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Ethical and Legal Standards for Research in Prisons

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Abstract

Biobehavioral research, especially that which is conducted with prisoners, has become much more closely regulated in the last 30 years. State and federal law, as well as professional standards, regulate the conduct of many types of research; in the case of prisoners, this regulation is even more stringent. However, currently no mandatory, uniform, national regulatory or oversight process exists, and many privately funded research endeavors are operating in a regulatory void. In response to this, the National Bioethics Advisory Commission has argued for the creation of a single, national, independent regulatory body to oversee all human participant research, regardless of funding source. As ethicolegal research standards evolve alongside advances in science and technology, an appreciation of the history of prisoner research and an awareness of current standards is critical to conducting ethical prison research.

Ethical and Legal Standards for Research in Prisons

Contemporary behavioral science research rests upon four fundamental tenets: (i) the independent review process (by ostensibly disinterested parties), (ii) informed consent (comprised of a competent, knowing, and voluntary decision to participate), (iii) minimization of harm, and (iv) privacy and confidentiality. These ideals apply equally to all human participants; however, in the case of special populations who may be more vulnerable, such as prisoners, extra attention must be paid to ethical and legal issues unique to their situation. Any environment in which prospective participants do not function in a fully autonomous manner necessitates careful attention to ensure voluntary participation. This is particularly true in correctional settings, where the environment may be perceived as inherently coercive (Stanley, Sieber, & Melton, 1996).

Historical Roots of Research in Prisons

Our current standards governing research have grown out of a long and troubled history of human experimentation (see, e.g., Garnett, 1996; Hoffman, 2000). The need for an established code of conduct is wryly noted by Brakel (1996):

> The use of human subjects in behavioral and biomedical research is today circumscribed by a quite elaborate set of rules, regulations,

> and guidelines. 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 any way 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 (p. 5).

The use of prisoners in research is by no means a modern phenomenon. Although investigators have become much more sensitized to the importance of respecting the diminished autonomy of prisoners, the truth is that physicians and researchers have utilized these "ideal" environments extensively for millennia. Hoffman (2000) notes the use of incarcerated populations dating back to ancient Persia, where physicians often utilized prisoners as research participants. Poisons were tested on captives of the Roman Empire, and in 18th century Europe prisoners were infected with venereal disease, cancers, typhoid, and scarlet fever to study disease course and outcome. The notorious experiments conducted by Nazi physicians in the mid-20th century are amongst the best-known abuses of prisoners in the name of science.

The legacy of prisoner experimentation in the United States is also troubling. Notwithstanding the aversiveness of the environment, correctional institutions possess many desirable features for behavioral

researchers attempting to control experimental conditions. In fact, it has been noted, “prisons are almost ideal places to conduct research. Life ... is subject to few variations. The population is relatively stable... . The imposition of experimental procedures that might inconvenience free-living subjects is not a burden on prisoners ... . It is also less expensive” (Annas, Glantz, & Katz, 1977, p. 103). The *Encyclopedia of Bioethics* cites the first recorded use of prisoner participants in 1914 (Reich, 1995). The Mississippi Department of Corrections allowed researchers to induce pellagra in 12 prisoners (a disease-causing dementia and, potentially, death). Despite experiencing severe symptoms—and submitting repeated requests to be released from the research—the prisoners were not allowed to terminate their participation. All participants survived and were granted pardons (see Hoffman, 2000).

Over the next 60 years, prison research flourished in the United States. Unlike European countries, which tended to avoid prisoner experimentation (no doubt sensitized by the Nuremberg Trials), most researchers in the United States had no such qualms about using this population (see Schroeder, 1983). There were few, if any, publicly voiced concerns about prisoner participation until the mid-1960s. Studies involving thousands of participants (many sponsored by the U.S.

government) included tropical diseases (e.g., malaria, sleeping sickness), sexual functioning and reproductive capacity (e.g., testicular transplants and testicular irradiation), plutonium injections, and radiation exposure (Advisory Committee on Human Radiation Experiments [ACHRE], 1996). Following a shift in funding regulations by the Food and Drug Administration (FDA) in 1962, agencies not funded by the federal government began to use prisoners almost exclusively in drug toxicity clinical trials. In 1969, 42 prisons in the U.S. provided prisoner participants for 85% of all new drug trials (Hoffman, 2000). By 1972, more than 90% of all investigational drugs were first tested on inmates (ACHRE, 1996).

