CONSIDERING BEHAVIORAL AND BIOMEDICAL RESEARCH ON DETAINEES IN THE MENTAL HEALTH UNIT OF AN URBAN MEGA-JAIL

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I. INTRODUCTION

In July, 1994, the Cook County Bureau of Health Services signed a contract with the Isaac Ray Center, Inc., for the latter to "furnish administrative, supervisory and professional clinical Mental Health Services to insure the provision of quality ambulatory and infirmary Mental Health Services" to detainees in the Cook County Jail in Chicago.¹ The Cook County Jail is one of the two largest jails in the country, housing some 9,000 inmates at any one time and "processing" a total of as many as 80,000 criminal defendants over the course of a year.²

The County Bureau of Health Services, the purchasing party to the contract, is responsible for delivering health care services within the Jail. It does so via an entity called Cermak Health Services.³ All other Jail services, basic population maintenance, security, and everything associated therewith, are provided under the auspices of the Cook County Department of Corrections.

Cermak Health Services provides a full range of medical services

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¹ A cardinal rule of contracts, one must assume, is that for a contract to be valid, everything has to be stated at least twice in the same sentence and with even greater redundancy throughout the document.

² This information is given, among other places, in the contract itself. Cook County Bureau of Health Services Cermak Health Services of Cook County Contract for Mental Health Services, June 23, 1994, at 2.

³ Named after Anton Cermak, a famous Chicago mayor not named Daley.
at the Jail, from general somatic, including surgical services, to the specialties of dental, substance abuse, and psychiatric care. While the nucleus of the Health Service is located in one building on the Jail grounds, called the Cermak Building or Cermak Hospital, there is a network of "sick call" areas and dental units scattered throughout the complex and the ten separate "divisions" in which inmates are housed. The Cermak Building contains a 520-bed Residential Treatment Unit for male detainees with chronic mental health or medical problems. There are also two infirmary units for inmates with acute problems, a 40-bed psychiatric infirmary, and a 25-bed medical/surgery unit. Female detainees are all housed in one division which is separate from the male units. Most basic services are provided on-site there, including primary health care via a six-bed infirmary, psychiatric care via a day program, and a substance abuse treatment program.

The vendor to the contract, the Isaac Ray Center, is a private, nonprofit institute for forensic psychiatry and psychology which was founded in 1978. In addition to offering evaluation and treatment services for mentally disordered offenders referred to by the courts, by defense and prosecuting attorneys, and by other law-related agencies, the Center operates special programs for people with sexual behavior problems, emotionally disturbed children and adolescents, and victims and witnesses of crime. The Center also supports a substantial research and education program. With a staff of 15 mental health care specialists, predominantly psychiatrists and psychologists, and one lawyer, plus a contingent of adjunct professionals and annually rotating post-doctoral "fellows" in psychiatry and law, the Isaac Ray Center is one of the largest institutes of its kind in the country. It retains its original links to Rush-Presbyterian-St. Luke's Medical Center by virtue of its location on the Rush campus in Chicago, and the fact that its psychiatric staff members hold faculty positions at the Medical College.

4. Most institutes of similar function are "public," that is, part of a state university or other public educational/research undertaking or agency. The University of Virginia's Institute of Law, Psychiatry, and Public Policy, combining faculty and other resources from both its medical school and its law school, is perhaps the best-known of these public models. The Isaac Ray Center, by contrast, is corporately separate from Rush, which is a private university to begin with.
II. PRIVATIZATION OF JAIL SERVICES: A SIDELIGHT

Part of a larger privatization movement that has gained considerable momentum over the past fifteen years, the “contracting out” of correctional services to private vendors is no longer an uncommon event. Today there are entire prison facilities run by private correctional companies which in some cases have also built, as well as “site selected” and financed, the physical plants from scratch. Moreover, the discrete provision by private vendors of a number of essential prison services such as food service, medical/dental care, and equipment maintenance is a longstanding practice, particularly in smaller institutions where the use of in-house staff for these purposes would not be efficient. Even so, the procurement of a contract for mental health services in a facility as large and visible as the Cook County Jail in Chicago represents an experiment in prison-services privatization that is unprecedented.

The uniqueness of the Cermak-Isaac Ray contract suggests that its implementation over the next few years is likely to draw the interest of students of the privatization phenomenon. The focus of this article, however, is on matters that are largely independent of the public/private service dichotomy.

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5. For discussion of the broad, if not stunning, range of recently “privatized” public services and entities, including corrections, see Samuel Jan Brakel, Prison Management, Private Enterprise Style: The Inmates’ Evaluation, 14 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 175 (1988), and Samuel Jan Brakel, “Privatization” in Corrections: Radical Prison Chic or Mainstream Americana? 14 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 1 (1988), especially the introductory pages. The decision in 1994 of the Hartford, Connecticut authorities to cede management of the public school system to a private operator signaled the continuation of the privatization trend and its extension to service arenas viewed as quintessentially “public.” Cf. proposals in Chicago, publicized in the final weeks of 1994, to privatize janitorial services in the public schools; a reported bastion of government patronage and public employee unionism.

6. Corrections Corporation of America (CCA), the leader in this industry today, has 44 contracts for the management of some 26,000 “beds” in prison and jail facilities in 11 U.S. states, Puerto Rico, the United Kingdom and Australia. In at least a third of these, the company undertook responsibility for the construction or major renovation of the physical plant. CORRECTIONS CORPORATION OF AMERICA, ANNUAL REPORTS.

7. On a smaller scale, Cook County has a contract with a private agency, the Gateway Foundation, for on-site substance abuse services for male and female detainees at the Jail.
III. THE CONTRACTORS' RESEARCH MISSION

The Isaac Ray Center is among other things a research institute. Part of the motivation of those who pushed for the contract on the County's side was that the Center's experience in mental health related research would be put to use at the Jail. Likewise, Cermak Health Services had, long before the signing of the contract, developed a reputation for innovation in the treatment of special classes of detainees and for sharing the results of its special program efforts with other correctional entities. The expectation that the Isaac Ray Center's professional staff would conduct research involving the Jail population under its care thus represents a continuation of the "academic" mission of both contracting parties.

