] and found that, overall, participants valued the opportunity to participate in research and felt they were sufficiently informed and free to enroll or withdraw at will, and nonparticipants did not object to this opportunity being available to others.

Id. at 121-122.

104. 1976 COMMISSION REPORT, *supra* note 52, at 12. With regards to the eagerness of the Michigan inmates to participate, the 1976 Commission placed this enthusiasm in a different context: “Participants gave many reasons for volunteering for research, including better living conditions, need for good medical evaluation, and desire to perform a worthwhile service to others, *but it was clear that the overriding motivation was the money they received for participating.*” *Id.* at 35 (emphasis added).

105. 2006 IOM REPORT, *supra* note 3, at 127.

proposals that include prisoners.¹⁰⁶ Working from Lisa Eckenwiler's 2001 article *Moral Reasoning and the Review of Research Involving Human Subjects*, the committee embraces this perspective to counterbalance its proposed risk/benefit shift away from prisoners' categorical restrictions as human subjects.¹⁰⁷ The IOM Committee also references scholarly work by Alex John London¹⁰⁸ and Madison Powers¹⁰⁹ to note that an evolved notion of justice "requires that [research with prisoners] must be done in a setting in which there is an adequate standard of health care in place."¹¹⁰

Although the ethical evolution involved in the IOM Committee's new understanding of justice will find few objections, there are still significant methodological problems with basing policy recommendations on literature reviews, particularly with regards to the IOM Committee's updated ethical framework on respect for persons. While there is certainly a place for assessing academic perspectives as part of the process of reviewing the adequacy of current regulations, prisons are profoundly unique environments whose every nuance and empirical reality must be brought into the policymaking process. There is a strong argument that the focus of the Committee's ethical reasoning—that "[i]deas about justice and respect for persons have evolved over the past three decades"¹¹¹—misses the point. The question is not simply whether academics, clinical practitioners, and other medical professionals have

106. The IOM Committee notes this

"involves acknowledging that groups are not monolithic and are themselves subject to a range of problems that should be addressed in the consultation process. This recommendation has two aspects: (1) including more lay people who match the local population and common subject groups in key respects; and (2) shaping IRBs so they are hospitable places for lay members."

Id. at 128.

107. The IOM Committee writes,

[A] new risk-benefit approach needs to be accompanied by an emphasis on collaboration. The ethical problems associated with research involving prisoners will manifest themselves differently in each correctional setting. The one-size-fits-all approach characterized by a focus on informed consent cannot adequately address the unique concerns presented by each setting. Thus all relevant parties should be involved (prisoners, correctional officers, medical staff, administrators) when creating and implementing a research protocol. This effort, combined with a more specific focus on risks and benefits, can lead to research practices that better incorporate justice and respect for persons.

Id. at 128-29.

108. Alex John London, *Justice and the Human Development Approach to International Research*, 35 HASTINGS CTR. REP. 24 (2005).

109. Madison Powers, *Theories of Justice in the Context of Research*, in BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 147-65 (Jeffrey P. Kahn et al. eds., 1998).

110. 2006 IOM REPORT, *supra* note 3, at 132. The committee notes,

that this expanded concept of justice is an important ethical development. Justice requires more than the protection of prisoners from harm caused by the research itself. Ethical research carries with it a responsibility to grapple with the fact that potential harm is ubiquitous in everyday prison life, creating an environment for research in which the choice to participate in a study can be inherently coercive and potentially dangerous.

Id.

111. *Id.* at 116.

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changed their minds, but more importantly whether the conditions giving rise to the 1976 Commission's ethical framework—such as coercion and lack of privacy—have been substantively addressed. The IOM Committee does not fully address this threshold question.

To be clear, the IOM certainly identifies the ways prisons have changed since the 1976 Commission issued its report; an entire chapter in the IOM report examines today's prisons in terms of shifting demographics, health issues, and the current environment.¹¹² In addition to the prison and jail population's astronomical growth since restrictions in prisoners' human subject participation were implemented—from 454,444 inmates in 1978 to 2.1 million in 2004—the committee dutifully notes a number of challenges to conducting ethical human subjects research under these conditions. These include serious overcrowding, racial and ethnic disparities, disproportionately high rates of mental illness and chronic and infectious disease, poor health care, and high rates of violence, rape, and suicide. Nearly twenty-five percent of all inmates report being injured at least once since entering prison.¹¹³

What is concerning, however, is that the IOM isolates these conditions in recommending greater oversight mechanisms—such as a public database for all research with prisoners—without discussing how these conditions bear on its chosen ethical framework, which drives its ultimate policy recommendation. Put differently, the realities of prison life are separated from the Committee's investigations rather than integrated and grappled with as part of the fundamental ethical inquiry. As an example, for a prisoner who is routinely sexually assaulted by other prisoners—a situation not uncommon among today's inmates¹¹⁴—what does privacy and informed consent mean and how would this shape said prisoner's ability to freely participate in human subjects research that might adversely affect his health? By limiting concerns over prison conditions to questions of oversight rather than to the ethical propriety of using prisoners as human subjects, the report gives little guidance as to how to answer such questions.

But the issue with the literature-review-as-public-policymaking approach is not simply that this method is problematic on its face, but also that the Institute of Medicine Committee uses this problematic method in a particularly problematic way. First and foremost, the literature review used to justify recommendations for substantial regulatory policy changes was not as robust as it could be. For example, to ground its claim that “[t]here seems to be agreement from a variety of perspectives that informed consent forms have consumed too much time and energy,”¹¹⁵ the IOM Committee points to one

112. *See generally id.*

113. *See generally id.* at 29-55.