Although remarkable, this historic reliance upon prison populations is not surprising. In 1947, a committee appointed by the governor of Illinois examined the famous World War II-era study involving the infection of prisoners with malaria (Leopold, 1958). The study was pronounced ethically sound—in fact, ideal—and consistent with rules of the American Medical Association (AMA) regarding human experimentation. The report was ultimately published by the AMA and became, in the United States, the voice of the medical establishment regarding the acceptability of prisoner participation. Perhaps the most

interesting aspect of this investigation is the fact that the committee was chaired by Andrew Ivy, an American physiologist, and the prosecution's chief expert witness on medical ethics at the Nuremberg Trials in post-war Germany (ACHRE, 1996). Given the official stamp of approval by the leading medical authority in the country, prison research continued unabated throughout the 1960s. However, by the early 1970s, due to increasing public scrutiny and outcry, the moral–ethical debate on utilizing vulnerable populations as research participants moved to the forefront of U.S. bioethics (Garnett, 1996).

But prisoners were not the only group to be treated unethically by investigators. The 1970s witnessed a growing public awareness of research employing other vulnerable populations in America. The Tuskegee Syphilis Study, conducted in impoverished Macon County in Alabama, has been termed "America's Nuremberg" (Caplan, 1992). The 1932 government-funded study investigating the course of untreated syphilis recruited 399 largely poor, rural, Black men promising "special free treatment" for the problem of "bad blood." In fact, these men were never informed that they had syphilis, received no treatment (other than placebo), but were actively led to believe that their cases were being therapeutically managed. For forty years, despite the discovery that

penicillin was an effective treatment for syphilis in 1947, the U.S. Public Health Service denied the participants treatment.

Despite a few isolated calls for inquiry into the ethics of the study as early as 1936 with publication of the first findings, both the Centers for Disease Control and Prevention (CDC) and the AMA were officially supporting the study and calling for its continuation as late as 1969. A year later the first news articles broke the story, and public outrage quickly mounted. By 1972, the study was halted: 28 men had died of syphilis, another 100 died of related complications, 40 spouses had contracted syphilis, and 19 children had been infected perinatally. The National Association for the Advancement of Colored People (NAACP) launched a class action suit in 1973 and received a nine-million-dollar settlement with lifetime medical benefits and burial insurance for participants and affected family members (CDC, n.d.). In 1997, President Clinton offered the first official apology to the participants and their families, calling the government's actions "deeply, profoundly, [and] morally wrong ... . What the United States government did was shameful" (Clinton, 1997).

In 1974, largely in response to the Tuskegee scandal, the federal government established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The members

considered evidence that showed that many thousands of individuals had been subjected to involuntary, undisclosed procedures and treatments—some benign, others less so—all in the name of science. The Commission was unified in condemning the identified abuses of participants and, in addition to other identified vulnerable populations, it singled out prison research in its consideration of the coercive aspects of institutions.

After an exhaustive survey of the field, and in light of what they believed was the impossibility of prisoners giving truly informed, voluntary consent (given the innately coercive environment of prisons), the Commission recommended a halt to nearly all research involving prisoners. Research in correctional institutions decreased dramatically. Notably, by 1980, only 15% of all drug testing was conducted with prisoner participants (see Schroeder, 1983). The reason for this rapid deceleration of research activity—and the guiding principles that emerged from the Commission's report—derived in part from the Nuremberg Code (1949), a body of ethical and legal regulation established by the Nuremberg Military Tribunal during the trial of Nazi physicians in post-war Germany. Interestingly, Moreno (1997) notes, at the time that the Nuremberg Code was drafted it was considered largely irrelevant by researchers in the United States because they believed themselves immune

to the problems faced by the European community as the latter struggled to come to terms with the atrocities perpetrated under the guise of medical experimentation.

The evolution of ethical standards.

Any history of codified law and regulation concerning human research participation must include consideration of the context in which each set of guidelines evolved and the problems they were designed to address. The ethics code generally accepted as the primogenitor of modern standards grew out of one of the most troubling periods of human history.

The Nuremberg Code.

In many ways the Nuremberg Code (1949) is the prototypical expression of values relating to human experimentation. Indeed, it continues to serve as the gold standard against which all subsequent policies and practices are judged. Nonetheless, its creation was predicated on unprecedented malevolence in medical experimentation. It is worthy of note, and particularly salient to the present discussion, that the first internationally recognized code of conduct for human experimentation was premised upon the ethical treatment of prisoners.