Those sensitive to the need to protect human subjects from the crasser motivations and methods of researchers could be forgiven for being a bit troubled by this implicit mission. Convenience, like power, can corrupt, and the fact that Isaac Ray's medical and research staff suddenly have at their disposal a nice, literally captive population to "experiment on" raises concerns that ought not be dismissed out of hand.

These concerns can, however, be substantially assuaged by pointing out the following realities: (1) whatever the research interests and expectations, the primary and only contractually stated mission of the Isaac Ray Center's staff is to ensure the provision of quality medical care, both psychiatric and psychological, to the Jail population; (2) the caregiving mission is not necessarily at odds with research objectives, especially where the results of the research have the potential to benefit the population studied; (3) all research in jails, prisons, or similar "total" institutions involves captive populations whose consequent need for a heightened level of protection is well enough acknowledged today that much of the machinery for ensuring such protection is in place; and (4) to the extent the contracting parties entered into the contract for the purpose of enhancing research capabilities, they can be expected to have greater than ordinary sensitivity to, or at least awareness of, legal and ethical constraints on research.

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8. Cermak's drug abuse treatment program, via subcontract to the Gateway Foundation, and its HIV testing, treatment and education program, funded in part by the Ford Foundation, are examples. Currently in the proposal stage is a major "social intervention" study to improve treatment compliance among tuberculosis patients after they leave the Jail.
conducted in the context of involuntary confinement and to the need to develop a finely tuned research protocol that will provide maximum protection of the subjects consistent with the needs of the research.9

IV. THE CURRENT LEGAL/ETHICAL CONTEXT

The use of human subjects in behavioral and biomedical research is today circumscribed by a quite elaborate set of rules, regulations and guidelines.10 These legal and ethical strictures give force to what are perceived as certain fundamental moral principles guiding man’s treatment of his fellow man. The source of these principles is variously traced to “natural law,” man’s “humanity,” or some other hopeful metaphysical construct whose observance would be considered, or so the aspiration is, a matter of course for all civilized societies. However, the articulation of these principles as in anyway binding, as law, has generally come in the aftermath of historical experience that directly contradicts the benign assumption that they are universally shared or adhered to.

For example, a comparatively recent international articulation of these “humanitarian” precepts and their application to experimentation on humans is found in the Nuremberg Code,11 a document that came into being following the Nazi Holocaust and the world community’s decision to sit in judgment on the more conspicuous individual perpetrators of the “crimes against humanity” committed massively, and with the sanction of the State, during this period. On a much smaller and contextually limited scale, widespread publicity surrounding a series of experimental research “scandals” in this coun-

9. At the risk of being self-serving, it could be suggested that the writing of this article is evidence of this sensitivity. Another example of this mentality might be the regular attendance of Isaac Ray personnel at research-ethics discussion sessions organized by the Cook County Bureau of Health Services.

10. See references, infra, to the guideline-style reports of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the extensive regulations promulgated by the Department of Health and Human Services and the narrower regulations of the Food and Drug Administration. In addition, many state health service agencies and even individual institutions have developed rules and guidelines covering the conduct of research in their respective domains.

try provided the impetus for Congress to create a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, with a mission to formulate guidelines and principles for the conduct of scientific inquiry that, as the Commission's name indicates, involves the use of human subjects. The Nuremberg experience provided much of the inspiration for the Commission's deliberations and for its formulation, reflected in its official reports, of the essential value conflict as one of medical progress versus the protection of persons; a dichotomy that acknowledges the potential threat posed by the unchecked pursuit of scientific objectives to our moral standards as a society and as individual human beings.

The work of the National Commission has in turn provided the foundation for the Department of Health, Education and Welfare ("HEW") to develop a detailed set of regulations for the "Protection of Human Research Subjects." The DHHS (today "DHHS") protections extend to any research conducted or supported by the federal government or coming directly under the substantive regulatory authority of the government or any of its agencies.

The DHHS regulations contain a special section of "additional

12. E.g., the Tuskegee syphilis study where research objectives trumped the obligation to treat, the Willowbrook State Hospital study in which retarded children were infected with hepatitis, and the study at Brooklyn's Jewish Chronic Disease Hospital where terminally ill patients were injected with live cancer cells under incomplete consent procedures.

13. See Samuel J. Bralek et al., The Mentally Disabled and the Law 288-94 (1983). A brief description plus citations to further literature on these "scandals" can be found in these pages. See generally Schroeder, infra note 23 and Macklin, infra note 27. The so-called seminal article on this subject, from which many of the others are at least partially derivative, is William J. Curran, Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies, 98 DAEDALUS 542 (1969). Other notable studies in the general area are Jay Katz, Experimentation with Human Beings (1972), and Robert J. Levine, Ethics and Regulation of Clinical Research (2d ed. 1986).


15. Today it is known as the Department of Health and Human Services ("DHHS").


17. The DHHS regulations were preceded more than a decade earlier by regulations promulgated by the Food and Drug Administration ("FDA"), which were also in good part premised on and inspired by the Nuremberg Code. The aim of the FDA regulations was, however, confined to drug research. In their present form they can be found in 21 C.F.R. § 312 (1994).
protections” for prisoners, owing to this population’s particular vulnerability, or as the section’s statement of purpose notes, because “their incarceration ... could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research.” Given that the definition of “prisoner” comprises “any individual involuntarily confined or detained in a penal institution,” including those “detained pending arraignment, trial, or sentencing” as well as “individuals detained in other facilities by virtue of ... commitment procedures,” these safeguards apply in principle to the detainee population covered under the Cermak-Isaac Ray contract. Their application in fact would be contingent on whether either of the parties to the contract receives federal money for managing or studying the population.

It is important to note that the current legal/ethical matrix regarding the conduct of research on prison and jail detainees is quite restrictive. This restrictive stance matches empirical developments over the last half-century. Whereas prisoners in this country served as a prominent population resource for biomedical research, the dominant one for drug testing, during World War II and the two immediately following decades, they are today all but excluded from the list of human subjects on which such research is conducted. One of the suggestions, although incidental, of this article is that this development may not be as desirable as it is generally touted to be.

V. WHAT CONSTITUTES RESEARCH?

A question to be addressed before getting into the matter of the ethics and values, or costs, risks, and benefits of human subjects research is: what constitutes research? The answer is more elusive than one may think. It presumes, in particular, a principled way of drawing the line between practice and research.