114. *See generally* HUMAN RIGHTS WATCH, NO ESCAPE: MALE RAPE IN U.S. PRISONS (2001).

115. 2006 IOM REPORT, *supra* note 3, at 117.

edited volume.¹¹⁶ For such a broad statement about an entire scholarly field and its wide reaching implications—beyond the question of using prisoners as human subjects—it is reasonable to think that the IOM would engage in a more nuanced discussion of this issue before concluding “[t]hese questions about an undue focus on informed consent influence our recommendations.”¹¹⁷

But in addition to the less than comprehensive nature of the Institute of Medicine’s literature review is the problem that very few of the key articles relied upon to give legitimacy to its updated or evolved ethical framework actually deal with the issue of conducting research in prisons.¹¹⁸ For example, Ezekiel Emmanuel et al.’s *JAMA* article *What Makes Clinical Research Ethical?* is heavily relied upon by the IOM Committee to justify its updated ethical framework. It substantially redefines informed consent and displaces categorical restrictions in favor of risk/benefit analyses. Yet, it does not discuss the unique ethical challenges posed by using prisoners as human subjects.¹¹⁹ And, contrary to the Committee’s assertion that this article reflects the ethical evolution it proposes, the author states in the opening paragraph that traditional informed consent continues to “reflect[] the preponderance of existing guidance on the ethical conduct of research,”¹²⁰ which belies the Committee’s argument that ethics *as a field* has evolved in a direction similar to its proposed framework. Similarly, albeit less problematically, the IOM Committee singularly cites Lisa Eckenwiler’s 2001 article as a basis for its evolved perspective on justice including collaborative responsibility when Eckenwiler’s discussion is not about the particular concerns raised by research in a prison context.

These concerns point to substantial tensions within the IOM’s proposed ethical framework. In its attempt to discuss the ethics of doing research in a fraught and historically disfavored environment such as prisons, the IOM Committee reviews literature *written outside of the prison context* that does not address its particularities, abstracts the principles from this scholarship as universally applicable, and then reincorporates them as morally and

116. See generally BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH (Jeffrey P. Kahn et al. eds., 1998). The IOM Committee cites to this one edited volume to ground its assertion that there is a consensus perspective among ethicists regarding informed consent. They cite to an article by Ezekiel Emanuel to discuss and ground an alternative risk/benefit approach, which they ultimately embrace.

117. 2006 IOM REPORT, *supra* note 3, at 118.

118. One exception is Jonathan Moreno’s “Convenient and Captive Populations,” which is part of the BEYOND CONSENT volume edited by Kahn et. al., which spends three and a half pages on conducting research in prisons. Jonathan D. Moreno, *Convenient and Captive Populations*, in BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 113-16 (Jeffrey P. Kahn et al. eds., 1998). This article does not appear to have played a major role in the IOM’s decision-making, unlike other articles that were written against a distinctly non-prison backdrop.

119. Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?* 283 *JAMA* 2701 (2000).

120. *Id.*

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situationally appropriate into an “updated” ethical framework that itself does not meaningfully engage with modern prison conditions. This is a strained methodology that privileges theory over lived conditions, which may very well be disastrous given prisoners’ vulnerable position.

Nevertheless, the Institute of Medicine Committee may very well justify this method of inquiry by highlighting that the task charged to it by the Department of Health and Human Services was “to review the ethics regarding research involving prisoners.”¹²¹ By emphasizing that ethics is a humanistic field that has traditionally existed outside of empirical inquiries, the IOM might defend its methods by arguing that ethical inquiries typically entail philosophical investigation into the human condition that can be most clearly ascertained through the relevant scholarly literature. Moreover, it may reasonably defend its approach by saying that given the structure of its study process as well as other institutional imperatives, the Committee is neither equipped nor designed to engage the type of empirical scrutiny encouraged by this Article.¹²²

Yet, this explanation leaves much to be desired. While ethics is often identified as a philosophical endeavor anterior to empirical social science, a strong body of literature has developed over the past few decades that has led to a growing movement of “empirical ethics” or “evidence-based ethics” that entails “the application of research methods in the social sciences (such as anthropology, epidemiology, psychology, and sociology) to the direct examination of issues in bioethics.”¹²³ Jacoby and Siminoff describe this shift through discussing the work of Renee Fox:

[In 1989] Fox . . . produced an eloquent analysis of the relationship between bioethics and the social sciences characterizing it as “. . . tentative, distant and susceptible to strain.” In her analysis, she described how each field contributed to the tension—bioethics largely due to its focus on individualism and equating the social sciences with a quantitative and non-humanistic perspective, and the social sciences due to their limited interest in studying values and beliefs and favoring structural and organizational variables which, she contended, reduced their understanding of the importance of ethical and moral values in society. Her conclusion was that the ethos of both fields, with resultant “blind spots,” constituted barriers to collaboration and synergy.

Since this bleak picture was articulated two decades ago, the relationship between the two fields has evolved to the point where bioethics is a multidisciplinary field of study (as opposed to a singular discipline), where moral philosophy, the medical sciences, the humanities, and the social sciences intersect.¹²⁴

121. 2006 IOM REPORT, *supra* note 3, at ix.

122. See generally THE NATIONAL ACADEMIES, OUR STUDY PROCESS, *supra* note 17.

123. Maya J. Goldenberg, *Evidence Based Ethics? On Evidence-based Practice and the ‘Empirical Turn’ From Normative Bioethics*, 6:11 BMC MED. ETHICS 1, 2 (2005), available at <http://www.biomedcentral.com/1472-6939/6/11>.