In 1946, 23 Nazi physicians were called to account for the experimentation atrocities committed against thousands of prisoners of

war. The prosecution charged them with failing to conform procedures to existing conventions and norms. In particular, in 1931, the German government itself had established a sophisticated and comprehensive policy to govern human experimentation following the tuberculosis-vaccine-related deaths of 75 children. These regulations included, among others, the requirement of informed consent. This policy along with most others had been dispensed with when the Nazi party seized power. Nonetheless, it was relied upon by the Nuremberg Tribunal as evidence that the physicians had violated an existing regulatory standard.

The defense countered with the argument that no such established code of conduct existed and that various guidelines that did exist were contradictory and ambiguous (Moreno, 1997). Unfortunately, they were correct. The prosecution prevailed, but the Tribunal had been made aware of a terrible regulatory void in local and international policy regarding medical experimentation.

The outgrowth of the Nuremberg trials was a codified set of ethical conditions that held, as a priority, respect for the dignity of all persons. Specifically, it emphasized the necessity of informed and voluntary consent of participants who “should be so situated as to be able to exercise free power of choice” (Nuremberg Code, 1949, Prin. 1). The first

articulated principle clearly sets the tone for subsequent recommendations: "The voluntary consent of the human subject is absolutely essential" (Prin. 1). The Code leaves no room for decisionally impaired participants and is considered by many scholars today as "unduly restrictive" (Gray, Lyons, & Melton, 1995, p. 36). Nonetheless, out of this war-era tragedy evolved an authoritative policy for conducting ethical research with human participants— received and acknowledged by the international community.

The spirit of the Nuremberg Code is mirrored in the provisions of the United Nations' Universal Declaration of Human Rights (1948), which facilitated the acceptance of these principles by each of the 51 signatory nations at that time.

By 1953, the first U.S. federal policy on human experimentation was published by the Clinical Center of the National Institutes of Health (NIH), drawing upon the ten principles of the Nuremberg Code (NIH, 1995). The following year, the World Medical Association (WMA) proposed its own set of guidelines, maintaining the spirit, but modifying the stricter, legalistic tone of the Nuremberg Code (see Babbo, 2000). This proposal would undergo several revisions before being adopted by the 18th World Assembly in 1964, as The Declaration of Helsinki.

The Declaration of Helsinki.

Although the Nuremberg Code (1949) was an excellent starting point for articulating ethical research principles, the World Medical Association (WMA) acknowledged a need for a more comprehensive set of guidelines. The Declaration of Helsinki was a document created by physicians for physicians, and was adopted by the WMA in 1964 (rev. 1975, 1983, 1989, 1996, and 2000). It consists of 32 principles, and is considered more lenient than its predecessor (Ryan, 1994/1995). Although it incorporates all previously articulated goals and principles of ethical research, the language is simultaneously somewhat more complex and vaguer. Notably, it does not preclude the participation of decisionally impaired individuals (fully three principles deal with the matter). Rather, the Declaration of Helsinki requires either consent from a legally authorized representative (along with the participant's assent when possible) or the option to obtain consent or assent or both—as soon as the participant or legal representative is able to give it.

Although not specifically designed to address prison research, a few principles appear relevant to institutional settings. The Declaration refers to populations that are "vulnerable and need special protection," including those "who may be subject to giving consent under duress," and

thus should be treated with special care (§A[8]). As an additional safeguard, experimental protocols are to be submitted for an ethics review by an Institutional Review Board (IRB) (§B [13]). One of the more unique contributions stipulates “in any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, [and] institutional affiliations of the researcher” (§B [22]).

Of the codified principles and guidelines that exist, this may be the strongest statement of the need for unambiguous and unequivocal disclosure by researchers. Although ideal, it is rare for this degree of explicit information to be communicated to research participants in general, and rarer still for it to be communicated to prisoner participants in particular. Not only is this degree of information not routinely disseminated, certain provisions—the Ethical Principles of Psychologists and Code of Conduct, for example—explicitly allow for deception of participants (APA, 1992, §6.15 [a][c]). Noteworthy in this regard, is that in the 2002 revision of the ethics code, the APA has added the stipulation that deception is warranted only if the “scientific, educational, or applied value” is “significant” and participants are allowed the option to withdraw their data upon debriefing (APA, 2002, §8.07 [a][c]). Although many

studies in the social sciences rely upon disinformation as part of the experimental design, every effort should be taken to ensure that certain critical information not implicated in the methodology (e.g., investigator affiliation) be communicated clearly to all participants—especially in correctional institutions— as there is strong evidence that misunderstanding is common (Stanley et al., 1996).