18. 45 C.F.R. § 46.301 (1994).
20. 45 C.F.R. § 46.303(c) (1994).
21. This includes the “political” posture or posturing today of officials with relevant authority.
22. Whether it is a matter of effect or cause is difficult to say.
At the extremes, or perhaps even at the norms, the distinction between medical/behavioral practice and similarly intentioned research is distinct enough. Prototypical medical practice involves the provision of standard, accepted therapy whose objective is to promote the well-being of the individual patient/client, whereas the classic research mode is represented by the administration of non-therapeutic, depersonalized tests or inquiries whose purpose is to uncover, confirm, or reject the viability of new theory or procedure. The lines of distinction become more blurred, however, the closer one gets to the middle of the practice-research continuum, or, as occurs with some regularity, when the two are conducted together. Moreover, the conceptual and operational muddling is only compounded by the fact that medical/behavioral therapies that are new or untested or that otherwise depart from standard practice are often called "experimental," a word which in its stricter meaning is exclusively associated with the research realm.

It should be self-evident, however, that not every implementation of an "experimental" technique, be it diagnosis or treatment, is research. The elements defining "true" research, such as hypothesis formulation and testing, or a methodology for testing that yields valid, generalizable conclusions may be lacking. But what the loose use of the term "experimental" does give notice of is that some medical practices present risks to patients similar to those that may be encountered by subjects of medical research. In sum, labels are not determinative. What is called research isn't necessarily. What is not called research, but passes for practice, may in fact have many of the earmarks of research, and ought to the extent feasible be conducted with the human-subject safeguards that apply to the research endeavor.

explicitly. The discussion in the text below is based in part on this report's treatment of the matter. Nancy Dubler also has written extensively on ethical issues pertinent to medical practice-research in prisons. See, e.g., NANCY N. DUBLER, HEALTH CARE IN PRISONS, JAILS AND DETENTION CENTERS: SOME LEGAL AND ETHICAL DILEMMAS (1983); Nancy Neveloff Dubler et al., Management of HIV Infection in New York State Prisons 21 COLUM. HUM. RTS. L. REV. 363 (1990).


26. Included also would be "representative" sampling of research subjects and the deliberate choice of conditions and procedures so as to permit replication.
VI. BASIC ETHICAL PRINCIPLES: RESPECT, BENEFICENCE AND JUSTICE

In one of its early reports, the National Commission identified three fundamental principles that its members felt should guide the conduct of research involving human subjects; respect for persons, beneficence, and justice.27

The principle of "respect" for persons is primarily permissive. It posits that individuals are free to do as they wish and that their life choices may not be interfered with so long as those choices do not impinge upon the rights of others.28 In other words, individuals are to be treated as autonomous agents. The only instances in which the "respect" principle suggests a prohibitive posture is when the individual’s autonomy is, for one reason or another, lacking or diminished.29 In such situations, the need may arise to protect the individual from himself and/or from others.

"Beneficence" has both negative and positive implications. In medicine, the negative articulation traditionally precedes the affirmative one, as per the canon that the physician, first, shall do no harm to the patient. As to the positive side, the potential benefit of medical intervention is its raison d'être in the practice setting. In research, this is less evidently true. Presumably, benefits are anticipated, but they may be less direct than in therapeutic practice, or they may not go to the patient/subject at all but to other, conceivably similarly-situated, population groups or, more grandiosely, to mankind as a whole. Most importantly, there are usually risks, small or large, in medical interventions of both the therapeutic and academic kind. This means that if proper deference is given to the concept of "beneficence," there will have to be a risk-benefit assessment before any project or procedure is permitted to go forward.

"Justice" in this context refers to the equitable distribution of the benefits and risks of any intervention.30 Whether the intervention is practice or research, therapeutic, non-therapeutic or not directly

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27. See generally THE BELMONT REPORT, supra note 14. For a philosophical analysis of these three constructs, see Ruth Macklin, Some Problems in Gaining Informed Consent from Psychiatric Patients, 31 EMORY L.J. 345 (1982).
28. See generally THE BELMONT REPORT, supra note 14, at 4-6.
29. Id. at 5.
30. Id. at 8.
therapeutic, the selection of patients/subjects must be rational, based on demonstrated "fit" or need, or random in the absence of demonstrable selection priorities. There can be no improper or irrational exclusions or inclusions of classes of individuals, and even within rationally selected classes, the distribution of benefits and risks must be individually "fair."

When applied to the specific issue of behavioral or biomedical research on prisoners and jail detainees, where do these basic principles lead?

A. Respect for Persons and Informed Consent

The respect-for-persons principle in legal terms is encapsuled by the doctrine of informed consent.\(^3\) Though its roots go far back in Anglo-American common law, the doctrine first gained explicit recognition in American courts only some three decades ago.\(^2\) Since that time, informed consent laws have been statutorily enacted in many states and a large literature has developed delineating the doctrine’s core meaning, its interjurisdictional variations, and its outside parameters.\(^3\)

For our purposes, it is enough to know that for an individual’s consent to be sufficiently "informed" by legal standards and to be deemed legally valid, it must have been given competently, knowingly and voluntarily.\(^4\)

1. Competence

In contrast to studies involving mental hospital populations, the subjects’ competency to give consent is not a dominant concern in regard to research in prisons or jails. Nevertheless, the issue cannot be neglected in the latter setting. Studies indicate, though their estimates vary so widely that the particular credibility of all is undercut, that mental illness is disproportionately high among prisoners and jail

\(^3\) Id. at 10. It is not unreasonable to assume that, at least at a basic level, the name of the doctrine adequately conveys its substantive essence.


\(^3\) See Charles W. Lidz et al., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY 3-23 (1984). The discussion should also satisfy those interested in the concept’s perimeters, one would suppose, or even its peripheries.

