

Not Situated to Exercise Free Power of Choice: Human Subject Research in Prison Settings

Rachel Wener*

I. INTRODUCTION

In June 2006, the Institute of Medicine (a private non-governmental organization that was created by congressional charter)¹ released a report recommending that the Department of Health and Human Services (HHS) lift its restrictions on almost all research involving incarcerated subjects.² These restrictions, which have been in effect since 1978, forbid all research on prisoners using HHS funds except for research specifically limited to incarceration, its causes or its effects on prisoners,³ and posing minimal risk to the subjects.⁴ Supporters of this change have argued that the twin protections of informed consent and the requirement of independent review that are currently in place reduce the risk of abuses such as those that occurred in the past,⁵ and that this risk pales in comparison to the potential benefits for society and for the prisoners themselves.⁶ However, these arguments do not adequately address

* Candidate for Juris Doctorate, 2008, Temple University James E. Beasley School of Law. I would like to thank Professors David Kairys and Susan DeJarnatt for their help and advice, and James Wong for his careful editing. Thanks also to my parents, Richard Wener and Virginia Kurshan, for their support.

¹ Institute of Medicine Frequently Asked Questions, <http://www.iom.edu/CMS/6008.aspx> (last visited Feb. 7, 2007).

² Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research, *Ethical Considerations for Research Involving Prisoners* (National Academies Press 2006) (hereinafter Committee).

³ Common Rule, Subpart C 45 C.F.R § 46.306 (2006).

⁴ *Id.*

⁵ C.K. Gonsalus, *An Examination of Issues Presented by Proposals to Unify and Expand Federal Oversight of Human Subject Research*, in *ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS D-1* (National Bioethics Advisory Committee, eds., 2001). See discussion *infra* regarding past abuses.

⁶ Ian Urbina, *Panel Suggests Using Inmates In Drug Trials*, N.Y. TIMES, August 13, 2006, at A1.

the inadequacies of the current system of Institutional Review Boards, nor the serious concerns with informed consent that occur with a population whose autonomy is severely restricted.

In Part I of this article, I will discuss the history of regulations on research involving prisoners, starting with the Nuremberg Doctors' Trial and the principles that grew out of it. In Part II I will discuss some of the (unfortunately vast) history of abuses in trials involving incarcerated subjects, focusing on the experiments at Holmesburg Prison in Philadelphia from the 1950s to the 1970s, where egregious abuses occurred in the prison's clinical research program. In Part III I will discuss the current regulatory framework that was created in response to these abuses, and some of its weaknesses. In Part IV I will examine current legal and psychological debates about whether any prisoner can freely consent to such an experiment. Finally in Part V, I will argue that because of inherent concerns about freedom of consent in a coercive environment, and because of specific practical concerns about lack of oversight, the current near-ban on prisoner research embodied in Subpart C of Title 45, part 46 of the Code of Federal Regulations ("Protection of Human Subjects") should not be lifted. Instead, specific portions of the Institute of Medicine's recommendations, which would expand federal protections of human research subjects and give significant enforcement power to a Director of Human Subject Protection, should be enacted. Ultimately, the possibility of coercion is too great to allow any but the most minimal and noninvasive experimentation, such as that which is already permitted by Subpart C, on incarcerated subjects.

II. REGULATION OF AND RESTRICTIONS ON PRISONER RESEARCH

Most of the international standards for research involving human subjects and especially vulnerable populations have roots in two documents: the Nuremberg Code and the Declaration of Helsinki.⁷ Although neither document explicitly addresses the question of prisoner research, both set forth ethical guidelines for research on human subjects that emphasize the need for non-coerced informed consent that may be withdrawn at any point. Since both documents were created in response to the revelations of the Nazis' experimentations on concentration camp prisoners, concerns about the role of incarcerated people in medical research are implicit in the documents.

The Nuremberg Code was compiled by the judges at the "Doctors' Trial" (one of the post-World War II War Crimes trials), in response to the Nazi's experiments on concentration camp victims.⁸ In this case, twenty-three physicians, scientists, and administrative officials were tried for crimes against humanity for their roles in planning and carrying out inhumane medical experiments on prisoners in concentration camps.⁹ In these experiments prisoners were subjected to anguish and death in order to answer such questions as how long it took a person to die when they had nothing but seawater to drink,¹⁰ or what the effect of high altitude was on

⁷ Michael J. Malinowski, *Choosing the Genetic Makeup of Our Children: Our Eugenics Past-Present and Future?* 36 CONN. L. REV. 125, 149, 158 (2003).

⁸ *Id.*

⁹ Telford Taylor, *Opening Statement of the Prosecution*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE 67* (George J. Annas & Michael A. Grodin eds., 1992).

¹⁰ *Id.* at 77.

the human body.¹¹ Many of the subjects died from these experiments; those who survived were often physically disabled and mentally scarred.¹² And of course, those who ran the experiments did not ask for or receive consent from their research subjects.

The goal of the Doctors' Trial¹³ was not merely to try the defendants but to demonstrate to the world the unacceptability of the ideologies that led to the sadistic experiments.¹⁴ As prosecutor Brigadier General Telford Taylor said in his opening statement,

The perverse thoughts and distorted concepts which brought about these savageries are not dead They must be cut out and exposed, for the reason so well stated by Mr. Justice Jackson in this courtroom a year ago. "The wrongs which we seek to condemn and punish have been so calculated, so malignant, and so devastating, that civilization cannot tolerate their being ignored because it cannot survive their being repeated."¹⁵

Accordingly, the court's decision did not deal simply with the defendants, but was written with an eye toward the stated goal of preventing future human rights abuses during the course of experimentation on human subjects. It included the principles for acceptable human experimentation, what is now known as the Nuremberg Code.¹⁶

The Code sets out ten principles for ethical research involving human subjects.¹⁷ It discusses the importance of avoiding pain and suffering, caring for the participant's safety, and the requirement that the experiment be conducted only when the humanitarian importance of the problem outweighs the risk to the participants.¹⁸ Most of the text of the Code, however, focuses on the question of consent. Section 1 states that "the voluntary consent of the human subject is absolutely essential" and the Code elaborates over another two paragraphs, far more text than is given to any other point, what voluntary consent entails.¹⁹

Aside from having legal capacity to consent and understanding the procedure, the participant must be "so situated as to be able to exercise free power of choice,

¹¹ *Id.* at 71.

¹² *See, e.g.,* Eva Mozes-Kor, *The Mengele Twins and Human Experimentation: A Personal Account, in THE NAZI DOCTORS AND THE NUREMBURG CODE* 53 (George J. Annas & Michael A. Grodin eds., 1992).

¹³ Officially *United States of America v. Karl Brandt et. al., Nuremberg Trial Introduction*, http://individual.utoronto.ca/jarekg/Ravensbruck/Trial_Introduction.html (last visited Feb 7, 2007). Unlike the first War Crimes Trial, which was conducted multilaterally with judges and court officials from the various Allied powers, the Doctors' Trial was one of twelve tried by an American military prosecutor before a court of American Judges. *See supra* note 10 at 4, also Harvard Law School Library, *Frequently Asked Questions about the Nuremberg Trials Project*, Nuremberg Trials Project Frequently Asked Questions, http://nuremberg.law.harvard.edu/php/docs_swi.php?DI=1&text=faq (last visited Feb 7, 2007).

¹⁴ Taylor, *supra* note 9, at 68.

¹⁵ *Id.*

¹⁶ *See* 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10. NUERNBERG, 181-82 (Washington, U.S. Govt. Print. Off., 1949-53) [hereinafter Nuremberg Code].

¹⁷ *Id.* (discussing the ten principles listed under "Permissible Medical Experts" that came to be known as the Nuremberg Code).