The National Research Act.

By the early 1970s, the American public was becoming aware of the various abuses of research participants, especially those recruited from vulnerable populations (see ACHRE, 1996; Babbo, 2000; Brakel, 1996; Garnett, 1996; Moreno, 1997; Schroeder, 1983). Amongst others, reports of abuses in the Tuskegee Syphilis Study were circulating, and the public was calling for an official investigation. The U.S. government responded swiftly, and the Senate Committee on Labor and Human Resources held hearings on this and other studies alleged to have involved the mistreatment of children and prisoners.

The outcome of those hearings was the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (NCPHSBBR), and the enactment of The National Research Act in 1974. Specific additional protections for certain

vulnerable populations were added: in 1975— pregnant women; in 1978 —prisoners; and in 1983 —children. This policy was revised, codified, and received approval in 1981, as Title 45 Part 46 of the Code of Federal Regulations (45 C.F.R. 46, 2001) [addressed below].

The Belmont Report.

During the years 1974–1978, the NCPHSBBR was charged with evaluating the Department of Health, Education, and Welfare (DHEW, now the Department of Health and Human Services, DHHS), offering suggestions for improvements, and issuing periodic reports. One such publication, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (NCPHSBBR, 1979), reflected a significant theoretical contribution to research policy.

Unlike its predecessors, the Belmont Report did not offer an exhaustive or detailed listing of specific articles, but rather suggested three fundamental ethical principles required of all human experimentation: (i) Respect for Persons, (ii) Beneficence, and (iii) Justice. It was hoped that "broader ethical principles [would] provide a basis on which specific rules [could] be formulated, criticized, and interpreted" (Introduction). The Belmont Report embodies a general and liberal ethic in a thoughtful and flexible manner—encouraging more questions than it seeks to answer. The

simplistic maxim “do no harm” was carefully considered. In the final analysis, drafters suggested that rigid, legalistic rules do little to resolve the complex ethical challenges that are far more common than not. The Belmont Report is considerably less concrete or legalistic than its predecessors—but in no way is it ethically lax.

Respect for Persons.

The first principle in the Belmont Report (1979) was designed to acknowledge the importance of the autonomy and dignity of the individual. At the same time, it stipulates special protections for those with diminished autonomy. This wording is significantly different from previous language that referred to individuals as decisionally impaired, or simply as members of vulnerable populations. By focusing on the degree of autonomy possessed, the Report avoided the implication that there was something intrinsically deficient about these individuals. The first principle articulates the consent process, confirming the importance and centrality of an informed, competent, and voluntary participant in research:

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 .. . . 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 (§B [1]).

Beneficence.

The second principle was specifically chosen by the Commission to reflect a level of care higher than that of mere obligation. The intent was to provide a synthesis of two complementary expressions: (i) do no harm, and (ii) maximize potential benefits while minimizing possible risk or harm. Even with this seemingly simple directive, the Report notes the ethical difficulty that, despite best intentions, “learning what will ... . benefit [participants] may require exposing persons to risk” (§B [2]). In other words, simply to be aware of potential risks necessitates previous experience with exposure to them.

Justice.

The concluding principle was intended to reflect the importance of fairly and equally distributing the burdens and benefits of experimental research. As an example, the authors cited the Tuskegee Syphilis Study, an investigation that targeted a severely disadvantaged population despite the

fact that the disease was affecting all segments of the population. Similarly, for many years, indigent and institutionalized people were often used in medical studies, the benefits of which were typically enjoyed by affluent private patients. In sum,

> The selection of research subjects needs to be scrutinized in order to determine whether some classes ... are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied (§B [3]).

Finally, the Report noted that, unless there were good reasons for an exception, individuals unlikely to benefit from current or future applications of the research should not be included as participants. Reflecting this concern for fairness and equity, the recent revision of the APA's ethics code has incorporated a new, similarly named principle, Justice, which articulates the entitlement of "all persons to access to and benefit from the contributions of psychology and equal quality in the processes, procedures, and services" (APA, 2002, Prin. D).