\(^4\) See supra note 31; see also Kaimowitz v. Dept of Mental Health, No. 73-19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973).
detainees as compared to the general population.\textsuperscript{35} There are also suggestions that mental retardation is more prevalent in prisons and jails than in the outside world.\textsuperscript{36} The evidence is indisputable that the average IQ level is significantly below the norm for incarcerated populations.\textsuperscript{37}

When, as in the case of the jail population for whose well-being the Isaac Ray Center's psychiatrists and psychologists are responsible, the inmates by definition have mental problems of one kind or another, the matter of the subjects' competency assumes considerably larger relevance. The likelihood is high that substantial numbers of the Isaac Ray clients fall into the category of what the regulatory community today refers to as "cognitively impaired persons"\textsuperscript{38} and that the impairment is sufficiently serious to at least call into question their capacity to make an informed decision about their participation in medical research.

It would be wrong, however, to presume as incompetent all mentally or cognitively impaired detainees and to exclude them from research as a class. Because mental impairment comes in many degrees and with facets whose effect on cognition is both varied and varying, the issue of capacity to consent should be assessed on an individual and time-specific basis. Consistent with this principle, the DHHS regulations prescribe no special restrictions or protections for cognitively impaired persons beyond those which apply to them by virtue of their institutionalization, if such is the case, in mental health or correctional facilities. It is more the fact of confinement, rather than cognitive impairment, that puts the Isaac Ray-Cermak population in the "especially vulnerable" class of subjects for whom special safeguards may be in order.

Two practical directives flow from the above: (1) that it would be \textit{advisable} to screen all jail detainees for their competency to consent to research participation; but (2) that for the Isaac Ray subgroup, such a screening should be treated as an \textit{imperative}.

\textsuperscript{35} \textit{See}, \textit{e.g.}, Linda A. Teplin, \textit{The Prevalence of Severe Mental Disorder Among Male Urban Jail Detainees: Comparison with the Epidemiologic Catchment Area Program}, 80 AM. J. PUB. HEALTH 663 (1990).

\textsuperscript{36} \textit{See}, \textit{e.g.}, James W. Ellis \& Ruth A. Luckasson, \textit{Mentally Retarded Criminal Defendants}, 53 GEO. WASH. L. REV. 414 (1985).

\textsuperscript{37} This is in part, if not wholly, a function of the fact that prison inmates are drawn predominantly from the lower socio-economic strata.

\textsuperscript{38} \textit{See}, \textit{e.g.}, \textit{PROTECTING HUMAN RESEARCH SUBJECTS: INSTITUTIONAL REVIEW BOARD GUIDEBOOK, SPECIAL CLASSES OF SUBJECTS}, 6-26.
Discussion of the precise content of such a competency screening instrument is beyond the scope of this article. There are available models and methods that could be used pretty much as they are. Alternatively, researchers could devise “original” tests, relying more loosely on the work of others.

The question remains: what to do with subjects who test out as not competent? The answer that they should be excluded from the research project may not be so self-evidently correct as it seems. First, the elimination of subjects lacking capacity to consent may in a population such as the Isaac Ray group eliminate too many of those whose participation is essential to the objectives and the validity of the research. Second, if there is substantial direct therapeutic benefit, or potential benefit, to the subjects, exclusion of the incompetent would work as a penalty on them. An informed assessment of risk may require competence, but it is less clear that a competent risk assessment is a necessary prerequisite to the opportunity to benefit from research, especially where the risk is objectively low. Substituted consent by a guardian may be one way out of this dilemma. Another approach would be to lower the consent standard “normally” required for such decisions.

2. Comprehension

The requirement that consent be “knowing” obligates the researcher to provide adequate information about the project to the potential participant and to ensure that the information is presented in such a manner that it can be understood, as the DHHS regulations emphasize. The comprehension issue shades into the issue of competency, of course, to the extent that incompetent subjects are presumed not to be able to understand and that special communication efforts may have to be made to marginally competent individuals, of whom, as noted, there may be a disproportionate number in prisons and jails.

Medical professionals in the treatment setting have what is called a therapeutic privilege which allows them to withhold aspects of information regarding the medical procedures to be conducted that it

39. See Bernard Barber, Informed Consent in Medical Therapy and Research 118 (1980).
would not be in the patient's interest to know. 41 This therapeutic privilege generally does not extend to the research setting, where full disclosure of the known facts, risks and benefits, is required. 42

Of course, even "full" disclosure is subject to interpretation. There are practical limits to what can be and needs to be told to an individual, particularly one not versed in the researcher's discipline. Where research has a therapeutic as well as a non- or pre-therapeutic component, the matter of precisely how much information must be disclosed becomes murkier yet.

By and large, neither regulation nor research practice puts much emphasis on whether the information imparted is in fact understood. 43 There are generally no requirements for testing subjects after they have been informed, and the common practice is simply to assume they comprehend. Taking the informed consent concept seriously probably requires rejection of this facile assumption. It would be better, especially for a research project on a population such as the Isaac Ray detainees, to incorporate along with the information-imparting procedure a basic comprehension test to ensure that the consent obtained is indeed sufficiently "knowing." Perhaps such a test could, together with the competency screening test advocated earlier, be collapsed into one inquiry.

3. Voluntariness

Ensuring that participation in the research is free and voluntary is the crux of the informed consent issue in institutions such as prisons and jails. It has been argued that voluntary consent is impossible in these settings because of the "situational coercion" that is an inescapable part of incarceration. 44 Both the National Commission and the federal regulatory agencies have flirted with this notion, at one point proposing what in effect would have been a ban on all non-therapeutic research in prisons. 45 The current position is somewhat less restrictive. Though it favors therapeutic research, 46 it also permits low-risk

41. Linz, supra note 33, at 18-19.
42. Id.
43. Schroeder, supra note 23, at 976.
44. This is, and was, in essence the position of the National Commission according to Schroeder, supra note 23, at 970.
45. Id. at 969-70.
46. 45 C.F.R. § 46.306(a)(2)(iv) (1994). Therapeutic research is defined in the regulations as "research or practices, both innovative and accepted, which have the intent and reasonable
behavioral studies and non-therapeutic medical research on "conditions particularly affecting prisoners as a class . . . ." 47

It could be conceded that wholly uncoerced consent is impossible to obtain in the prison setting. But that need not lead to the conclusion that "voluntary," "informed" consent is out of reach by legal standards. Law, after all, is a pragmatic enterprise, even if this is not always understood by legal purists. Ultimately, if one wants to get philosophical about it, there is no such thing as un uncoerced decision by anyone, in prison or in the "free" world. It would be like encountering an unmotivated decision, a psychological, if not a logical impossibility.