124. LIVA JACOBY & LAURA A. SMINOFF, EMPIRICAL METHODS FOR BIOETHICS: A

Examples of the increasing incorporation of empirical methods into bioethics abound.¹²⁵ At bioethics' inception as a modern field of study in the mid 20th century, empirical methods were not widely used to explore issues such as human subject protections due to social scientists' initial detachment from the field (which was then dominated by philosophers and theologians¹²⁶), communication disjunctions across disciplinary boundaries, and meta-ethical distinctions between descriptive pursuits of "the is" and normative conclusions over "the ought."¹²⁷ Indeed, it was believed that empiricists and bioethicists operated in two distinct fields, where the former collected data and the latter assessed them. But, the advantages of greater integration between the fields quickly became apparent in its ability to supplement abstract theory with practical accounts of reality. That is, it has become increasingly acknowledged that credible accounts of what we ought to do should be grounded in an accurate assessment of lived conditions. This is precisely the contribution offered by empirical ethics.

Hence, while the IOM Committee may have identified certain evolutionary trends in the field of ethics since the 1976 report, its failure to recognize this major trend towards grounding ethics in empirical assessments and its relevance to the Committee's inquiry erects a substantial barrier to its recommendations. To not pursue a serious empirical investigation of how modern prison conditions shape the ethical question of research in this environment—let alone recognize the importance of such an investigation in its literature review—severely limits the report's recommendations. Moreover, even if one concedes that a literature review is an appropriate basis for regulatory policymaking, then the review ought to be more substantive than citing one or two articles as a basis for recommending changes to over three decades of regulatory precedent. And if the study process for IOM Committees

PRIMER 2 (Liva Jacoby and Laura A. Siminoff eds., 2008).

125. For interesting overviews of the empirical turn in bioethics, see Richard E. Ashcroft, *Constructing Empirical Bioethics: Foucauldian Reflections on the Empirical Turn in Bioethics Research*, 11 HEALTH CARE ANALYSIS 3 (2003); Pacal Borry, Paul Schotsmans, and Kris Dierickx, *The Birth of the Empirical Turn in Bioethics*, 19 BIOETHICS 49 (2005).

126. See generally ALBERT R. JONSEN, *THE BIRTH OF BIOETHICS*, chs. 2, 3 (1998).

127. Descriptive ethics is the field in which empirical data about moral issues are gathered. It is the domain par excellence of sociology, anthropology, psychology, and epidemiology, and it aims at describing peoples' temporal values, rules, preferences, norms, and actions. These disciplines describe how reality is constructed—they describe what 'is.' However, they can never tell how people ought to behave, or what kinds of decisions are morally acceptable. According to most authors, this fundamental distinction stems from a small paragraph of David Hume's *Treatise of Human Nature* (1740), and is traditionally called the naturalistic fallacy. It is a logical mistake to infer a necessary conclusion from premises that are contingent in their modality, or to assign contingency to a conclusion that is inferred from premises that are necessary in their modality. The naturalistic fallacy consequently stresses that it is false reasoning to draw an ought-conclusion from premises that entirely consist of is-statements—one can never extrapolate an 'ought' from an 'is.' For this reason, ethicists became convinced that the results of social science research could never be useful for ethical reflection.

Borry, et al., *supra* note 125, at 60.

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cannot support empirical inquiries as basic as that which was pursued by the 1976 Commission (e.g. multiple site visits across diverse penal institutions), then perhaps it is not the appropriate organization to weigh in on such issues.

2. Contextual Critique

The Institute of Medicine report uses past abuses with research in prisons as the main basis from which to situate its recommendations. This means that this history functions as the primary contextual backdrop informing how the IOM understands the situation, the risks and dangers involved, and the sensitive ethical terrain that needs to be navigated. This history provides a context that informs every aspect of the report, perhaps as a way to demonstrate a commitment to not allowing the past to become present. This is evident in different ways. The most explicit example is the report's second chapter, where the Committee discusses current prison demographics, health issues, and research environment in relation to the past.¹²⁸ This chapter provides a veritable laundry list of all the conditions that complicate the idea of conducting ethical research in prison environments—and how these conditions have worsened in just about every conceivable way. Health care is abysmal,¹²⁹ the incarcerated population has exploded and prisons are overcrowded,¹³⁰ racial minorities are disproportionately represented,¹³¹ the number of incarcerated women has

128. The second chapter's opening sentence reads, "The conditions of confinement in today's prisons and jails have many of the same characteristics that were of concern to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research . . . some 30 years ago." 2006 IOM REPORT, *supra* note 3, at 29.

129. For example, the 2006 IOM report says,

Health care within some prison systems is less than satisfactory. . . . [A] federal district court judge placed California's entire prison medical health-care system into federal receivership, taking it out of control of the state and placing it under the control of a trustee appointed by the court. In addition, the entire state prison mental health system is being monitored by another federal court after being found to be providing constitutionally inadequate mental health services to inmates with serious mental illnesses. . . . And New York regulators have faulted the private firm Prison Health Services in several deaths within the state's prison system.

Id. at 29-30.

130. The IOM Committee notes "the correctional population has expanded more than 4.5 fold between 1978 and 2004—from 1.5 million to almost 7 million. Prisons and jails house 2.1 million prisoners; an additional 4.9 million are on probation and parole." *Id.* at 58.

131. The report discusses racial disparities:

Blacks and Hispanics are disproportionately represented in prison and jail populations. At midyear 2004, an estimated 12.6 percent of all black males in their late 20s were in prisons or jails compared with 3.6 percent of Hispanic males and 1.7 percent of white males. Young Black men are particularly hit hard. One in eight black men in their late 20s is incarcerated on any given day. A report of the National Center on Institutions and Alternatives indicated that in the District of Columbia, 50 percent of young black men ages 18 to 35 were under criminal justice supervision (in prison, jail, probation, parole, out on bond, or being sought on a warrant).