APA Ethical Principles of Psychologists and Code of Conduct

In the course of its history, the APA has endeavored to establish a high standard for the ethical treatment of research participants. As noted, the ethics code now incorporates an overarching principle of Justice. However, overall, the latest iteration of the code may reflect some

movement away from protection of research participants.

Ethical responsibility and compliance with existing law.

The 1992 code, in a spirit similar to that of the Belmont Report, promulgated guidelines for the ethical treatment of research participants which highlighted the importance of preserving the "dignity and welfare" of individuals (§6.07 [a]). Although specific groups were not identified as vulnerable, the code stated "psychologists [should] consult [those] with expertise concerning any special population under investigation" (§6.07 [d]). Special mention was made of the need to conform research endeavors to "federal and state law and regulations," as well as existing "professional standards" (§6.08). This stated deference to existing state and federal law may have promised more than it could deliver. Given the sometimes inconsistent and ambiguous statements of policy, and the fact that the federal code currently still applies only to federally funded or conducted research, this well-intentioned aspiration may have been somewhat hollow. The point, however, may be moot with the introduction of the new 2002 code of ethics.

The APA, in its most recent revision, has deleted significant sections of the 1992 code, including those enumerated above. Although elements of other standards have been subsumed under different sections,

the standards pertaining to the "dignity and welfare of participants" (§6.07 [a]), and the need to consult with experts in the area under investigation (§6.07 [d]), have been eliminated. Of particular note, the standard addressing compliance with existing federal and state law (§6.08),[1] has been deleted. What impact, if any, these changes will have on behavioral science research is difficult to predict.

Informed consent.

The attention given to informed consent has become successively more focused with each iteration of the code. Specific elements to be included as part of the disclosure process include (i) purpose of the research, expected duration, and procedures, (ii) right to withdraw at any time, (iii) foreseeable consequences of declining or with- drawing, (iv) reasonably foreseeable risk or adverse effects, (v) prospective benefit from participation, (vi) limits of confidentiality, (vii) incentives, and (viii) names of study contacts (APA, 2002, §8.02 [a]). Dispensing with informed consent is addressed (APA, 2002, §8.05), as is consent to be

[1]APA, 1992, *Ethical Principles of Psychologists and Code of Conduct* §6.08: Compliance With Law and Standards states ''Psychologists plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants and animal subjects'' [*deleted from Code, 2002*]

filmed or recorded (APA, 2002, §8.03). This emphasis on content and documentation of consent is consistent with the more legalistic principles articulated in earlier codes. However, as has been pointed out, the spirit of informed consent is much more challenging to honor (Gray et al., 1995; Stanley et al., 1996). Respect for the individual requires much more than the conveyance of information—it necessitates a dialogue between researcher and participant. That dialogue necessarily becomes much more complicated when deception is a component of the study's design.

Deception in research.

As is evident in the APA's ethical standards, deception in research is acknowledged as necessary at times. Kazdin (2003) notes the inherently difficult role assumed by behavioral researchers who, by the very nature of the research they conduct, must often withhold or distort information and implement treatment conditions that may lead to unpleasant experiences for the participant. Nonetheless, he observes, "the problem with forms of deception and surprises in an experiment is that the professional context of an experiment may lead people to expect full disclosure, candor, and respect for individual rights" (p. 503). The onus, he asserts, must remain on the investigator, at all stages, to justify the use of deception, and he proposes three criteria, which mirror the APA code: (i) the study must

propose to obtain important information, (ii) less deceptive or non-deceptive measures have been seriously considered and ruled out, and (iii) the aversiveness of the deception must be judged relative to the importance of the information gathered (p. 505).

Code of Federal Regulations, Title 45, Part 46

As previously noted, the research provisions in the Code of Federal Regulations (see Protection of Human Subjects, 45 C.F.R. 46, 2001) grew out of the National Research Act (1974). With each subsequent revision, the regulations have become more comprehensive and specific.

Jurisdiction.