B. Beneficence versus Respect

A strictly prohibitive attitude toward research on prisoners, whether classified as therapeutic or not, is both unnecessary and undesirable. It stems from an overprotective paternalism that robs prison and jail inmates of what little autonomy they have. Not merely undesirable, such paternalism appears to be undesired by the very persons it purports to protect. Anecdotal evidence suggests that inmates want to have an opportunity to participate in research and to decide for themselves whether to do so or not. When federal regulators proposed their prohibitive restrictions on non-therapeutic research, it was a group of inmates at the State Prison of Southern Michigan at Jackson, where a substantial amount of biomedical research was still being conducted, who filed a lawsuit challenging the proposal. 48

Other evidence tending to undercut the notion that "situational coercion" precludes meaningful choice among inmates lies in the reality that in every research project only a minority of the eligible inmates participates. 49 The majority do not, suggesting that they, at least, are capable of resisting the pressure. If the argument is that the participant minority is more susceptible to the situational coercion, that this group's choice is coerced even if others freely refuse, the empirical evidence contradicts this as well. Studies show that in the

48. Fante v. Dep't of Health and Human Servs., No. 80-72778 (E.D. Mich. filed July 29, 1980); see also Schroeder, supra note 23, at 969 n.4.
49. Schroeder, supra, note 23, at 996. "Situational coercion" is defined as the social and economic deprivation inherent in prison institutions. Id.
main it is prisoners with the better jobs, pay, and housing arrangements in the institution who participate in research in disproportionately high numbers;⁵⁰ those least affected by pressure to ameliorate their economic and situational deprivation. Further, the empirical fact that participating prisoners tend to have higher IQs and better education than nonparticipants undercuts the charge that those who do choose to take part are duped by low intelligence and inadequate understanding of the nature of the research project and its risks.⁵¹

The Isaac Ray patients/detainees will have disabilities beyond those of the average prisoner or detainee, but the idea that they as a group should be excluded automatically from research is no more compelling than for the general jail or prison population.

1. The Risk Level

The relative risk inherent in a research project has a bearing on voluntariness, albeit an indirect one, in several ways. For example, if the central procedure is a simple blood test, the specter of coercion becomes almost irrelevant, or as lawyers might say, "moot."⁵² If "free" persons would readily subject themselves to such a procedure for a small inducement, why not prisoners? The follow-up question which suggests itself then is, why not use non-prisoners? Presumably, the only ethically correct answer to that is that doing the research on nonprisoners is not feasible, either for reasons of methodology or because of the substance of what is researched.

When the risks inherent in the research go up, the matter of voluntariness as such is not negatively affected. Indeed, it may be easier for prisoners to refuse high-risk research than low-risk. But the level of ethical and legal scrutiny goes up. That is the lesson of the famous Kaimowitz case from the mental health field which prohibited a high-risk, experimental therapeutic procedure irrespective of the patient's consent.⁵³ Thus, when procedures more invasive than blood

⁵⁰ Id. at 976.
⁵¹ Id. at 974-75.
⁵² The United States Supreme Court in the case of Schmerber v. California, 384 U.S. 757 (1966) ruled that compelling a drunk driving suspect to take a blood alcohol test does not offend the Constitution. Id. at 760. This suggests that the procedure is considered minimally invasive and that the competent consent of a prisoner would be considered valid, despite the possibility of some "situational coercion."
⁵³ Kaimowitz v. Dep't of Mental Health, No. 73-19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973); see also Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973).
tests are contemplated on a prison population, one can expect that the agencies of review—the courts, human subjects commissions, internal review boards, etc., will apply a stricter standard for ascertaining voluntariness. In the case of highly intrusive and/or high-risk procedures, it may be concluded that the research should not be done period, regardless of how many careful measures are taken to ensure voluntary and informed consent.

The DHHS regulations reflect the above analysis. They permit behavioral research, supported by the federal government, on prisoners only if it poses "no more than minimal risk and no more than inconvenience to the subjects." The conduct of biomedical research in prisons is not circumscribed by similar limitations, but that may be largely because the scope of such research is otherwise restricted. It is permitted only when it is on medical “conditions particularly affecting prisoners as a class” or when it has direct therapeutic benefit. In addition, research review bodies such as institutional review boards are instructed by the regulations to approve research on prisoners only if “[t]he risks involved . . . are commensurate with risks that would be accepted by nonprisoner volunteers.”

2. Aftercare

Follow-up examinations and care subsequent to the research procedure reduce the risk level of research and in that way may reduce concern about, or scrutiny for, voluntariness. It is therefore advisable for research projects to build in such post-research safeguards.

3. The Drop-out Option

Another method of promoting maximum voluntariness is to give each participant an option to drop out of the research at any time for any reason, without penalty. This option is specifically provided for in the DHHS’ list of “general requirements for informed con-

55. 45 C.F.R. § 46.306(a)(2)(iii) and (iv) (1994). Among conditions affecting inmates as a class, the regulations list hepatitis, drug and alcohol abuse, and sexual assault. 45 C.F.R. § 46.306(a)(2)(iii) (1994). One would be safe today in adding HIV and tuberculosis, the latter’s resurgence in institutional and other deleterious settings being directly related to the former epidemic.
sent,\textsuperscript{58} and as a practical matter is a standard provision found in most research protocols.\textsuperscript{59} While the exercise of this option may be detrimental to the research project, the option cannot ethically be withheld. One may not compel or coerce continued participation of "volunteers" by threatening or exacting penalties, other than termination of further pay or related participation benefits.

\textsuperscript{58} 45 C.F.R. § 46.116 (1994). The drop-out option is the last of eight "basic elements" of informed consent listed in this regulatory section. The others are:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.


A list of six "additional elements" follows, to be communicated to the subject of research "when appropriate:"

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.


\textsuperscript{59} THE BELMONT REPORT, supra note 14, at 11.
4. Information Imparting and Comprehension Testing

Already alluded to in discussion of the "knowing" aspect of informed consent, the point to be made here is simply that the provision of maximum relevant and understandable information to the subject maximizes the chance that the choice made is truly voluntary. As the level of completeness, relevance and comprehensibility of the information goes down, so does the information recipient's freedom of choice on how to act on it. Recognition of this principle is especially appropriate for subject groups such as the Isaac Ray detainee/patients.