¹⁸ *Id.* at 182.

¹⁹ *Id.*

without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion...²⁰ In addition, the subject must be “at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seemed to him to be impossible.”²¹

The Nuremberg Code is widely considered to be the touchstone for research ethics, both in the United States and internationally. It is generally seen as an ethical guide rather than a set of professional rules or part of a court decision with force of law.²² Other international bodies have adopted some of the Code’s principles, especially its articulation of what constitutes informed consent, into documents that carry significant weight.²³

The Declaration of Helsinki, which was adopted in 1964 by the World Medical Assembly and subsequently amended, focuses on the ethical responsibilities of the physician conducting medical research.²⁴ The Declaration is a professional guide for physicians rather than a statement of ethical principles. The Declaration, like the Code, expresses the belief that research on humans is a method of last resort, to be used with great caution and when vital information cannot be obtained any other way.²⁵ Many of the Declaration’s sub-parts focus on the extra responsibilities of a physician conducting research on human subjects, and like the Nuremberg Code, the Declaration emphasizes the importance of ensuring that the subject’s consent is informed and freely given, with precautions taken for subjects in vulnerable positions such as minors or those otherwise mentally incapable of giving informed consent.²⁶

In the United States, in addition to the Nuremberg Code and Declaration of Helsinki, the Belmont Report is considered foundational.²⁷ This report was published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, after four years of research and deliberation.²⁸ The commission was created by an Act of Congress in 1974, amid

²⁰ *Id.*

²¹ *Id.* at 182 (9).

²² George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency*, in *THE NAZI DOCTORS AND THE NUREMBERG CODE 201* (George J. Annas & Michael A. Grodin eds., 1992). It is curious that in this country, although the Doctors’ Trial was in fact decided by a panel of American judges under American rules, that it has almost never been cited as precedent.

²³ See, e.g., United Nations International Covenant on Civil and Political Rights art. 7, Dec. 16, 1966, 1966 U.S.T. 521, 999 U.N.T.S.171.,175.; WORLD HEALTH ORGANIZATION, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, 2002, http://whqlibdoc.who.int/emro/2004/9290213639_annex2.pdf; Evelyne Shuster, “Fifty Years Later: the Significance of the Nuremberg Code,” 337 *NEW ENGLAND J. MED.* 1436 (1997).

²⁴ World Medical Assembly, Declaration of Helsinki, 18th Assembly (adopted 1964, amended 1975, 1983, and 1989), <http://history.nih.gov/laws/pdf/helsinki.pdf>.

²⁵ *Id.* (“Medical progress is based on research which ultimately must rest in part on experimentation involving human subject Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects.”) *Id.* at 1.

²⁶ *Id.*

²⁷ George J. Annas and Michael A. Grodin, *THE NAZI DOCTORS AND THE NUREMBERG CODE*, 147 (George J. Annas and Michael A. Grodin, eds. 1992); Malinowski, *supra* note 7 at 163. The documents are also available on the Department of Health and Human Services’ Office for Human Research Protections at <http://www.hhs.gov/ohrp/>.

²⁸ Leonard H. Glantz, *Influence of the Nuremberg Code on U.S. Statutes*, in *THE NAZI DOCTORS AND*

the outrage caused by revelations of the Tuskegee Syphilis Experiment.²⁹ The report they produced, entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” discusses the importance of respecting the autonomy of research subjects, and the need to take extra precautions in cases where the autonomy of the subject is diminished due to “illness, mental disability, or circumstances that severely restrict liberty.”³⁰

The Report addresses the question of prisoner research at some length, as an example of the competing interests and issues raised by research on people with diminished autonomy:

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.³¹

This passage sets up a balancing test that leaves to the discretion of the researcher decisions about what is best for the vulnerable subject, the opportunity to participate or protection from coercion.

The recommendations and principles set forth in the Nuremberg Code, the Declaration of Helsinki and the Belmont Report are embodied in the United States Department of Health and Human Services’ rules for the Protection of Human Subjects,³² which were first promulgated in 1981 and became known generally as the Common Rule.³³ These regulations apply to all human research that is supported by federal funds, whether it is conducted by a government agency or by private institutions supported who receive federal funds.³⁴

THE NUREMBURG CODE 187 (George J. Annas & Michael A. Grodin eds., 1992).

²⁹ The Tuskegee Syphilis Study is perhaps the most infamous medical experiment in American History. Over four decades, researchers studied the course of untreated syphilis. When treatment became available, it was not offered to the subjects. The subjects participated in response to advertisements of “special free treatment” and were unaware that they had been given ineffective treatments. Allen M. Brandt, *Racism, Research and the Tuskegee Syphilis Study*, 8 THE HASTINGS CENTER REPORT 21 (December 1978); Robert L. Kerr, *Unconstitutional Review Board? Considering a First Amendment Challenge to IRB Regulation of Journalistic Research Methods*, 11 COMM. L. & POL’Y. 393, 394 (2006).

³⁰ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education & Welfare, *The Belmont Report* (DHEW Publication No. (OS) 78-0012 1978), at 1.

³¹ *Id.* at 6.

³² The Common Rule, 45 C.F.R. § 46 (2006) [hereinafter Common Rule].

³³ Kerr, *supra* note 29, at 410. See also Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1, 5 (2004) (explaining that the regulations were originally applicable to research funded by the Department of Health, Education and Welfare (DHEW) but were later expanded to cover research funded by other federal agencies). The Food and Drug Administration has its own parallel regulations, which are very similar to the Common Rule. 29 C.F.R. § 50 (2005).

³⁴ 45 C.F.R. § 46.101(a).

The Common Rule is notable for mandating Institutional Review Boards (IRBs), which review proposed research and certify that the study in question contains adequate protections for human subjects.³⁵ IRBs are semi-independent of the research institution, and include members from the community, including from the subject population. They conduct both initial and continuing reviews of the research, and their approval is a precondition of federal financial support.³⁶

Institutional Review Boards grew out of a decentralized system of research review committees, required for certain federally-funded research beginning in 1966³⁷ and refined over the next several years until their inclusion in the Common Rule in 1974.³⁸ They are given wide discretion by the Common Rule to ensure that research subjects give truly informed consent. An IRB may require additional information, above and beyond what the Rule requires, be given to the subjects when “in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects.”³⁹

Under the original Common Rule, research involving subjects from vulnerable populations is considered to be problematic but it is not forbidden outright. The Rule lists a number of populations considered to be vulnerable⁴⁰ to coercion or undue influence, or at risk of greater harm than a normal person.⁴¹ IRBs are directed to be “particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”⁴² Additional safeguards are set up to ensure that these subjects are free from coercion.⁴³ However, the text of the rule assumes that such research will occur and with proper safety measures, can be done in an ethical manner.

In practice, the Rule takes a stricter attitude when dealing with research involving prisoners. Subpart C of the Rule addresses this specific vulnerable population at great length and forbids all biomedical or behavioral research except studies relating to incarceration: its causes, effects, research on prisons as structures, or similar topics that are designed to benefit prisoners as a class,⁴⁴ or other research that poses

³⁵ 45 C.F.R. §46.109.

³⁶ 45 C.F.R. §46.103 (b).

³⁷ Erica Heath, *The History, Function and Future of Independent Review Board*, in ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS E-6 (National Bioethics Advisory Committee, eds. 2001) (acting in response to an article published that year detailing the abuses in several research studies, National Surgeon General William Stewart issued a policy statement calling for research review of a “committee of peers” at the institution, and “assurance statements” to the funding agency).

³⁸ *Id.*

³⁹ 45 C.F.R. § 46.109(b).