Id. at 38.

increased significantly,¹³² and prisoners are routinely exposed to violence.¹³³

But are changing prison demographics the only relevant context from which to think through the ethical challenges presented by using incarcerated people in scientific research? What is remarkable about how the IOM conceptualizes prisoners' vulnerability is that it frames it largely as a function of "what happens in prisons" rather than the commercial forces that, in some instances, can lead researchers to seek prisoners in the first place. Put differently, the IOM Committee understands the potential for abuse stemming only from *prison conditions*, not the *market conditions* that can make prisons attractive places for research entities to find cheap and plentiful human subjects and perhaps not uphold the highest ethical standards.

A bit of background may be helpful in understanding how the need for more human subjects intersects with research interests that may exacerbate prison research abuses. The same period that witnessed significant changes in prison demographics and conditions overlaps with a period of substantial changes in the pharmaceutical industry and clinical trial landscape. When Jonas Salk developed a polio vaccine in 1954, over 1.8 million people became "Polio Pioneers" by volunteering to test the experimental vaccination. People's goodwill and trust were key to finding an effective treatment. Yet, these sentiments waned after the quickly approved vaccine was linked to accidentally infecting 220 children with polio. This, along with other human subject scandals such as Tuskegee, increased people's skepticism and reluctance to volunteer.

At the same time this human subject supply dwindled, genetic engineers began developing biotech techniques that sparked innovation and drug development. Sonia Shah notes, "[j]ust as the biotech revolution took off, the pipeline turning those new compounds into sellable products had started to clog."¹³⁴ There were "36,839 new clinical trials from 2001 to '04, six times

132. "Between 1980 and 1998, the number of female inmates under the jurisdiction of federal and state correctional authorities increased more than 500 percent, from about 13,400 in 1980 to roughly 84,000 at year end 1998, according to the U.S. General Accounting Office. In 2004, that number had risen to 104,848." *Id.* at 35-36.

133. The report acknowledges that,

[p]risoners face violence and injury within correctional settings. More than one-quarter of state and federal inmates reported being injured since admission to prison. The likelihood of injury increases with time served in prison, as does the likelihood of a medical problem.

In 2000, there were 34,355 assaults by state and federal prisoners against other inmates, and 51 prisoners died as a result of those violent actions. . . .

In 1999, nearly 22 percent of state inmates had a history of being injured while in prison. Overall, 7 percent of state inmates were injured in a fight while in prison.

According to the 2003 Prison Rape Elimination Act, more than 1 million people have been sexually assaulted in prisons over the past 20 years. The act also describes the devastating effects of sexual assault in this context: an increase in other types of violence, including murder, involving inmates and staff, and long-lasting trauma, which makes it even more difficult for people to succeed in the community after release.

Id. at 47-48.

134. SONIA SHAH, *THE BODY HUNTERS: TESTING NEW DRUGS ON THE WORLD'S*

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more than in the period between 1981 to '85."¹³⁵ The rapid increase in drug development diametrically opposed the diminishing number of human subjects, creating considerable slowdowns in moving drugs from clinical trials to the market.

This clog in the drug development pipeline has now turned into what many consider to be a full-blown crisis. Hundreds of new drugs that might save or improve lives are not reaching market as quickly as they might if human subject supply met demand. Drug development has largely outpaced human subject availability. But the crisis is not only humanitarian. It also affects the pharmaceutical industry's bottom line. Central to a conversation that is ultimately about developing medicines to improve life is the reality that pharmaceuticals are big business. According to the Fortune 500 annual ranking of America's largest corporations, pharmaceuticals had the third most profitable return on revenues of any industry in 2007.¹³⁶ Like any other for-profit endeavor, shareholders do not simply expect this performance to continue. They expect it to improve.

Human subject shortages hamper drug companies' humanitarian and shareholder interests; as much as \$5 million is lost each day a new medication's approval stalls, not to mention countless opportunities to improve patients' lives.¹³⁷ Eighty percent of all drugs tested on humans never receive FDA approval, partly as a result of this shortage.¹³⁸ While the pharmaceutical industry did not play a formal role in the IOM's recommendations, it would not be implausible to think that the inadequate supply of human subjects, their high demand, and the strong financial incentives to resolve this imbalance may have influenced the sensibility to relax current restrictions:

Currently, there is a significant demand for pharmaceutical testing. From 1995 to 2005, the contract research industry, grown out of the increasing need for subject recruitment for clinical trials, has grown from a 1 billion to a 7 billion dollar per year industry. Along with increasing testing needs has come high profile cases of drug toxicity, and these cases have created increased public awareness about the need for study and surveillance of drug toxicity. For example, it has been suggested that increased testing of Vioxx would have prevented the delay in discovering its cardiovascular toxicity.¹³⁹

Another financial pressure point exacerbating this human subject shortage is lost revenues associated with expiring patent exclusivity. For example, when

POOREST PATIENTS 3 (2006).

135. David Evans et al., *Big Pharma's Shameful Secret*, BLOOMBERG MARKETS, Dec. 2005, at 5.

136. Fortune 500 Most Profitable Industries 2008, FORTUNE, May 5, 2008, available at <http://money.cnn.com/magazines/fortune/fortune500/2008/performers/industries/profits/index.html>.