Originally only applicable to DHHS-funded research, the regulatory authority of the amended code was extended in 1991 to all federally funded research. Since its creation, the code has been adopted and codified individually by many additional government agencies and departments as the "Common Rule"[2] (45 C.F.R. 46, Subpart D, 2001). As

[2] The ''Common Rule'' (Federal Policy) for the Protection of Human Subjects is also codified, for example, at 7 CFR 1c (Department of Agriculture); 10 CFR 745 (Department of Energy); 14 CFR 1230 (National Aeronautics and Space Administration); 15 CFR 27 (Department of Commerce); 16 CFR 1028 (Consumer Product Safety Commission); 22 CFR 225 (International Development Cooperation Agency; Agency for International Development); 24 CFR 60 (Department of Housing and Urban Development); 28 CFR 46 (Department of Justice); 32 CFR 219 (Department of Defense); 34 CFR 97 (Department of Education); 38 CFR 16 (Department of Veterans Affairs); 40 CFR 26 (Environmental Protection Agency); 45 CFR

the current authority governing human research, the federal policy, or Common Rule, embraces three general issues: (i) informed consent, (ii) institutional review boards, and (iii) institutional assurances.

Currently, the federal policy governs most (but not all) (i) research conducted by federal government departments, (ii) federally funded studies, and (iii) commercially sponsored research conducted on behalf of drug and medical device companies. Any organization or institution conducting research that is federally funded must pledge its commitment to the principles by signing and filing a Federalwide Assurance (FWA or "assurance"). The purpose of this filing is to formalize the researcher's commitment to the protection of all human participants involved in research.

Unlike the aforementioned research activities, private and nonfederally related or funded research exists in a sort of regulatory limbo, with some types of investigation subject to the code and others not. Even where guidelines do exist, their relevance and application at the state level is often ambiguous, confusing, and inconsistent.

However, in general,

690 (National Science Foundation); 49 CFR 11 (Department of Transportation).

> If an institution receives [D]HHS funding or support to conduct human subjects research then it must have an OHRP [Office for Human Research Protections]-approved assurance under which it pledges to conduct its federally funded or supported research in accordance with the human subjects' protections of 45 C.F.R. 46 ... . Alternatively, an institution that receives no federal funding or support for human subjects' research may or may not pledge to uphold the standards articulated in the regulations at 45 C.F.R. 46. Where such an institution does not avail itself of the assurance process and pledge to uphold the regulations at 45 C.F.R. 46, OHRP would have no jurisdiction (E. I. Summers, J.D., OHRP, personal communication, April 18, 2002).

Scope.

The federal policy governing research is built around three mechanisms for protection of participants: (i) voluntary informed consent, (ii) the institutional review process, and (iii) quality assurance oversight at the federal level by the Office for Human Research Protections (OHRP, formerly the Office for Protection from Research Risks, OPRR), a newly formed office within the DHHS. Unlike other guidelines that address these issues in general terms, the federal code is quite explicit—especially in the case of prisoner participants.

Informed consent.

Federal regulations governing informed consent as well as guidelines concerning the involvement of prisoners as research participants are clearly articulated. The code specifies a near-exhaustive list of information to be included—and a warning that there should be no

"exculpatory language through which the subject ... is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence" (45 C.F.R. §46.116, 2001). Informed consent is often conceptualized as consisting of three basic principles: (i) disclosure, (ii) competence, and (iii) voluntariness. Disclosure refers to the responsibility of the researcher to convey information regarding risks, benefits, and possible alternatives to the treatment proposed.

This process is ideally an interactive communication, as opposed to the far more common rote recitation of a standard paragraph crafted by researchers or an institutional oversight committee. The second principle, competence, refers to the ability of participants to understand (i.e., comprehend the information), appreciate (or relate information to themselves in a personally meaningful manner), and apply reason (or manipulate the information logically) to arrive at a decision consistent with their own preferences. Finally, to give an informed consent voluntarily implies an absence of coercion or deception in the decisional process (see Stanley et al., 1996).

Whether institutionalized individuals can freely and voluntarily consent to participation, given their diminished autonomy, is a matter of

longstanding debate (see Brakel, 1996; Gray et al., 1995; Hoffman, Schwartz, & DeRenzo, 2000; Schroeder, 1983; Stanley et al., 1996). Regarding prisoner participation in research, 45 C.F.R 46 (2001) explains that

> Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable (§46.302).

In an effort to mitigate any undue influence deliberately or unknowingly perpetrated, the code stipulates the following conditions:

> Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired (§46.305[a][2]).

Regarding the incentive of "good time" often utilized in correctional settings, and a potential source of coercion, the federal policy demands that adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole (§46.305 [a] [6]).

Institutional review boards.