⁴⁰ See 45 C.F.R. § 46.107(a); 45 C.F.R. 46.111 (a)(3) (identifying children, prisoners, pregnant women, “handicapped or mentally disabled persons,” and “economically or educationally disadvantaged persons” as vulnerable populations and giving each group its own Subpart of the Rule with additional restrictions on their participation as research subjects).

⁴¹ 45 C.F.R. § 46.111(b).

⁴² Common Rule, *supra* note 32.

⁴³ 45 C.F.R. § 46.111(b) (subpart C safeguards include the requirement that a member of the vulnerable subject population or an advocate for them sits on the IRB, and that the majority of the rest of the IRB members have no affiliation with the prison). 45 C.F.R. 46.304.

⁴⁴ 45 C.F.R. § 46.306.

no more than minimal risks to the subjects.⁴⁵ More institutions, and therefore more research populations, are subject to these regulations, because this subpart applies not only to research conducted with federal funds, but to private institutions that receive federal funding for any purpose, even if the research in question is privately funded.⁴⁶ Because of the large proportion of medical research that is conducted by institutions that receive funds from the Department of Health and Human Services or its agencies, this prohibition has significantly curtailed research on prisoners since the Common Rule went into effect three decades ago.⁴⁷

III. HOLMESBURG PRISON - AN EXAMPLE OF ABUSIVE PRISONER RESEARCH

Legal and scientific scholars have argued that the Common Rule's protections for human research subjects are strong enough that there is no good reason to keep Subpart C's restrictions on prisoner research.⁴⁸ They argue that permitting prisoners to participate is beneficial to society as a whole, as increased ease of clinical trials moves the field of medicine forward.⁴⁹ Others argue that such research is good for the prisoners themselves, who would have the opportunity to receive experimental treatments from which they may receive benefits.⁵⁰

It is true that involving prisoners in clinical trials may benefit the larger non-incarcerated society. However, that is not the relevant question according to the Nuremberg Code or any of the grounding medical ethics documents discussed above. The ethics of the use of human research subjects is overwhelmingly focused on the risks and benefits to the individuals,⁵¹ and the before the Common Rule was adopted, many clinical trials involving incarcerated people produced little benefit for the subjects, and often inflicted serious harm.

Dermatological experiments conducted at Holmesburg Prison in Philadelphia illustrate many of the serious ethical problems with medical research involving prisoners.⁵² These experiments, which were conducted over the course of several decades, led to severe and lasting injuries to many of the research subjects.⁵³ The experiments were conducted before the adoption of the Common Rule and show the degree of damage that can be done in such research settings.

⁴⁵ *Id.*

⁴⁶ Glantz, *supra* note 28 at 190. The revision of the Common Rule to include Subparts B and C (specific protections for children and prisoners) "apply specifically only to research conducted or funded by The Department of Health and Human Services (DHHS) However, in their general assurances to the DHHS, institutions must provide a statement of "principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding." This requirement expands the populations who are protected by these regulations." *Id.*

⁴⁷ See Urbina, *supra* note 6.

⁴⁸ See, e.g., Kathleen Schroeder, Note: *A Recommendation to the FDA Concerning Drug Research on Prisoners*, 56 S. CAL L. REV. 969 (1983); see also Sharona Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 IND. L. REV. 475 (2000).

⁴⁹ See Schroeder, *supra* note 48, at n. 29.

⁵⁰ See Hoffman, *supra* note 48, at 497-498.

⁵¹ See, e.g., the Nuremberg Code, *supra* note 16.

⁵² Allen M. Hornblum, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* (Routledge 1998).

⁵³ *Id.*

The research program at Holmesburg Prison was spearheaded by Dr. Albert Kligman, a dermatologist affiliated with the University of Pennsylvania Medical School.⁵⁴ He was originally invited into the prison by a pharmacist for help in treating a prison outbreak of athlete's foot,⁵⁵ and became intrigued by the prison as a place for research. His statement that "all [he] saw before [him] were acres of skin....like a fertile field"⁵⁶ exemplifies his attitude to the prisoners – that they provided ideal subjects for research. The prisoners were in an environment where their movements and actions could be controlled twenty-four hours a day,⁵⁷ which made for unusually good laboratory conditions. Although the compensation that Dr. Kligman and his assistants offered was a fraction of what non-incarcerated research subjects would receive, the compensation was still far more than prisoners at Holmesburg could earn in any other prison job. Interviews with some prisoners make it clear that money was the motivation for the majority of those who participated in the experiments.⁵⁸

Dr. Kligman and the company he founded, Ivy Research Laboratories, tested many products and drugs at Holmesburg, ranging from innocuous products like mouthwash⁵⁹ to painful skin treatments such as the anti-wrinkle drug Retin-A,⁶⁰ to carcinogens such as dioxin,⁶¹ to chemicals that caused hallucinations, and were tested for their possible use as chemical weapons.⁶² Prisoners have also alleged exposure to radioactive isotopes in experiments performed by Ivy Research Laboratories on behalf of the United States Army.⁶³ The clinical trials at Holmesburg included Phase I tests, the first stage of human trials, which focus on the safety or toxicity of the drug rather than its efficacy.⁶⁴ Over two decades, many widely-used dermatological products were first tested at Holmesburg.⁶⁵

The researchers at Holmesburg, though they insisted that their research was not dangerous to the prisoners,⁶⁶ expressed the belief that the quality of life of institutionalized research subjects was low enough without their intervention that research with harmful effects had little effect.⁶⁷ The fact of compensation also seems to have justified the risk to the prisoner-subjects. Dr. Kligman described the experiments as a straightforward rental of the prisoner's physical being: "All the prisoner taking part in a test has is money. We pay him to lend us his body for some

⁵⁴ *Id.* at 32.

⁵⁵ *Id.* at 37.

⁵⁶ *Id.*

⁵⁷ Hornblum, *supra* note 52, at 38.

⁵⁸ *Id.* at 6, 22.

⁵⁹ *Id.* at 20.

⁶⁰ *Id.* at 211.

⁶¹ *Id.* at 163-164.

⁶² Hornblum, *supra* note 52, at 127-29.

⁶³ *See, e.g., id.* at 27.

⁶⁴ *Id.* at 104. *See also* National Cancer Institute, What is a Clinical Trial? <http://www.nci.nih.gov/clinicaltrials/learning/what-is-a-clinical-trial> (last visited February 7, 2007) (explaining the different phases of a clinical trial).

⁶⁵ Hornblum, *supra* note 52, at 221.

⁶⁶ *See id.* at 38.

⁶⁷ *See, e.g., id.* at 35 (Dr. Kligman's description of institutionalized children's eagerness for attention).

time.”⁶⁸

Holmesburg was not an anomaly in the country’s correctional system: at the time, almost all Phase I experimentation was conducted on incarcerated subjects, according to the former FDA official in charge of clinical investigations, Dr. Alan Lisook.⁶⁹ Other physicians, and pharmaceutical companies, began to conduct their research at Holmesburg, and the United States Army contracted with Dr. Kligman and the research program to fund research on the effects of chemical warfare,⁷⁰ radiation,⁷¹ and other areas that had military applications.⁷²

The prisoners who participated in the various experiments and clinical trials suffered side effects ranging from rashes and cramps⁷³ to chemical burns⁷⁴ to hallucinations.⁷⁵ The risks from some of the experiments were more severe – when Dr. Kligman published an article in the *Journal of the American Medical Association* about his attempt to dose subjects with testosterone to stimulate hair growth, the *Journal* felt it necessary to publish an editorial warning of the severe risks caused by such research, including cancer and birth defects.⁷⁶

IV. ADMINISTRATIVE, LEGAL AND LEGISLATIVE RESPONSE TO HOLMESBURG

Dr. Kligman was investigated by the Food and Drug Administration (“FDA”) for poor research methodology in investigative new drug (IND) trials,⁷⁷ and in 1966, the FDA stated that he had failed to comply with accepted IND procedures, and was henceforth not an acceptable researcher for pharmaceutical companies to employ to conduct their drug trials.⁷⁸ However, the ban was quickly lifted⁷⁹ and the program continued for another eight years.⁸⁰

Lawsuits brought by prisoners against Dr. Kligman and Ivy Research Laboratories have been largely unsuccessful. In 1976, a Federal District Court in Philadelphia, Pennsylvania granted summary judgment to Dr. Kligman and his colleagues in a lawsuit⁸¹ brought against them by Jerome Roach, a former inmate at Holmesburg. Roach alleged that the research in which he participated constituted cruel and unusual punishment.⁸² The court stated that Roach’s claim of coercion on the part of the prison officials and researchers – because he was not supplied with “minimal needs and comforts”⁸³ such as soap and writing paper, and had to

⁶⁸ *Id.* at 38.