137. Evans et al., *supra* note 135, at 6.

138. *Id.*

139. Timothy J. Wiegand, *Captive Subjects: Pharmaceutical Testing and Prisoners*, 3 J. MED. TOXICOLOGY 37, 37 (2007).

Schering-Plough lost U.S. exclusivity on Claritin in December 2002, sales fell 18% the following year; the company reported a net loss of \$92 million compared to a \$1.97 billion profit the previous year when their Claritin patent was secure.¹⁴⁰ Market researchers estimate that drug companies making the 28 top selling drugs will lose upwards of \$50 billion in revenue as their patents expire between 2003-2008.¹⁴¹ The only way to stave off this tide is by developing new drugs, performing clinical trials to obtain FDA approval, and securing market exclusivity in new areas of pharmaceutical treatment. Human subjects are not only essential to the continuing health of an aging population, but also to these companies' economic viability. Many pharmaceutical companies are already trying to fulfill this need by outsourcing clinical trials to developing countries.¹⁴² But more human subjects closer to home would surely be beneficial.

It is surprising that the Institute of Medicine does not acknowledge how profit motives and market dynamics can play as significant of a role as prison conditions in giving rise to potentially abusive research environments. The search for new blockbuster drugs is a powerful motivator for corporations seeking to maintain their profitability. Sectors of the research industry immediately recognized how loosened regulations concerning prisoners' participation in scientific research can dramatically improve their bottom lines, as noted in this pharmaceutical newsletter:

The pharmaceutical industry, who said it was not involved in the panel's decision, will be thrilled at the news, as it continues to struggle to recruit enough suitable patients for clinical trials. Patient recruitment is now consuming thirty per cent of clinical trial time—more time than any other clinical trial activity—and almost half of all trial delays result from patient recruitment problems. These delays are costing drug companies over half a million dollars for specialty products and more than \$8m (€6.7m) for blockbuster brands in lost sales and are also causing the cost of running clinical trials to skyrocket. Meanwhile, the 2.3m-strong US prison population remains an untapped resource for patients who are perfect for clinical trials, including racial minorities, women, as well as people with mental illness and

140. Evans et al., *supra* note 135, at 5.

141. Evans et al., *supra* note 135, at 5.

142. Shah writes,

Just as automakers and apparel manufacturers had fled the stringent labor and environmental laws of the West to set up shop in the developing world, drug companies and [contract research organizations] streamed across the border. Although companies aren't required to alert the FDA before testing their drugs on non-U.S. patients, nor does the FDA track research by location after approving new drugs, it is clear that the tectonic plates have shifted. Between 1990 and 1999 the number of foreign investigators seeking FDA approvals increased sixteenfold, the Department of Health and Human Services' Office of the Inspector General found. By 2004, the FDA estimated, drug companies angling for FDA approval of their new products were launching over sixteen hundred new trials overseas every year. The most popular destinations are not Western Europe and Japan, but rather the broken, impoverished countries of Eastern Europe and Latin America. Russia, India, South Africa, and other Asian and African countries have proven equally fruitful.

SHAH, *supra* note 134, at 7.

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communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis.¹⁴³

The crucial role that human subjects play in the profitability of research efforts draws attention to the pressures that can lead to vulnerable populations' questionable treatment by researchers.

The Institute of Medicine Committee may respond to the critique that conditions beyond the immediate prison environment—such as the for profit drug development industry—might complicate these ethical questions by arguing that we should assume that researchers are virtuous in their endeavors. Indeed, this presumption that researchers can be trusted to protect human subjects drives the IOM Committee to move away from the strong protectionist approach favored by the 1976 Commission and towards a moderate approach:

Advances in ethical thinking about protectionism suggest a new regulatory model. In particular, the committee rejects strong protectionism because it discounts the notion that researchers can be trusted to act virtuously in the protection of subjects. Researchers have responsibility for protecting subjects in their studies, especially those who are most vulnerable.¹⁴⁴

While the IOM Committee acknowledges that “given the troubling history of research abuse in prisons, weak protectionism is not an option,”¹⁴⁵ the Committee's blind normative assertion of the research industry's categorical virtue may miss the point. Recommending that the protectionist sentiment embedded in current regulations should be revoked in favor of an approach that emphasizes placing the responsibility for human subject protection in the hands of the very industry that stands to profit from loosened regulations raises several questions concerning appropriate oversight.

Regardless, there have been and continue to be numerous examples of the research industry's failure to uphold basic research ethics regarding human subject protection, which belie the IOM Committee's categorical confidence in preexisting institutional mechanisms. For example, an intriguing piece of investigative journalism from a 2005 *Bloomberg Markets* special report details how pharmaceutical companies engage private testing centers and private IRBs to coordinate their research efforts, including the recruitment of test subjects. The report notes:

The FDA's own enforcement records portray a system of regulation so porous that it has allowed rogue clinicians—some of whom have phony credentials—to continue human drug tests for years, sometimes decades. The Fabre Research Clinic in Houston, for example, conducted experimental drug tests for two decades even as FDA inspectors documented the clinic had used licensed employees and endangered people repeatedly since 1980. In 2002, the FDA linked the clinic's wrongdoing to the death of a test participant.

143. Kirsty Barnes, *Prisoners May Be Used to Fill Clinical Trial Patient Shortage*, OUTSOURCING-PHARMA.COM, Aug. 17, 2006, <http://www.outsourcing-pharma.com/Clinical-Development/Prisoners-may-be-used-to-fill-clinical-trial-patient-shortage>.

144. 2006 IOM REPORT, *supra* note 3, at 121.