C. "Justice" Concerns

Distributional fairness in research on human subjects may be hindered by the research's methodological requirements, such as scientific sample selection, and the need to induce subjects to participate via rewards whose attractive power will vary with the individual subject.

1. Sample Selection Procedures

For the purpose of ensuring scientific validity of the research, it is customary to "randomize" the selection of the participant subjects. In the prison setting, random selection has the added advantage of guarding against the possibility that the risks or benefits will be malapportioned among the inmates. The fear has been expressed, for example, that high-risk research will more likely be done on inmates who are disadvantaged by racial or ethnic characteristics, social or economic status, or low intelligence. Conversely, inmates more advantaged in the above respects may, it has been argued, be more likely to participate in and reap the rewards of low-risk, high-benefit research. It would appear that these fears stem mainly from non-institutional incidents such as the Tuskegee syphilis "experiment," for there is little, if any, empirical evidence that invidious discriminations of this kind are perpetrated intra-institutionally on inmate populations.

The problem with randomizing is that it may not always be possible or desirable. For example, where the research's focus is such

60. Schroeder, supra note 23, at 977-80 (citing the National Commission's 1976 Report for the prominence of these concerns).
61. Id.
that relatively few inmates will qualify as subjects because the condition or behavior investigated has a low "base rate," random selection from the total inmate population is likely to yield a numerically inadequate sample. Instead, every qualified inmate, assuming a priori identification is possible, may have to be deemed available and every consenting inmate taken into the research "cohort." Randomization would still be feasible for obtaining a "control group," as the DHHS regulations in fact require.62

If the selection process yields a sample of inmates which appears skewed in racial/ethnic, economic, educational or intra-institutional status, the urge to correct for this by dropping certain subjects may have to be resisted. As noted above, it could result in an inadequate sample size. More importantly, these particular characteristics would be "naturally" associated with the primary variable to be investigated, and it would invalidate the research to tinker with this relationship. Finally, where the research project has potential benefits for the participants, it would seem to defy reason to redistribute these benefits according to some ulterior notion of social or intellectual advantage or disadvantage.

2. Distributive Fairness and Undue Inducements

Traditionally, prisoners who elect to participate in biomedical research have been paid a small amount of money, comparable to pay for other prison "jobs."63 One reason for not paying them more is that it might make such participation too attractive, motivating prisoners to accept undue risks and possibly even creating an unseemly competition among the inmates.64 The disadvantage of nominal pay is that it makes the conduct of biomedical research in prisons too attractive for researchers, potentially motivating them to forego opportunities to conduct their work in other settings like the free world.65 In other words, it can lead to a maldistribution of research risks as between prisoners and free citizens. One way of resolving

63. Schroeder, supra note 23, at 990-91. The Cook County Bureau of Health Services prohibits "pay" to human subjects of research, though it allows liberal "reimbursements" for time and travel costs that in fact amount to pay for many of the subjects.
64. Id.
65. Given that the DHHS' regulations essentially allow research on prisoners only when it is to their benefit as a class or as individual subjects, it is unlikely that researchers today have a free-world alternative as a practical matter.
this problem is to require researchers to pay inmates at the market rate, with the difference between that and the prison-job pay rate going into a trust fund for the benefit of all inmates in the prison.

Other, less formally acknowledged rewards may also come to prisoners who participate in research ventures: better housing within the prison, like an honor dorm, medical ward, single cell, or any other arrangement that segregates the prisoner from "general population" and the conditions and individuals he has to contend with there; avoidance of hard labor or otherwise undesirable prison jobs; better treatment by staff; and even early release via a Parole Board that knows of and rewards such participation.66

Such informal rewards have been criticized as unfair or even corrupt or corrupting. The theory is that they increase the coercion on the one hand and, on the other, penalize nonparticipating prisoners who do not receive these benefits.67 Indeed, as regards the early release inducement, the DHHS' formal position is that Parole Boards may not be informed that any particular prisoner is a research participant.68

It is possible to disagree with this general perspective on rewards on a variety of grounds. Some "informal" benefits, such as special or better housing are dictated by the needs of the research or researchers, and as such are unavoidable by-products. To avoid them would be tantamount to voiding the bulk of biomedical and behavioral research that still takes place in prisons. One may also question the notion that these rewards are necessarily illegitimate or corrupting. A perfectly defensible view is that they are deserved or "earned." Also, the "equal protection-style" argument that something is taken away from nonparticipants just because participants receive it, or are eligible for it, is neither morally nor logically compelling. As to the early release benefit, the strongest argument against it is that it is valued too highly by inmates and hence too coercive. This could be mitigated by clarifying that participation in research is no guarantee of early release but only a factor to be weighed along with others by the Parole Board and by limiting the time benefit attainable to a relatively short one. The DHHS regulation stating that the advantages

67. Id. at 998 (citing G. ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA (1977)).
68. 45 C.F.R. § 46.305(a)(b) (1994).
and disadvantages of participating in research should not be so great as to impair choice is in line with this approach and could be seen to preclude the need for blanket prohibitions.\textsuperscript{69}

3. The Relevance of Institutional Conditions

The National Commission at one point put forward a series of "minimum requirements" that prisons and jails must meet if biomedical research is to be allowed on their inmate populations.\textsuperscript{70} The idea is that if an institution falls below the standards, the deprivations suffered by the inmates will be so great that uncoerced consent will be unobtainable. The theory may have merit when applied to conditions that are truly deplorable and inhumane. However, the Commission set the standards so high as to trivialize the theory. It put forth a list of 17 criteria that few facilities in the nation could meet in total and several of which exceeded and continue to exceed constitutional standards set by the courts.\textsuperscript{71} It is highly doubtful that the Cook County Jail, or for that matter the Cermak Health Services part of the enterprise, would currently satisfy all of these standards. But the idea that, because of this, valid consent is not obtainable and that all research should therefore be banned seems excessive. The better, more realistic, position is that all research proponents should acknowledge the possibility of "situational coercion" in the prisons and should design their investigative and consent procedures in such a way as to reduce as much as possible the chance that harsh condi-

\textsuperscript{69} 45 C.F.R. § 46.305(a)(2) (1994). Jail detainees cannot benefit from parole, which is applicable to convicted prisoners only. The equivalent for jail inmates would be a break from the court; probation instead of imprisonment. The probation benefit, however, is an excessive inducement for reasons that it (1) allows the beneficiary to avoid incarceration altogether and (2) conflicts directly with equal justice concerns.