⁶⁹ *See id.* at 43.

⁷⁰ *See* Hornblum, *supra* note 52, at 46-47, 49.

⁷¹ *Id.* at 152-53.

⁷² *Id.*

⁷³ *Id.* at 24.

⁷⁴ *Id.* at 120.

⁷⁵ Hornblum, *supra* note 52, at 119.

⁷⁶ *Id.* at 51.

⁷⁷ *Id.* at 52-53.

⁷⁸ *Id.* at 54.

⁷⁹ *Id.* at 56.

⁸⁰ Hornblum, *supra* note 52, at 63.

⁸¹ *Roach v. Kligman*, 412 F. Supp. 521, 523 (E.D. Pa. 1976).

⁸² *Id.* at 523-24.

⁸³ *Id.* at 526.

participate in order to earn the money to pay for these items – failed because the items in question were not denied to him, only not supplied, and because he could have found a different prison job.⁸⁴ The court in Roach also declined to hear Roach's pendant state tort claim for trespass.⁸⁵ At least two inmates' claims were settled,⁸⁶ while another suit brought by 298 former Holmesburg inmates in 2002 was barred by the statute of limitations.⁸⁷

In 1973, two prisoners from Holmesburg testified to the Senate Labor Committee about their experiences as research subjects.⁸⁸ Because the prisoners needed money and because the research program was by far the best-paying option in the prison, "any claim of voluntary participation ... [was] a cruel hoax," according to former prisoner Allen Lawson.⁸⁹

At the time, public interest in research ethics was high due to publication of high-profile articles⁹⁰ on prisoner research,⁹¹ and especially due to the recent revelation of the Tuskegee Syphilis Study.⁹² The widespread concern the "use of vulnerable populations as guinea pigs"⁹³ and the high profile Senate hearings⁹⁴ led to Congress' creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission produced the Belmont Report. Congress also passed the National Research Act, which required the Department of Health, Education and Welfare to create regulations for human subject protection, regulations that became the Common Rule.⁹⁵ Prison research programs began to shut down in response to the changed national environment,⁹⁶ and with the adoption of the Common Rule this kind of research was no longer permitted.⁹⁷

⁸⁴ *Id.* at 526-27.

⁸⁵ *Id.*

⁸⁶ Walker v Kligman, 7 Phila. 189 (1982), 1982 WL 290297 (Pa. Com. Pl.); See also Jonathan Kaye, *U. Involved in Chemical Tests on Prisoners*, THE DAILY PENNSYLVANIAN, May 19, 1995, available at <http://media.www.dailypennsylvanian.com/media/storage/paper882/news/1995/05/19/Resources/U.Invol ved.In.Chemical.Tests.On.Prisoners-2178101.shtml> (mentioning Walker's health problems and his lawsuit against Dr. Kligman).

⁸⁷ Abdulaziz v. City of Phila., 47 F. App'x 131, 132 (3d. Cir. 2002) (granting summary judgment for defendants because the statute of limitations had tolled). See also *Prisoners Can't Sue Over Experiments*, MILWAUKEE JOURNAL-SENTINEL, Sept. 26, 2002, at 08A (describing the effect of the Third Circuit's ruling).

⁸⁸ Allen Hornblum, *Subjected to Medical Experimentation: Pennsylvania's Contribution to "Science" in Prisons*. 67 PENNSYLVANIA HISTORY 415, 424 (Spring 1999).

⁸⁹ *Id.*

⁹⁰ Jessica Mitford, *Experiments Behind Bars: Doctors, Drug Companies, and Prisoners*, 231 ATLANTIC MONTHLY 64 (Jan. 1973).

⁹¹ Jonathan D. Moreno, *Protectionism in Research Involving Human Subjects*, in ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS I-1 (National Bioethics Advisory Committee, eds. 2001).

⁹² Hornblum, *supra* note 88 at 424.

⁹³ *Id.* at 423-424.

⁹⁴ *Id.* See also National Institutes of Health Regulations and Ethical Guidelines, Appendix 1, <http://ohsr.od.nih.gov:16080/guidelines/GrayBooklet82404.pdf> (last visited Feb. 7, 2007).

⁹⁵ National Institutes of Health Regulations and Ethical Guidelines, *supra* note 94.

⁹⁶ Hornblum, *supra* note 88 at 423-424.

⁹⁷ Common Rule, *supra* note 32.

V. THE RESTRICTIONS ON PRISONER RESEARCH SHOULD NOT BE LIFTED

Holmesburg was not unusual among contemporary correctional institutions for housing a human subject research program.⁹⁸ If the restrictions against prisoner research embodied in Subpart C of the Common Rule were lifted, it is likely such research would again become the norm. Prisoners are an ideal subject population from a researcher's perspective. Inmate movements can be documented and controlled around the clock, inmates work cheaply, and few people are concerned about their welfare.⁹⁹ But researchers need not be sadistic or depraved for serious harm to result from prisoner research. All the factors that make prisons ideal sites for research also make it difficult, if not impossible, to determine if a prisoner has actually given free and informed consent. For this reason, the restrictions ought to remain in effect.

A. The Inadequacy of Current Human Subject Protections to Protect Prisoners

The Common Rule's human subject protections are a significant improvement from the lax environment of prior decades, and they are likely in theory to prevent recurrences of the kinds of abuses that occurred at Holmesburg and elsewhere. However, there are practical concerns about the effectiveness of those protections. Proponents of prisoner research argue that because the Common Rule's protections have become standard, it is unnecessary to ban prisoner research in order to protect prisoners.¹⁰⁰ They argue that the safeguards currently in place will protect them adequately.¹⁰¹

It is true that there have been important improvements. For example, it is no longer considered acceptable consent to make an inmate sign a form full of technical language, as occurred at Holmesburg.¹⁰² Instead, the details and risks of the experiment must be communicated in a manner that ensures the prisoner understands the information.¹⁰³ The ubiquity of Institutional Review Boards is another major difference in the current research environment. All research subject to the Common Rule¹⁰⁴ and FDA regulations¹⁰⁵ must be approved by an IRB, which maintains continuous oversight to ensure protection of human subjects. However, in practice IRBs are overloaded with experiments to supervise, and often cannot watch researchers as closely as necessary.¹⁰⁶ There have also been questions raised regarding conflicts of interest faced by IRB members.¹⁰⁷ Furthermore, although the regulations were created at a time when most biomedical research occurred in

⁹⁸ See Hornblum, *supra* note 52 at 80.

⁹⁹ See *id.* at 43.

¹⁰⁰ See Hoffman, *supra* note 48; see Schroeder, *supra* note 48.