145. *Id.*

Review boards can have blatant conflicts of interest. The one policing the Fabre clinic was founded by Louis Fabre, the same doctor who ran the clinic. Miami-based Southern IRB has overseen testing at SFBC and is owned by Alison Shamblen, 48, wife of E. Cooper Shamblen, 67, SFBC's vice president of clinical operations.¹⁴⁶

When such conditions and conflicts intersect with human subjects from vulnerable communities, there can be harmful effects for both the participants and research integrity. The *Bloomberg Markets* report details how undocumented persons evade basic research protocols and simultaneously participate in multiple clinical trials to get much needed cash.¹⁴⁷ This puts their lives at risk in that unknown drug interactions can be deadly. Moreover, taking multiple drugs at once muddies the data the researchers analyze in order to determine safety and efficacy.¹⁴⁸

These are far from the only examples of questionable practices in the modern research industry. Pfizer has partially settled a lawsuit stemming from clinical trials of Trovan in Nigeria,¹⁴⁹ where they allegedly tested a drug on sick children without written consent or legitimate ethics approval, leading to eleven deaths.¹⁵⁰ A recent Congressional sting operation highlighted deficiencies in

146. Evans et al., *supra* note 135, at 2.

147. For example,

Roberto Alvarez, 36, an Argentine in the U.S. on a visa; Efrain Sosa, 35, a Cuban native; and Marlon Matos, a 27 year old immigrant from Venezuela, say they've participated in more than one clinical trial in Miami at the same time or gone from one test to another, ignoring required waiting periods. They say they do it for the money, without telling the test centers, and that no one has ever caught them violating the rule.

"We maintain many safeguards to help ensure that the participants of our clinical trials are not participating simultaneously in multiple clinical trials," SFBC's Hantman says. SFBC fingerprints participants to keep track of their tests at the company, he says. "Unfortunately, there is no clearing house that we're aware of that would allow us to find if they were participating in another trial at the same time."

In April, Alvarez signed up for a 36-day clinical trial at Miami testing company Elite Research Institute for a new sustained-release form of donepezil, an Alzheimer's drug that Tokyo-based Eisai Co. sells in the U.S. with New York-based Pfizer. At the time, Alvarez was in the middle of a 212-day test sponsored by Madison, New Jersey-based Wyeth at SFBC for an experimental muscular dystrophy drug, according to consent forms he signed. "I hop around to get around that," says Alvarez, a part time construction worker. . . . "They ask, but I just don't tell them. Everybody does that."

Id. at 3.

148. "Steve Simon, a research biostatistician at Children's Mercy Hospital in Kansas City, Missouri, says that when people participate in more than one clinical trial at a time, it can be harmful to people and research. 'When neither researcher knows about potential interactions with the other trial, that raises concerns about scientific validity. . . . You don't know how these things might interact. It's asking for trouble.'"

Id.

149. "Pfizer signed a \$75 million agreement Thursday with Nigerian authorities to settle criminal and civil charges that the pharmaceutical company illegally tested an experimental drug on children during a 1996 meningitis epidemic. . . . Charges filed against Pfizer by Nigeria's federal government, which is seeking about \$6 billion in damages, are unaffected by the settlement."

Joe Stephens, *Pfizer to Pay \$75 Million to Settle Trovan-Testing Suit*, WASH. POST, July 31, 2009, at A15.

150. Joe Stephens, *Pfizer Reaches Settlement in Nigerian Drug-Trial Case*, WASH.

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both IRB oversight of proposed clinical trials and government oversight of private IRBs. Based on a previously rejected (and dangerous¹⁵¹) application, the Government Accountability Office proposed a fake clinical trial and submitted it to three private IRBs, in which one (Coast IRB¹⁵²) approved the study. The GAO also created a transparently fictitious IRB¹⁵³ to see if the Department of Health and Human Services would register it. It did. Large surveys also continue to show that there are pervasive conflicts of interest between IRBs and industry.¹⁵⁴ This all suggests that the very system deferred to by the IOM as being presumptively virtuous enough to soften the current “strong protectionist” stance on prison research is questionable at best. Moreover, it highlights the extent to which the conditions that shape human subjects abuse are not simply those that come from the living conditions of participants, but also those that shape the financial interests of the industries conducting the research. While there has been conversation about the changes needed in prison environments before such research can be truly ethical, there needs to be more thought about the changes that need to occur within the research industry before they are once again given greater access to prison populations.

3. Substantive Critique

This leads to the third critique: isolating the ethical questions surrounding the use of prisoners as human subjects from broader normative paradigms directly relevant to prisoners’ daily lives—most importantly, human rights—may obscure the full impact of the IOM recommendations. The *methodological critique* concerned itself with how the IOM Committee came to its

POST, Apr. 4, 2009, at A3.

151. A reviewer from one of the IRBs that rejected the fake GAO clinical trial proposal said, “We realized it was a terrible risk for the patient . . . It is the worst thing I have ever seen.” Alicia Mundy, *Sting Operation Exposes Gaps in Oversight of Human Experiments*, WALL ST. J., Mar. 26, 2009, available at <http://online.wsj.com/article/SB123811179572353181.html>.

152. Jesse Reynolds notes,

Coast seems to epitomize the shortcomings of private companies which approve research on humans. It advertises its fast 48 hour turnaround time on submissions, and even publishes a coupon for a free review, offering prospective customers to “take us for a free test drive” and to “coast through your next study.” In the last five years, Coast approved all 356 submitted protocols. And in the case of the GAO’s faked application, Coast didn’t even examine the submitted data.

Jesse Reynolds, *Human Research Subjects Protection: Under Fire From Congress*, BIOPOLITICAL TIMES, Mar. 31, 2009, <http://www.biopoliticaltimes.org/article.php?id=4614>.