\textsuperscript{70} Schroeder, supra note 23, at 984.

\textsuperscript{71} These criteria are summarized in Schroeder, supra note 23, at 994 n.175. The Commission required:

- that prisons not exceed design capacity;
- the availability of single-occupancy cells;
- segregation of offenders by age, degree of violence, prior criminal record, and physical and mental health requirements;
- compliance with fire and safety codes;
- adequate plumbing; access to showers; regular issuance of clean linen and articles of personal care;
- adequate recreation time and facilities; good medical facilities;
- adequate mental health services; opportunities for work, education and vocational training;
- frequent visits; large, well-trained prison staff, with racial composition concordant with that of prisoners; opportunity for inmates to lock their own cells, where consistent with security needs; and compliance with environmental health and nutritional standards.

\textit{Id.}
tions unduly influence the choice of any given inmate.

4. The Role of Institutional Review Boards

An early recommendation by the National Commission, incorporated into the DHHS regulations and widely implemented, is that each institution create an internal review board (IRB) responsible for assessing the scientific and ethical merits of all research proposals, with an eye toward protecting the institution's residents from undue risk or harm. The recommendation is theoretically sound and its widespread adoption confirms its practicability. There is empirical evidence that these boards work well if they operate in a non-adversarial mode, as most apparently do. Rather than giving single "thumbs-up" or "thumbs-down" rulings, the boards tend to work with the research proponents, suggesting changes in the first-draft protocol so that later drafts may meet the established scientific and ethical requirements. In most cases, the researchers are reported to be able to accommodate their designs to the boards' stipulations. Where they feel they cannot, the general practice is to withdraw the research proposal rather than risk an open confrontation and the stigma and associated consequences that may come from receiving an outright "no" from the board.

Though, as indicated, the internal review board system appears to be an operational success, various suggestions appear from time to time whose aim is to improve the boards' legitimacy. One is that the boards' function be expanded from mere initial proposal review to continued monitoring of the research project. Another goes to the composition of the boards, particularly those in institutions like prisons and jails, the suggestion being that they include an inmate member. There would appear to be nothing inherently unworkable in these proposals, and in fact the DHHS regulations today incorpo-
rate both ideas. The general or "basic" provisions call for the IRBs to "conduct continuing review . . . appropriate to the degree of risk, but not less than once per year," while the special protections for prisoners that speak to the matter of board composition require that "at least one member . . . be a prisoner or prisoner representative . . . ." Any research to be done on the Isaac Ray-Cermak population will only benefit from supervision by a board having such expanded role and membership characteristics.

VII. LEGAL ISSUES

While this paper has sketched out some of the major principles, specific regulations and practical issues that must be considered by researchers proposing behavioral or biomedical research in the prison setting, there are a number of unaddressed legal questions standing in the background. A partial list of these questions can be provided here, but their exhaustive consideration will have to be for another time and document.

A. Constitutional Questions

There is a smattering of case law on the matter of prisoner participation in biomedical research. It generally supports the proposition that prisoners can give voluntary consent to participate and that they ought to be allowed the choice. It also suggests, however, that invasive, high-risk procedures, like Kaimowitz in the mental health context, are out of bounds. The cases tend to turn on the interpretation of constitutional provisions, most notably the First, Eighth, Fifth and Fourteenth, and Tenth Amendments to the federal constitution.

The interesting aspect of this constitutionally centered analysis is that each of the provisions identified can be used as easily by those in favor of in-prison research as by those opposed to it. For example, the First Amendment's freedom of speech clause has been invoked by opponents of research, particularly drug research, on the theory that the procedure or substance administered to the prisoner-partici-

81. 45 C.F.R. § 46.109(e) (1994).
82. 45 C.F.R. § 46.304(b) (1994).
84. See, e.g., Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973).
pant may unconstitutionally invade his thought and speech processes. However, proponents of the research can argue, no less plausibly, that not allowing the prisoner to make the choice whether or not to undergo the procedure violates his First Amendments rights.

By the same token, one side has argued that the Eighth Amendment's cruel and unusual punishment prohibition bars researchers from "inflicting" intrusive "experiments" on prisoners, while the other side can with equal plausibility contend that preventing prisoners from freely electing to participate just because they are prisoners adds a needless, and thereby cruel, component to their punishment of incarceration.

Similarly, the "due process" and "equal protection" principles of the Fifth and Fourteenth Amendments to the Constitution can be used as readily to argue that the potential harm of research may not be visited on a disadvantaged and "situationally coerced" population such as prisoners, as to support the position that precluding prisoners from participating violates their right to be treated with the same respect and deference to their autonomy accorded other citizens.

Finally, the Tenth Amendment, which reserves to the states and "the people" all powers not explicitly granted to the federal government, is most plausibly used by in-prison research proponents as a basis for the argument that federal agencies such as the DHHS and the FDA should stay out of the business of regulating research in state institutions, let alone issue blanket prohibitions. But any imaginative lawyer knows that it is no great leap to argue to the contrary that the Constitution's intent is clearly to give the federal government power to protect vulnerable populations such as prisoners from injurious action by the states or state-sanctioned private actors.

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85. *Cf.* Kaimowitz v. Dep't of Mental Health, No. 73-19434-AW (Mich. Cir. Ct., Wayne County, July 10, 1973). In *Bailey*, the prisoner plaintiffs made a "privacy" claim in a case involving consensual vaccine tests for infectious diseases such as typhoid, influenza and malaria, but the court rejected it out of hand saying that such First Amendment-grounded claims apply only to involuntary treatments or, as in *Kaimowitz*, to high-risk, experimental procedures that directly invade the subjects' mental processes. *Bailey*, 481 F. Supp. at 221.