¹⁰¹ See Hoffman, *supra* note 48; see Schroeder, *supra* note 48.

¹⁰² Hornblum, *supra* note 52 at 26-27.

¹⁰³ 45 C.F.R. § 46.116 (2005).

¹⁰⁴ Common Rule, *supra* note 32.

¹⁰⁵ 29 C.F.R. § 50 (2005).

¹⁰⁶ See Coleman, *supra* note 33 at 11 ("A 1996 General Accounting Office study found that IRBs are overburdened, underfunded, insufficiently prepared, and often too willing to rely on investigators' good intentions as the primary method for protecting subjects").

¹⁰⁷ See Kerry Burke, Note, *Loose-Fitting Genes: The Inadequacies in Federal Regulation of Institutional Review Boards*, 3 B.U. J. SCI. & TECH. L. 10, para. 40 (1997).

academic or in other federally-funded institutions, today a great deal of such research is conducted privately by pharmaceutical companies, who do not receive federal funds and are subject only to FDA licensing requirements.¹⁰⁸ In private settings, researchers are often subject only to the IRB's external oversight.¹⁰⁹

The other protection afforded to research subjects currently is informed consent – the requirement that subjects be informed about and freely consent to the risks they are running.¹¹⁰ Although the Nuremberg Code, and the later documents that built upon it stressed the importance of informed consent, it was not always seriously. At Holmesburg, for example, a waiver filled with technical language was considered adequate to ensure informed consent, even though some of the prisoners read at only a third-grade level)¹¹¹ Kligman said about the beginning of his research at Holmesburg, “things were simpler then. Informed consent was unheard of.”¹¹²

The Common Rule requires that for consent to be informed, information must be conveyed to research subjects in language that they can understand.¹¹³ It also requires that a potential subject must have adequate time to consider whether or not to participate.¹¹⁴ Further information must be given including descriptions of “any reasonably foreseeable risks or discomforts to the subject,”¹¹⁵ as well as potential benefits to the subject or to others.¹¹⁶ The subject must also receive information about medical treatment for injuries resulting from participation,¹¹⁷ contact information for questions regarding a research subject's rights,¹¹⁸ and a clear statement that no one will be penalized for refusing to participate or withdrawing from the study.¹¹⁹ Finally, the Rule forbids the inclusion of a waiver of the subject's legal rights or of the researchers' liability on the part of the institution.¹²⁰

However, there are serious flaws with the Rule's protections that leave vulnerable subject populations, including prisoners, at risk of harm and abuse from dangerous medical experiments.¹²¹ Institutional Review Boards are overworked and susceptible to conflicts of interest, which renders their effectiveness questionable.¹²² It can be difficult even for trained psychologists, much less busy IRB members, to determine if a person has freely consented to participate.¹²³

A 1998 report of the Office of the Inspector General of the Department of Health

¹⁰⁸ Coleman, *supra* note 33 at 7.

¹⁰⁹ *Id.* at 12.

¹¹⁰ Heath, *supra* note 37.

¹¹¹ Hornblum, *supra* note 52 at 26-27.

¹¹² *Id.* at 37.

¹¹³ Common Rule, *supra* note 32.

¹¹⁴ *Id.*

¹¹⁵ 45 C.F.R. § 46.116.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ See Sharona Hoffman, Continued Concern: Human Subject Protection, the Institutional Review Board, and Continuing Review, 68 TENN. L. REV. 725, 729-730 (2001).

¹²² See generally *id.*

¹²³ See generally Paul S. Appelbaum & Loren H. Roth, Clinical Issues in the Assessment of Competency, 138 AM. J. PSYCHIATRY 1462 (1981).

and Human Services acknowledges that IRBs are overworked,¹²⁴ and their oversight is inadequate as a result.¹²⁵ The number of initial reviews conducted by IRBs increased by an average of 42% from 1993 to 1998.¹²⁶ However, resources for IRBs have not been increased at the same rate.¹²⁷ As IRB members are not personally compensated at all, they are being asked to do increasing amounts of work for free.¹²⁸ These facts, combined with the lack of guidance for IRBs in the federal regulations,¹²⁹ means that continuing review is severely inadequate. The OIG report quotes an IRB member who says that it would take a subject's death to make him investigate further.¹³⁰

IRBs have also been accused of conflicts of interest. Many IRB members are faculty or employees of the institution that sponsors the project in question,¹³¹ and may prefer not to make decisions that would cause their institution to lose funding.¹³² In addition, they may be inclined to give their colleagues the benefit of the doubt rather than scrutinizing their proposals carefully.¹³³ While vulnerable populations receive increased protection under the Common Rule via an advocate for that population on the IRB,¹³⁴ this still amounts to only one out of the five-person IRB membership.¹³⁵ A better result would be to make IRBs fully independent of research institutions.

Fixing the problems with IRB oversight is an important task, but even with that accomplished, there would still be significant problems with prisoner research. Measuring a subject's degree of consent is extremely difficult if not impossible, and the environment of a prison makes the danger of coercion much greater. The difficulty with informed consent is not merely a problem of lax oversight which could permit abuses. Rather, it is the fact is that in an environment such as a prison, research subjects are susceptible to a degree of coercion that makes their consent questionable at best.

B. Factors of Informed Consent

Informed consent consists of several different factors, according to both legal and psychological standards. The exact number and definitions vary but three are generally considered essential: competency, understanding, and voluntariness.¹³⁶ A

¹²⁴ Office of the Inspector General, Department of Health & Human Services, *Institutional Review Boards: A Time For Reform* (1998).

¹²⁵ Hoffman, *supra* note 121, at 726-727.

¹²⁶ *Id.* at 737.

¹²⁷ *See id.*

¹²⁸ *Id.* at 732, 737.

¹²⁹ *See* Office of the Inspector General, *supra* at note 124.

¹³⁰ *Id.*

¹³¹ Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 959 (2006).

¹³² Burke, *supra* note 107, at paragraph 38. Burke notes that finding disinterested IRB members is extremely difficult because often similarly situated faculty or employees are the only available people with the expertise to competently review the research proposal. *Id.*

¹³³ *See id.* at 44.

¹³⁴ 45 C.F.R. § 46.305.

¹³⁵ 45 C.F.R. § 46.107.

¹³⁶ *See, e.g.,* Joanne Lynn, *Informed Consent: An Overview*, 1 BEHAVIORAL SCIENCES AND THE LAW 29 (1983).

“competent [subject] who is acting voluntarily and with adequate access to the relevant information”¹³⁷ is a subject who has given informed consent.

Competence is based on factors that can, in theory, be objectively measured, such as age of majority and ability to reason.¹³⁸ Psychologists have developed tools for assessing competence (or capacity), however those tools are not necessarily reliable;¹³⁹ in contrast, coercion appears not to have been measured much at all.

Psychological researchers who have examined whether a prisoner can give informed consent have often focused on the question of “decisional capacity.”¹⁴⁰ However, this concept is hard to define and even harder to measure.¹⁴¹ One state statute defines decisional capacity in reference to medical care as “the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or foregoing life-sustaining treatment”¹⁴² Decisional capacity is a *clinical* judgment,¹⁴³ made by a physician, but one that has legal consequences.¹⁴⁴ Minority and mental illness are factors that can impair decisional capacity and render consent illegitimate.¹⁴⁵

Psychiatric experiments to determine whether environmental factors such as being incarcerated also affect decisional capacity are inconclusive. A recent study attempting to measure decisional capacity in a group of prisoners found that the prisoners did worse than a control group on a test measuring competence¹⁴⁶ particularly in measurements of the subjects’ understanding and appreciation of the situation.¹⁴⁷ However, another exam showed that the prisoner group was more vulnerable to coercion in a number of different respects.¹⁴⁸ Despite this, the researchers found the prison group to have “adequate decisional capacity” as measured by a different test, an Evaluation to Sign Consent.¹⁴⁹ The researchers concluded that although it is important for researchers to take extra care with prisoners, they were on the whole capable of consenting to participate in medical experimentation.¹⁵⁰ However, this finding more likely to demonstrate that decisional capacity is not the best standard for determining whether someone can

¹³⁷ *Id.* at 30.