153. “The committee, working with the Government Accountability Office, Congress’s investigatory arm, named the CEO of the fake IRB Truper Dawg, after a staffer’s three-legged dog, now deceased. Other fake names included ‘April Phuls’ and “Timothy Wittless,” which lawmakers said should have signaled irregularities to HHS. The department registered the IRB.” Mundy, *supra* note 151.

154. See, e.g., Eric G. Campbell et al., *Financial Relationships Between Institutional Review Board Members and Industry*, 355 NEW ENG. J. MED. 2321 (2006).

recommendations and the *contextual critique* examined which set of conditions the Committee acknowledged as relevant to its deliberations. This *substantive critique* deals with how the Committee engages the substance of its ethical deliberations with other normative paradigms relevant to the treatment of human subjects. Notably, the IOM's failure to meaningfully engage with established human rights norms and standards—such as those laid out in the Universal Declaration of Human Rights—is troubling. To be sure, the IOM discusses the ways in which prison settings complicate traditional notions of informed consent and non-coercion. But it is one thing to discuss these complications as merely a matter of research ethics. It is quite another to engage them as a matter of human rights.

Although the Institute of Medicine might resist this type of dual engagement with both ethics and human rights as being too far afield from its mandate and area of expertise, such responses to this critique fail to acknowledge the interconnected nature of biomedical ethics and human rights.¹⁵⁵ University of Pennsylvania bioethicist Arthur Caplan has noted, “bioethics was born from the ashes of the Holocaust.”¹⁵⁶ Similarly, human rights took on a new importance during this period. George Annas notes in his timely book *American Bioethics: Crossing Human Rights and Health Law Boundaries* that ethics and human rights “have a natural symbiosis . . . [that] can be most closely discerned in crimes against humanity that have historically involved physicians, such as torture, imprisonment, execution, and lethal human experimentation.”¹⁵⁷ This passage draws attention to the unique role prisoners have played in the development of ethics and international human rights. While they are often considered to be two distinct fields, a growing number of scholars are realizing that “[h]uman rights and medical ethics are complementary, and the use of the two together maximizes the protection available to the vulnerable patient.”¹⁵⁸

Michael Peel identifies at least two differences between human rights and ethics. First, human rights “focus[es] on state-level action rather than a person-to-person relationship.”¹⁵⁹ Second, the notion of benevolence—at the heart of any ethical discussion—is absent from human rights in that “rights do not depend on the empathy of other actors.”¹⁶⁰ Despite these distinctions, bringing

155. An example of the increasing awareness of the relationship between bioethics and human rights can be seen in UNESCO's UNIVERSAL DECLARATION OF BIOETHICS AND HUMAN RIGHTS (2005). See generally Roberto Andorno, *Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights*, 33 J. MED. ETHICS 150 (2007).

156. GEORGE J. ANNAS, *AMERICAN BIOETHICS: CROSSING HUMAN RIGHTS AND HEALTH LAW BOUNDARIES* 161 (2005).

157. *Id.* at xiv.

158. Michael Peel, *Human Rights and Medical Ethics* 98 J. ROYAL SOC'Y. MED. 171, 173 (2005).

159. *Id.* at 172.

160. *Id.*

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a human rights framework into conversations on the research ethics pertaining to prisoners' participation as human subjects has at least three major benefits. First, human rights "give fundamental protections that allow equal participation in a democracy...[that] prevent the worst excesses of democracy because no society can vote to take those rights away."¹⁶¹ For prisoners who have most of their freedoms restricted, a human rights framing draws attention to core rights that may not receive the same sensitivity under a unilateral focus on research ethics. Second, "conventional bioethics has difficulty addressing broad issues of inequity,"¹⁶² an issue that is at the center of any human rights analysis. Lastly, bioethics' emphasis on individual autonomy¹⁶³ can mask how group dynamics can lead individuals to choose to partake in research that may ultimately lead to unethical if not harmful outcomes. Human rights frameworks offer a safety net to ensure that bioethics' privileging of individual autonomy over other principles does not trump core rights that vest in every human.

The connections between bioethics and human rights is far from coincidental; vesting internationally agreed upon rights in every person and creating ethical standards for research involving human subjects were and continue to be seen as two sides of the same coin shielding humanity from reliving its darkest moments. As Annas points out in *American Bioethics*, this is evident in the documents discussing these normative commitments:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion¹⁶⁴

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services¹⁶⁵

As a whole and in their cited portions, these documents take on two separate issues—one placing informed consent and non-coercion at the cornerstone of all ethical human subject research, the other addressing the human right to medical care. Together, however, they make a more perfect union: that biomedical ethics—and in particular, research ethics—are most legitimate when subjects' human rights are secure. It makes little sense for ethical

161. *Id.* at 171.

162. Paul Farmer and Nicole Gastuneau Campos, *New Malaise: Bioethics and Human Rights in the Global Era*, 32 J.L. MED. & ETHICS 243, 245 (2004).

163. See generally Paul Root Wolpe, *The Triumph of Autonomy in American Bioethics: A Sociological View*, in *Bioethics and Society: Constructing the Ethical Landscape* (Raymond DeVries & Janardan Subedi, eds., 1998).

164. The Nuremberg Code (1947), available at <http://www.hhs.gov/ohrp/references/nurcode.htm>.

165. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948).

inquiries to isolate themselves from human rights. Continuing to do so can lead to situations where ethics can be misused to exacerbate human rights violations; subjects living in conditions where basic human rights are not upheld might agree to participate in studies that they otherwise might not—a subtle but important form of coercion.