To avoid conflicts of interest and ensure adequate representation of participants on IRBs, 45 C.F.R. 46 (2001) is explicit: (i) a majority of the Board must have no institutional affiliation with the correctional facility, and (ii) at least one member of the Board must be a prisoner (current or former), or a prisoner representative with appropriate experience and interests (§46.304). In addition to monitoring board composition, IRBs are charged with ensuring that the magnitude of risk posed to prisoners is no greater than the level of risk a non-prisoner would be willing to assume (§46.305 [d] [3]), and that participant selection is fair and free from intervention by prison officials (§46.305 [d] [4]).

Quality assurance oversight.

As noted, all recipients of federal research funds are required to file a Federalwide Assurance (FWA) as a formal commitment to the principles of the Common Rule. The recipient of federal funds must also ensure that subcontractors and collaborators (or each legally separate entity) hold an OHRP-approved Assurance prior to their induction into the research program. Once approved, the FWA will be listed on OHRP's website, and only then can human participant research begin.

Permissible types of research.

According to the federal policy, the subject matter of prison research must conform to permissible categories of inquiry, of which there are four: (i) studies of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided the studies present no more than minimal risk, (ii) studies of prisons as institutional structures or of prisoners as incarcerated persons, provided the studies present no more than minimal risk, (iii) research on conditions particularly affecting prisoners as a class (e.g. hepatitis, AIDS), or (iv) research on practices both established and innovative, which have the intent and reasonable probability of improving the health or well-being of the participants (45 C.F.R. §46.306, 2001).

A Call for National Oversight

As the foregoing discussion indicates, prison research has been closely scrutinized, and is now highly regulated by the federal government. However, inconsistencies at state and federal levels of implementation still exist. Although not binding upon private institutions, many have adopted modified and integrated versions of the research guidelines found in such documents as the Nuremberg Code, Belmont Report, and the Common Rule, as guides to maintaining ethical

integrity in the conduct of research with human participants. Nonetheless, others have offered the observation that current laws and regulations governing human experimentation are a "crazy-quilt of hortatory codes and maxims, scattered federal laws and regulations" (Garnett, 1996, p. 473).

Indeed, the lack of a mandatory uniform national regulatory and oversight process may become increasingly more problematic as we move toward even greater privatization of research endeavors (see Ethical and Policy Issues in Research Involving Research Participants, 2001; Hoffman et al., 2000; Moreno, 1998), and correctional facilities (Brakel, 1996). However, efforts to remedy this situation may be forthcoming; Moreno (1998) reports there is "growing Congressional concern about research that does not come under federal informed consent requirements, either because it is privately funded or because the sponsors do not plan to pursue FDA approval for a drug or device" (pp. 17–18). Recently, this concern was echoed by the National Bioethics Advisory Commission (NBAC, 2001).

A fundamental flaw in the current oversight system is the ethically indefensible difference in the protection afforded participants in federally sponsored research and those in privately sponsored research that falls

outside the jurisdiction of the Food and Drug Administration (FDA). “As a result, people have been subjected to experimentation without their knowledge or informed consent .. . . This is wrong. Participants should be protected from avoidable harm, whether the research is publicly or privately financed” (66 F.R. 46001).

Prisoners as Research Participants: Early Cases

Early lawsuits reveal the compelling interests that fostered the development of contemporary protective regulation. These early cases laid the groundwork and stimulated public interest in human research participant protections. On occasion, they had unexpected outcomes.

Kaimowitz v. Michigan Department of Mental Health (1973)

One of the earliest and best-known prison research cases involved an individual, J. Doe, who had been committed to a state facility for nearly two decades with a diagnosis of “criminal sexual psychopath,” and was identified as a potential research participant for a study of “uncontrollable aggression.” The study proposed to compare levels of male hormones in drug versus psychosurgery conditions. Doe was designated as appropriate for the surgery treatment group. Investigators obtained IRB approval and informed consent from both Doe and his parents. However, when the public learned of this investigation, opposition mounted. As the result of

negative publicity, the study was ultimately terminated, and the court agreed to grant a writ of habeas corpus.

Surprisingly, despite IRB approval and the informed consent obtained, the court ruled that the high-risk procedure combined with the uncertainty of outcome to create an unacceptable level of risk to visit upon Mr. Doe. It observed, as a given, the impossibility of ever obtaining "truly informed consent from such populations" (Kaimowitz, 1976, p. 148). In the opinion of the court, the experimental nature of the surgery rendered it impermissible (implying that traditional procedures might have been acceptable).