¹³⁸ *See id.* at 34-36.

¹³⁹ *See* text accompanying notes *infra* 148-153.

¹⁴⁰ *See* David J. Moser et al., *Coercion and informed consent in research involving prisoners*, 45 *COMPREHENSIVE PSYCHIATRY* 1 (2004).

¹⁴¹ *See id.* (discussing the many concerns that the authors had when choosing test subjects and the reasons that these choices could affect the outcome of the experiment).

¹⁴² Act of July 29, 1997, Pub. Act No. 90-246, sec. 10, 40/10, 1997 Ill. Legis. Serv. 2934 (West).

¹⁴³ *See generally* Peter V. Rabins, *Issues Raised by Research Using Persons Suffering from Dementia Who have Impaired Decisional Capacity*, 1 *J. HEALTH CARE L. & POL’Y* 22, 31 (1998) (discussing different impairments that may “impair decisional capacity”).

¹⁴⁴ *See id.* at 23.

¹⁴⁵ *Id.*

¹⁴⁶ The MacArthur Competence Assessment Tool –Clinical Research. David J. Moser, Stephen Arndt, et al., *Coercion and Informed Consent in Research Involving Prisoners*, 45 *COMPREHENSIVE PSYCHIATRY* 1 (January/February 2004).

¹⁴⁷ *Id.* at 5.

¹⁴⁸ *Id.* The MacCAT-CR provides “a great deal of quantitative information” but not “specific cut-off scores for determining whether a subject has adequate decisional capacity or not.” *Id.*

¹⁴⁹ *Id.* at 4, 5. “The ESC [Evaluation to Sign Consent], although much briefer [than the MacCAT-CR], does have specific criteria that subjects must meet in order to demonstrate adequate understanding.” *Id.*

¹⁵⁰ *Id.* at 6-7.

give free consent. Rather, it is more important to examine voluntariness – if people can freely decide to participate in a clinical trial when they are without basic autonomy. Unlike decisional capacity, which is an *internal* measure of comprehension and decision-making ability, similar to a clinical determination that a defendant is competent to stand trial, voluntariness concerns the effect of the subject's environment on that subject's decisions.

The concerns about prisoner research are mostly about the degree of voluntariness of the prisoners' consent.¹⁵¹ The question is not whether prisoners possess the ability to understand their situation and make decisions about it (though the significant rate of serious psychiatric illness in the prison population calls this into question as well).¹⁵² Rather, the question is whether incarcerated research subjects are vulnerable to coercion to participate in experiments. Even more important is whether a prison environment is so inherently coercive that no incarcerated person is, in the words of the Nuremberg Code, "so situated as to be able to exercise free power of choice."¹⁵³

Coercion, like capacity, does not have one clear definition. In attempting to define coercion, some scholars (and courts) have focused on the purpose or intent of the coercer.¹⁵⁴ The Model Penal Code, for example, defines coercion as making "specified categories of threats . . . with the purpose of unlawfully restricting another's freedom of action to his detriment."¹⁵⁵ This definition of coercion is too narrow, as it does not examine the how the coercion affects the subject.

Some scholars have found the argument that prisoners are not free to make uncoerced choices regarding participation in medical experiments to be a form of "paternalism."¹⁵⁶ They argue that when a prisoner is competent¹⁵⁷ and fully informed of the risks of the experiment¹⁵⁸ there is no reason no reason to prohibit his participation in medical research as a subject. To do so would deny the prisoner agency¹⁵⁹ and restrict the pool of human subjects available.¹⁶⁰ However, this argument ignores the very real vulnerability of a prisoner's situation, and its effect on the prisoner's ability to refuse to participate in or withdraw from a study.¹⁶¹

Some argue that it is possible to protect prisoners from coercion that prison conditions create by ensuring that the standard of living is adequate (so that prisoners

¹⁵¹ See Moser et al., *supra* note 140 at 2, 7.

¹⁵² William Kanapaux, *Guilty of Mental Illness*, PSYCHIATRIC TIMES, Jan. 2004, available at <http://www.psychiatrictimes.com/p040101a.html>.

¹⁵³ Nuremberg Code, *supra* note 16.

¹⁵⁴ See M.Gregg Bloche, *Beyond Autonomy: Coercion and Morality in Clinical Relationships*, 6 HEALTH MATRIX 229, 245-249 (1996).

¹⁵⁵ MODEL PENAL CODE § 212.5 cmt. 2, at 264 (1980), *quoted in* Scheidler v. NOW, Inc., 537 U.S. 393, 408 n.13 (2003).

¹⁵⁶ *E.g.*, Schroeder, *supra* note 48, at 982-83.

¹⁵⁷ *Id.* at 983. Here, competence is defined as an IQ of 70, clearly a minimal level. *Id.* at 974.

¹⁵⁸ *Id.* at 975.

¹⁵⁹ *Id.* at 983 n.103.

¹⁶⁰ *Id.* at 989-90. See also Vera Hassner Sharav, *Cheaper than Chimpanzees*, Statement Before the Committee on Ethical Consideration for Revisions to DHHS Regulations on Protection of Prisoners Involved in Research (July 18, 2005), available at <http://www.ahrp.org/testimonypresentations/CheaperThanChimpanzees0705.php>.

¹⁶¹ See Colleen M. McCarthy, *Experimentation on Prisoners: The Inadequacy of Voluntary Consent*, 15 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 55, 60-65 (1989).

are able to obtain medical care, food, and income without having to participate in a study) and that prisoners are not subject to threats of violence (so that they do not volunteer in a study simply to ensure their own safety).¹⁶² The author of one article blithely suggests that the Eighth Amendment requires these things to be provided to prisoners already, so prisoner research will not be coercive.¹⁶³

This opinion ignores the gap between the guarantee of a safe and adequate environment and the reality of many prisons. Poor facilities and fears of violence exist, whether or not they are Constitutional, and to pretend otherwise is naïve. At the very least, until prison conditions are much closer to adequate, research carries unacceptable risks of coercion.

An Inherently Coercive Environment

Even if prisoners around the country were free from violence and enjoyed satisfactory conditions, the risk of coercion is still present simply by the fact that they are imprisoned. Detention by the state, whether in prison or temporary police custody, is an inherently coercive environment.¹⁶⁴ In such an environment, although individual people may expressly consent to participate in an experiment, it is not easy to tell if they have genuinely done so. Institutional control over a prisoner's movements, activities, living conditions, and possibility of release give the appearance (if not the reality in every case) of coercion. There is always the possibility that those factors could be incentives or threats to make prisoners participate. Coercion is an inherent and pervasive element in a prison environment. Psychological or situational coercion may not rise to the level of legal coercion as interpreted by a court, but it may be coercion nonetheless. The coercive effect of armed officers in towers surrounding the prison's perimeter and uniformed officers in every living, dining, and recreational space is obvious. So too is the ability of the correctional staff to mete out punishment for virtually any infraction in the form of confinement, loss of early release time, and other similar tools. Dangerous situations can cause security tactics to escalate to chemical and electrical devices.¹⁶⁵ Not every factor that can affect a person's decision to participate is coercive, but in the case of prisoners whose freedom is, by definition, restricted, many otherwise innocuous incentives can be coercive. For instance, a prisoner is not free to shop around for medical care, to weigh options for employment, etc. Researchers need to take more than ordinary care to ensure that incarceration does not coerce a prisoner to participate as human research subject.