The wide-ranging human rights violations documented in prisons by organizations such as the ACLU and Human Rights Watch suggest that conditions are often deplorable: inadequate medical care, unprovoked physical assaults, and sexual coercion are but a few of these concerns.¹⁶⁶ And the relations between guards and prison populations raise even brighter human rights red flags. As an example, an October 2006 Human Rights Watch report documents how many prisons routinely use terror tactics such as subjecting prisoners to snarling guard dogs as population control measures.¹⁶⁷

Biomedical and research ethics are not the only source of normative commitments by which physicians and researchers should abide. As such, the ethical challenges raised by proposals to loosen current restrictions on using prisoners as human subjects may very well be a tremendous opportunity to fully integrate ethical deliberations with human rights sensibilities. What makes their integration so urgent is that without it, one set of norms developed to protect vulnerable subjects can be used unwittingly to destabilize the other. To prevent this, ethical and human rights frameworks must be seen as interconnected rather than disjointed. Otherwise, one ethic for treating people with dignity can be paradoxically used to exploit holes in the other—a strikingly unfortunate ethical outcome for subjects caught in the crosshairs.

Is it possible to conduct ethical research with prisoners in a way that is consistent with various human rights norms? This is an important empirical and legal question that is beyond this Part's narrow focus on a substantive deficit within the IOM's chosen ethical framework.¹⁶⁸ But without this deeper analysis and integrated framework that substantively brings both ethical and human rights considerations directly into its policy deliberations, the IOM's

166. For example, California's prison health care system was deemed to be so substandard and harmful to prisoners, a federal district court judge placed it under receivership. The court noted, "By all accounts, the California prison medical care system is broken beyond repair. The harm already done in this case to California's prison inmate population could not be more grave, and the threat of future injury and death is virtually guaranteed in the absence of drastic action." Findings of Fact and Conclusions of Law Re *Appointment of Receiver* at 1, *Plata v. Schwarzenegger*, No. C01-1351 TEH (N.D. Cal. Oct. 3, 2005), available at <http://www.cprinc.org/docs/court/PlataFindingsFactConclusionsLaw1005.pdf>. See generally HUMAN RIGHTS WATCH, NO ESCAPE: MALE RAPE IN PRISON (2001), available at <http://www.hrw.org/reports/2001/prison/index.htm>; HUMAN RIGHTS WATCH, ALL TOO FAMILIAR: SEXUAL ABUSE OF WOMEN IN U.S. STATE PRISONS (1996), available at <http://www.hrw.org/reports/1996/Us1.htm>.

167. See generally HUMAN RIGHTS WATCH, CRUEL AND DEGRADING: THE USE OF DOGS FOR CELL EXTRACTIONS IN U.S. PRISONS (2006).

168. For an interesting discussion on the problems associated with research in today's prisons, see Reiter, *supra* note 1, at 520-34.

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recommendation to loosen current restrictions might have the unintended effects of exposing prisoners to additional health risks and exacerbating ongoing human rights violations.

CONCLUSION

To date, the recommendations put forth by the 2006 IOM report have not led to any changes in the regulations governing human subjects research with prisoners, although changes to Subpart C are still under consideration. This Article argued that the recommendations put forth by the IOM should not be adopted due to (1) its *methodological shortcomings* that forgo an empirical understanding of how research ethics interact with prison conditions in favor of a literature review, (2) its *contextual limitations* that situate prisoners' vulnerability to abuse as only a product of prison conditions rather than also looking at how market conditions might exacerbate such concerns, and (3) its *substantive* limitations whereby the proposed ethical framework fails to engage other normative commitments relevant to human subject protection such as human rights. Before the Department of Health and Human Services moves forward with any further consideration of the IOM report, these issues should be taken seriously.

It is likely that state and federal governments will continue to face numerous ethical dilemmas involving prisoners. As an example, lawmakers in South Carolina have considered legislation that attempts to relieve the state's kidney shortage by shaving 180 days off inmates' sentences if they agree to become organ donors.¹⁶⁹ Further developments in human biotechnology may also come into play. A tremendous amount of excitement has centered around the therapeutic potential of human embryonic stem cell research. And, given the shortage of eggs available to pursue certain types of stem cell research with human embryos,¹⁷⁰ it is not difficult to imagine a state providing similar incentives to incarcerated women who might agree to become egg donors. Outside of the prison environment, ethics are also likely to impact regulatory policy and administrative agencies over the next several years, whether it is the appropriate regulation of reproductive and genetic technologies by the Food and Drug Administration or other regulatory bodies, increased oversight of direct-to-consumer genetic tests by the Federal Trade Commission, or increased oversight of the use of genetic technologies by the Justice Department.

These are complicated issues, pitting what some might call the ability to save and improve human life against maintaining all people's human dignity. What is important is that as biomedical and research ethics are sought to inform

169. See generally Associated Press, *Wanna Cut Your Jail Time? Donate A Kidney!*, CBSNEWS.COM, Mar. 8, 2007, <http://www.cbsnews.com/stories/2007/03/08/national/main/2548860.shtml>.

170. See generally Geoff Brumfiel, *Egg Shortage Hits Race to Clone Human Stem Cells*, 453 NATURE 828 (June 11, 2008).

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increasing areas of regulatory policy that there is a *broad recognition that ethics are not, in and of themselves, a source of public policy*. While the contribution of ethical inquiries are invaluable, this Article has argued that too much is at stake when such policy recommendations are not methodologically robust, do not acknowledge the rich and overlapping contexts that inform the issue, and isolate one set of moral principles without a substantive engagement with other relevant norms. Regrettably, in these and other failures, the IOM's report may very well come to stand for the proposition of how not to infuse ethics into regulatory policy.