Over time, a paternalistic approach has given way to an assumption of more autonomy—albeit diminished—on the part of incarcerated participants. More than two decades later, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, rejected the idea that prisoners are incapable of informed and voluntary consent (see, e.g., Winick, 1997).

Bailey v. Lally (1979)

On the heels of Kaimowitz, prisoners brought a class action against the State of Maryland alleging that research participants had suffered a violation of due process, privacy, and protection against cruel and unusual

punishment. The latter Eighth Amendment challenge was closely scrutinized by the court, which eventually ruled against the plaintiffs. The facts of the case included concerns about the physical state of the Maryland House of Correction (MHC), established in 1879, and originally intended to hold approximately 1000 inmates. By the early 1970s, the facility was at 160% capacity, with no hot water, heat, or cooling systems for the prisoners. Many inmates had no regular activities (i.e., school or work), and as a result often spent up to 17 hours a day locked in their cells. For those who were employed, the daily rate of pay was approximately one dollar.

In the late 1950s, the University of Maryland established a medical research unit at MHC to conduct nontherapeutic research into various infectious diseases. They created live-in facilities that had heating and cooling systems, hot water, and color television. Research pay was two dollars a day in addition to whatever income was derived from regular employment. Roughly a third of all participants were housed in the research unit. Although research participation was not a consideration in parole decisions, not all prisoners were advised of this.

The prisoners' suit alleged that their participation in the research had, in fact, been coerced. They argued that they had been incapable of

giving truly informed consent because of the dismal prison conditions, overcrowding, and the research pay (which was significantly greater than any other prison job). In short, the conditions of research participation were so far superior to their regular standard of living that inmates were rendered unable to choose freely from alternatives.

The court rejected the argument, holding that the researchers had acted ethically with due care and concern for the participants, avoiding harm, and communicating the risks and benefits of participation. Furthermore, it opined that not only was there an absence of coercion, the actions of MHC were "not incompatible with evolving standards of decency" (Bailey v. Lally, 1979, p. 219).

Although the plaintiffs did not prevail in this case, the circumstances giving rise to their claim nevertheless have influenced policymakers. Current federal regulations have created a far different standard for contemporary research in prisons, in part, in response to alleged abuses such as those articulated in Bailey. Greater sensitivity to the institutional context has resulted in guidelines that provide direction in all of the areas of concern identified in Bailey.

Conclusion

"It is commonplace that the evolution of research ethics, and

especially regulatory changes, is driven by scandal" (Moreno, 1998, p. 16).

In the United States, the lessons learned in more than a century of human experimentation have contributed to the development of elaborate, comprehensive, and sensitively drawn ethical guidelines. However, the patchwork nature of regulations as well as gaps in both federal and state law is revealed in the lack of a uniform and coherent national policy. Combined with the increasingly complex and sophisticated world of biobehavioral research, this regulatory inconsistency is extremely troubling to both researchers and the public alike (see Brakel, 1996; Hoffman, Schwartz, & DeRenzo, 2000). In response to the call for a more unified and comprehensive oversight process, NBAC (2001) has outlined a proposal to institute a policy of accountability that would extend to privately funded research:

> A credible, effective oversight system must apply to all research, and all people are entitled to the dignity that comes with freely and knowingly choosing whether to participate in research, as well as to protection from undue research risks. There is still no such single authority ... . Indeed, some areas of research are not only uncontrolled, they are almost invisible .. . . The time has come to have a single source of guidance for these emerging areas, one that would be better positioned to effect change across all divisions of the government and private sector, as well as to facilitate development of specialized review bodies as needed ... . a new independent oversight office that would have clear authority over all other segments of the federal government and extend

> protections to the entire private sector for both domestic and international research (66 F.R. 46001-46002).

A commitment to ethical prison research is not merely an abstract theoretical statement of general beneficence. Ethical and legal issues facing researchers in the 21st century are complex, and sometimes in conflict with each other. Even where explicit guidelines exist, they do not ensure adherence, nor do they relieve the investigator of the responsibility for balancing difficult and competing concerns. Nonetheless, as biobehavioral research matures alongside advances in science and technology, it becomes increasingly imperative that researchers remain informed of current legal and ethical issues, and strive to comply at every level of protocol development and implementation. At a minimum, this requires (i) an awareness of statutory and regulatory frameworks and legal requirements, (ii) ongoing monitoring and adherence to the mandates of legal precedence, and (iii) a philosophical as well as practical commitment to evolving normative ethical principles.

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