There are many coercive effects of the prison environment and as already stated, they need not come from an intent to take away a person's free consent. The promise of payment, medical care, and the chance to get out of prison earlier are all factors that could contribute to an environment in which a person would feel constrained to participate in a study regardless of his or her inclinations.

Coercion can come from a belief (real or perceived) that participation in a clinical

¹⁶² Schroeder, *supra* note 48, at 995; Hoffman, *supra* note 48, at 489.

¹⁶³ Schroeder, *supra* note 48, at 995.

¹⁶⁴ See *Miranda v. Arizona*, 384 U.S. 436, 533 (1966) (White, J., dissenting) (noting that the majority views in-custody interrogation as inherently coercive).

¹⁶⁵ David L. Thomas and J. Morrissa Watson, *Advance Directives in a Correctional Setting*, 4 PSYCHOL. PUB. POL'Y & L. 878, 886 (1998).

trial is the best or only way to receive medical care.¹⁶⁶ In a recent study of non-incarcerated participants in clinical trials, several participants “explicitly said that they had nowhere else to turn for medical care, and a few said that without the research intervention, they would have died.”¹⁶⁷ The authors of that study emphasize the difference between this attitude - the hope of medical benefit from participation in a study, and true voluntariness. “The notion of voluntary “choice is inevitably different in settings where there are few reasonable alternatives for medical care.”¹⁶⁸ This is more likely to be true in a prison, where a person cannot simply find a different doctor if one is unable to help.

Beyond this, prison and other detention settings are places where health care options are limited and the quality of care provided is often substandard to begin with. In 2005 and 2006, the *New York Times* ran a series of articles exploring this problem.¹⁶⁹ The articles examined the conduct of a private, for-profit company, Prison Health Services (PHS), which provides medical services to 237,000 inmates in detention facilities in 28 states.¹⁷⁰ The *Times* reported that neglect and errors on the part of PHS personnel have led to serious injuries and deaths in prisons, jails, and youth detention centers. Prison clinics are understaffed and poorly supplied.¹⁷¹ Furthermore, complaints by patients have been ignored or minimized,¹⁷² sometimes with tragic results. Mental health patients have received especially poor care.¹⁷³ In a prison environment where substandard medical care is often all that is available, prisoners may be especially vulnerable to the kind of coercion described above.

Prisoners may also be vulnerable to coercion due to their desire to be released, and their belief that participation in a clinical trial will reflect favorably on them when they are considered for parole.¹⁷⁴ In earlier decades, the connection between participation and parole in prison-based research has been quite explicit.¹⁷⁵ Prisoners “were often rewarded for their services as research subjects by early parole or commutation of sentence.”¹⁷⁶ As recently as 1979, in *Bailey v. Lally*, one doctor

¹⁶⁶ Nancy E. Kass, Suzanne Maman, & Joan Atkinson, *Motivations, Understanding and Voluntariness in International Randomized Trials*, 27 ETHICS AND HUMAN RESEARCH 1, 7 (2005).

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ See Paul von Zielbauer, *As Health Care in Jails Goes Private, 10 Days Can Be a Death Sentence*, N.Y. TIMES, Feb. 27, 2005, at A1; Paul von Zielbauer, *Rikers Suicide Called a Glaring Example of Poor Care*, N.Y. TIMES, Apr. 4, 2005, at B1; Paul von Zielbauer, *Investigators Called Rikers Medical Contract Illegal, State Panel Says*, N.Y. TIMES, Nov. 22, 2005, B1; Paul von Zielbauer, *A Company's Troubled Answer for Prisoners With H.I.V.*, N.Y. TIMES, Aug. 1, 2005, at A1; Paul von Zielbauer, *Evaluation of Medical Care Provider in the City's Jails Is Questioned*, N.Y. TIMES, Dec. 26, 2005, at B1.

¹⁷⁰ See Paul von Zielbauer, *As Health Care in Jails Goes Private, 10 Days Can Be a Death Sentence*, N.Y. TIMES, Feb. 27, 2005, at A1.

¹⁷¹ *Id.* (“In Alabama, one prison has only two doctors for more than 2,200 prisoners; one AIDS specialist, before she left this month, called staffing “skeletal” and said she sometimes lacked even soap to wash her hands between treating patients”).

¹⁷² *Id.* The article relates the story of Victoria Williams Smith, who died of a heart attack after her complaints of chest pains were ignored.

¹⁷³ See, e.g., Paul von Zielbauer, *Rikers Suicide Called a Glaring Example of Poor Care*, N.Y. TIMES, Apr. 4, 2005, at B1 (stating that suicide is “the leading cause of death in American jails”).

¹⁷⁴ McCarthy, *supra* note 161, at 63.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

wrote a letter to a parole board on behalf of a prisoner who had participated in a study.¹⁷⁷

Prisoners are no longer told that participation in research will help them with the parole board, but the perception that it could be helpful is powerful, and may have a coercive effect on potential research subjects. In *Bailey*, the court stated that this perception did not constitute coercion, since the prisoners were informed that participation would have no effect on parole decisions, and because the doctors did not know if letters from them would have any effect.¹⁷⁸ However, even the slight chance of affecting parole is a powerful incentive and could well have the effect of causing someone to participate who otherwise would not.

Finally, payment for study participation is an extremely powerful incentive that has the demonstrated potential of affecting prisoners' decisions to participate in research. Former prisoners who participated in experiments at Holmesburg almost universally cited the money they received as their motivation for participating.¹⁷⁹ At first glance this seems to be a straightforward incentive, not any form of coercion. Compensation does, after all, cause many people to do things they would not do uncompensated, and this fact is not generally considered to be oppressive. However, in a prison setting the possibility of earning money is especially strong where job opportunities are limited by the fact of incarceration. In prisons like Holmesburg, the only other options for earning money often pay a fraction of what a prisoner can earn as a research subject.¹⁸⁰ More importantly, money is important to many aspects of incarcerated life, from purchasing toiletries to raising bail (in jails) to paying a lawyer.¹⁸¹ The combination of restricted options, low pay and the need for money to exercise one's rights creates a risk that financial compensation will have a coercive effect upon research subjects.

Recent figures from the Bureau of Justice Statistics confirm that the incarcerated population from which research subjects would be drawn is especially vulnerable to economic coercion. Sixty-eight percent of the prison population did not have a high school diploma in 2003,¹⁸² and almost half of those without a diploma made less than \$1,000 a month before they were incarcerated.¹⁸³ Ten percent of that population reported being homeless in the year before incarceration. Incarcerated people are more likely to be poor upon entering prison, and without the education which could lead to employment that could lift them out of poverty once they are free.

Concerns beyond consent

Beyond the question of autonomy and consent, there are good reasons to be wary of prisoner research. The history of medical research in the United States (as

¹⁷⁷ *Bailey v. Lally*, 481 F. Supp. 203, 221 (D. Md. 1979); McCarthy, *supra* note 161.

¹⁷⁸ *Id.*

¹⁷⁹ Hornblum, *supra* note 52, at 21-23.

¹⁸⁰ *Id.* at 22.

¹⁸¹ *Id.* at 23-24.

¹⁸² CAROLINE WOLF HARLOW, EDUCATION AND CORRECTIONAL POPULATIONS, BUREAU OF JUSTICE STATISTICS, January 2003, available at <http://www.ojp.usdoj.gov/bjs/pub/pdf/ecp.pdf>.