86. *Mackey v. Procunier*, 477 F.2d 877 (9th Cir. 1973), for example, was a cruel and unusual punishment claim where the prisoner plaintiff had been given succinylcholine as part of "shock treatment," to which he had consented. *Id.* at 877. The drug is a relaxant recommended as an adjunct to ECT, but the plaintiff alleged he had not consented to this ancillary treatment whose effects he described as "breath-stopping and paralyzing." *Id.* The trial court dismissed the action, but the Court of Appeals reversed and remanded the case for further proceedings on the merits. *Id.* at 878-79.

87. The states-rights argument, as well as the separation-of-powers argument, is in
In sum, there is a good deal of constitutional law doctrine that has a bearing on the "legality" of behavioral or biomedical research involving prisoners. The fact that it appears inconclusive, cutting both ways on the final issue of whether such research should or should not be permitted, suggests that it is susceptible to much more intensive analysis than the outline-style exposition offered here.

B. Other Legal Doctrines and Their Relevance

As indicated, the legal doctrine most relevant to the question of whether or on what basis behavioral or biomedical research on prisoners or jail detainees may be conducted is that of informed consent. However, other theories may also be brought into play by those who propose or review such research.

1. The Right to Refuse Treatment

The right-to-refuse-treatment doctrine has been argued to be applicable, but it is not easy to see how. In research without a treatment component, the doctrine appears wholly inapposite. Even where there are therapeutic aspects to the research, its relevance is tenuous. Though vigilance is a serviceable posture in this area, there is no need to abandon as a general matter the perception that the interest of the researcher is not to force treatment on unwilling prisoners, but to get prisoners to willingly participate. Conceivably, where the consent obtained is perceived to be less than willing, or knowing, competent and voluntary, the argument can be made that the consenting prisoner was not accorded a full and fair opportunity to consider his participation, and thus inferentially that his right to refuse was violated. How serviceable that argument is depends on a range of legal and political intricacies presumably known to those who practice this sort of law.

88. See supra Part VI.A.
89. The leading cases in the civil mental hospital setting are Rennie v. Klein, 653 F.2d 836 (3d Cir. 1981) and Rogers v. Okin, 634 F.2d 650 (1st Cir. 1980), which suggest a viable right to refuse even for involuntarily committed patients. The case of Washington v. Harper, 494 U.S. 210 (1990), intimates that a prisoner's right to refuse treatment he does not want is more restricted.
2. The Right to Treatment

A more apposite doctrine, at least for research involving therapeutic objectives, is the right to treatment. Particularly if the research contemplates a control group of subjects who, despite having an "affliction" similar to that of the treated group, are not treated, questions may arise that can logically be framed in terms of the right to treatment or the violation of that right. While this right is stronger and more clearly spelled out in the mental health setting than in the prison setting, the particular characteristics of the Isaac Ray-Cermak population, as well as the contractual and institutional misrepresentation of the Isaac Ray staff (medical service delivery), suggest that the argument that this right is violated will be readily sustained where a subgroup of this population, specifically identified as likely to benefit from the treatment, has it withheld for experiment-control purposes.

3. Confidentiality

Finally, some behavioral and biomedical research on prisoners may generate serious questions under the law of confidentiality. For example, the identification through research of an offender's crime as psychologically or biologically compelled has very significant implications for what should be done with the offender, and the State and the offender are likely to have conflicting interests in the dissemination and use of this information. The same is likely to be true of information regarding the offender's medical treatment or treatability. Of all the arguably relevant legal and constitutional issues to the matter of research on prisoners or jail detainees, the conflict between disclosure needs and confidentiality principles is perhaps the most

90. See Rouse v. Cameron, 373 F.2d 451 (D.C. Cir. 1966), for the first judicial reference to the right-to-treatment doctrine.

91. Though the right to treatment has not quite achieved the status of constitutional mandate from the U.S. Supreme Court, that court has recognized the concept as the sole rational justification for the involuntary commitment of non-dangerous individuals. See O'Connor v. Donaldson, 422 U.S. 563 (1975) and Youngberg v. Romeo, 457 U.S. 307 (1982). Lower federal courts have gone so far as to find the right constitutionally compelled in the civil setting. See Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971). The treatment rights of prisoners are not nearly as strong. The U.S. Supreme Court has managed only a negative articulation. In Estelle v. Gamble, 429 U.S. 97 (1976), the Court held that prisoners had a constitutionally based claim against prison officials when these officials exhibited "deliberate indifference to [the prisoners'] serious medical needs." Id. at 104. This holding says little about prison authorities' affirmative duties to provide treatment.
real. And particularly for a population segregated for purposes of mental treatment such as the Isaac Ray-Cermak population, the confidentiality issue is most in need of serious attention when researchers propose to pursue their research objectives.92

VIII. CONCLUSION

The conduct of behavioral and biomedical research on prisoners or jail detainees is today circumscribed by an elaborate set of rules, regulations and ethical guidelines. History confirms the need for special protections for individuals in “total” institutions where coercion to accede to the requests of authority-figures, including medical researchers, may be inherent in the setting. The Isaac Ray Center’s novel venture in the “privatization” of mental health services in the Cook County Jail raises the likelihood that research projects will be proposed to study the “captive” population covered by the service contract. Given that this population, by definition suffering from mental impairments of one sort or another, is even more “vulnerable” than the general jail population, special caution should be exercised in the design and approval of any studies. Acknowledging the need for a heightened level of protection for this population does not, however, imply that research should be altogether banned. That conclusion would be excessively paternalistic and needlessly destructive of what little autonomy the detainees have. Also, it would potentially deprive them of benefits which are objectively in their interest and which they may subjectively value. Finally, the preservation of confidentiality is probably the dominant legal as well as practical concern for jail inmates who participate in behavioral or biomedical research.

92. Suffice it to say that there is considerable tension in both law and professional ethics between the principle of treatment confidences and the security needs of fellow patients, the holding institutions, and “society at large” (whether that last interest comes into play via the legal construct of civilly litigating patients, criminal defendants who put their sanity “at issue,” identifiable victims who must be warned, or any “reasonably foreseeable” patient or ex-patient “incident” for which therapists may be held to legal account). Sometimes even the patient’s own (medical) interests may require an infringement of his confidentiality rights.