¹⁸³ Bureau of Justice Statistics, Key Facts at a Glance, <http://www.ojp.usdoj.gov/bjs/glance.htm> (last visited Feb. 7, 2007).

elsewhere) involves too many examples of powerless groups being used as research subjects in experiments that were not designed for their benefit, but for society as a whole. From Holmesburg and other prisons, to Willowbrook,¹⁸⁴ to the infamous Tuskegee syphilis experiments on poor Black men,¹⁸⁵ people whose lives were considered less valuable historically have borne many of the risks that medical advances were based on. The danger of society deciding that some lives are expendable is a real one, and something we must guard against.

Although Tuskegee and similar events are universally looked back upon with horror, the idea that some people could appropriately be used as means to the end of other people's health is by no means dead. This is especially true of prisoners who are viewed as owing a 'debt to society,' one which some argue may be paid with their bodies. Legal scholars have debated whether prisoners ought to be permitted to donate organs for transplants¹⁸⁶ and at the most extreme, whether organs should be harvested from executed prisoners.¹⁸⁷ This instrumentalist view of human beings is ethically offensive and has the potential to lead to even greater abuses.¹⁸⁸

Some scholars point to an abstract concept of the dignity of human beings¹⁸⁹ which is offended by harmful or abusive treatment, whether or not the people involved consent to it.¹⁹⁰ Others have discussed the potential damage to the public trust in the medical profession if its members are permitted to conduct dangerous or painful interventions even with consent.¹⁹¹ This critique applies to all human research subjects, however prisoners are especially vulnerable.

VI. CONCLUSION – PROTECT HUMAN SUBJECTS WITHOUT LIFTING THE PRISONER RESEARCH BAN

The Institute of Medicine's report¹⁹² recognizes the vulnerability of prisoners as research subjects and makes recommendations that are intended to compensate for this vulnerability. Some of these recommendations ought to be implemented.

¹⁸⁴ Willowbrook is another infamous case of unethical medical research conducted on a population considered expendable. Willowbrook was an institution for mentally handicapped children in New York. Between the 1950s and the 1970s physicians studied the course of hepatitis by infecting residents with it. Like with Tuskegee the researchers insisted that their actions were ethical because they were not altering the course of nature, since residents would in all likelihood become infected on their own (hepatitis was rampant at Willowbrook). See Brandt, *supra* note 29; see David J. Rothman, *Were Tuskegee & Willowbrook 'Studies in Nature'?*, 12 THE HASTINGS CENTER REP. 5, 6 (Apr. 1982).

¹⁸⁵ See Brandt, *supra* note 29.

¹⁸⁶ See Mark F. Anderson, *The Prisoner as Organ Donor*, 50 SYRACUSE L. REV. 951 (2000); Whitney Hinkle, Note, *Giving Until It Hurts: Prisoners Are Not the Answer to the National Organ Shortage*, 35 IND. L. REV. 593 (2002).

¹⁸⁷ Anderson, *supra* note 186; Laura-Hill M. Patton, Comment, *A Call for Common Sense: Organ Donation and the Executed Prisoner*, 3 VA. J. SOC. POL'Y & L. 387 (1996) (arguing that organs harvested from executed prisoners provides "viable, transplantable organs to desperate and terminally ill patients").

¹⁸⁸ See Hinkle, *supra* note 186, at 597-98. For example, China routinely harvests organs from executed prisoners. *Id.* at 597. It has been argued that the increase in death sentences is because of the need for organs rather than being a 'unanticipated benefit.' *Id.* at 598.

¹⁸⁹ See, e.g., Richard W. Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATH. LAW. 455, 488-90 (1996).

¹⁹⁰ *Id.*

¹⁹¹ Coleman, *supra* note 33, at 10.

¹⁹² Committee, *supra* note 2, at 1.

However, they should not be tied to lifting the larger restrictions of prisoner research as the Committee recommends.

The most important of these recommendations is the expansion of the Common Rule's protections for human research subjects. The Committee recommends expanding the definition of "prisoner"¹⁹³ from the current definition in Subpart C of the Common Rule (a person who is "involuntarily confined or detained in a penal institution"),¹⁹⁴ to include people on parole or probation, or who otherwise have their "liberty... restricted by the criminal justice system."¹⁹⁵ This change would expand the population covered by more than 200 percent.¹⁹⁶

The Committee also calls on Congress to implement uniform guidelines for treatment of all human research subjects by extending the Common Rule's protections to all human research subjects, regardless of whether the study or trial is federally or privately funded.¹⁹⁷ All sponsors of research, including agencies currently following the Common Rule, other federal agencies, and state, local, or private sponsors of research, would be required to follow an expanded version of the Common Rule.¹⁹⁸ This change is extremely important because of the increase in non-federally funded medical research, which places more human research subjects beyond the current reach of the Common Rule.¹⁹⁹

These recommendations should be implemented. However, they are not enough to ensure the safety and voluntary consent of incarcerated research subjects. The Commission makes other proposals intended to protect research subjects, such as a centralized public database of all experimentation involving prisoners,²⁰⁰ and a requirement that prisoners make up no more than half of the subjects in any given trial.²⁰¹ These proposals would likely limit the kinds of egregious abuses that have occurred in the past, however they do not address the inherently coercive nature of prisoner research.

Legislation exists that will add these necessary protections without opening the doors to increased prisoner research, as the Commission's recommendation does. In the past several Congresses, dating back to 1997, bills have been introduced that extend Common Rule protections to all human research subjects.²⁰² The Protection for Participants in Research Act, introduced by Representative Diana DeGette (D-CO) in Congress in 2006, is the most recent version.²⁰³ This Act would create the position of Director of the Office for Human Research Protections within the

¹⁹³ *Id.* at 4-5.

¹⁹⁴ 45 C.F.R. § 46.303(c).

¹⁹⁵ Committee, *supra* note 2, at 4-5.

¹⁹⁶ *See id.* The Committee states that in 2004, 2.1 million people were covered under the current protections, and with the proposed change another 4.9 million would be covered. *Id.*

¹⁹⁷ *Id.* at 6.

¹⁹⁸ *Id.*

¹⁹⁹ Memorandum from Harold T. Shapiro, Chairman, National Bioethics Advisory Commission (NBAC), to President Clinton (May 4, 1999) (cited in Beverly Woodward, *Challenges to Human Subject Protections in US Medical Research*, 282 J. AM. MED. ASS'N 1947, 1951 (1999)).

²⁰⁰ Committee, *supra* note 2, at 7.

²⁰¹ *Id.* at 9.

²⁰² *See, e.g.*, Human Research Subject Protections Act of 1997, S. 193, 105th Cong. (1997); Protection for Participants in Research Act of 2003, H.R. 3594, 108th Cong. (2003).

²⁰³ Human Research Subject Protections Act of 2006, H.R. 5578, 109th Cong. (2006).

Department of Health and Human Services, and it would give the Director of that office the power to audit any entity conducting research with human subjects, and to limit or suspend the projects if they were found not to be in compliance with the Common Rule.²⁰⁴ The Director would also have the power to audit Institutional Review Boards to ensure that they are taking their duties of oversight seriously and if necessary, to invalidate an IRB's approval of research proposals.²⁰⁵ This bill is an important step forward and should be enacted.

As long as prisons are places where people fear violence and intimidation, where they have extremely limited opportunities for services or earning money, human subject research risks exploiting that vulnerability and harming inmates. Although individuals may in fact be freely consenting to participate in a study, it is not easy to determine who is being coerced and to what degree. The danger of coercing people into becoming research subjects is not something that can be balanced by a societal benefit; it goes against fundamental ethical principles of medicine and society. The ban on prisoner research ought to remain in place.

²⁰⁴ *Id.*

²⁰⁵ *Id.*