

JLME COLUMN

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### Discerning Minimal Risk in Research Involving Prisoners as Human Subjects

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In May 2004, the Bureau of Justice Statistics of the U.S. Department of Justice reported that the number of persons held in U.S. prisons and jails was 2,078,570, a new record. While troubling enough, other facts bear mention as well: the nation's incarceration rate continues to climb, exceeding that of any other country in the world; the rate of increase in the growth of prison populations is highest among women; and persons of minority background constitute the majority of all prisoners.<sup>1</sup> The implications of the growing, apparently intractable phenomena of a large imprisoned subculture in this country are many. These include – to name just a few – the fostering of tens of thousands of children of parents who are incarcerated; diversion of millions of persons from otherwise potentially productive livelihoods to an existence almost wholly supported by scarce public resources; congregate living settings characterized largely by violence and hopelessness; and a large underclass (1 in every 140 U.S. residents) comprised of individuals who are unlikely to be successfully reintegrated into communities upon their release.

Incarceration is one of society's quintessential coercive powers. Any further act – official or otherwise – involving prisoners, including research, must be carefully scrutinized for its retributive or extra-punitive purpose or nature. Thus, prisoners should not feel compelled to take part in research as a condition or consequence of their incarceration. This is the position of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, as reflected in both its *Belmont Report* and *Research Involving Prisoners* report.<sup>2</sup> Federal regulations pertaining to prisoners as human subjects mirror the Commission's position on the issue of coercion, and provide for "additional safeguards for the protection of prisoners" who may be involved as subjects in research.<sup>3</sup>

Among these safeguards is restricting research conducted or supported by the U.S. Department of Health and Human Services to one of four categories of permitted research, including two categories of research of particular interest: research into the "causes, effects and processes of incarceration, and of criminal behavior"<sup>4</sup> (or "Category A"), and research of "prisons as institutional structures or of prisoners as incarcerated persons...."<sup>5</sup> (or "Category B"). As a necessary predicate

for conducting research that falls into these two permitted categories, the research must present "no more than minimal risk and no more than inconvenience" to the prisoner subjects.<sup>6</sup> No great stretch of the imagination would be required to realize that many different studies of matters pertaining to prisoners or prisons (e.g., history of arrest or incarceration, disciplinary infractions, prison violence, coping skills, participation in prison programs) might be included within these two broad classes of permitted research. However, the necessary predicate for conducting Category A and B research – that the study presents "no more than minimal risk" – appears significantly less discernible, a situation aggravated by the lack of related federal guidance and ambiguous policy-making history. The subject of what constitutes minimal risk has been considered by a number of national bioethics commissions, with little in the way of meaningful response from federal regulators.<sup>7</sup> This article examines the regulatory background and implications of the concept of "minimal risk" within the context of research involving prisoners, and provides some proposals as to how the concept might be addressed in the research review (IRB) process.

#### Background Regarding Minimal Risk

All research conducted or supported by the U.S. Department of Health and Human Services that involves prisoners as human subjects of research is subject to not only Subpart A (or the "Common Rule") of the federal regulations at 45 CFR 46,<sup>8</sup> but to Subpart C of the regulations as well.<sup>9</sup> As described above, such research is limited to one of four categories of permitted research, including two categories of interest here: research of the "possible causes, effects, and processes of incarceration, and of criminal behavior"<sup>10</sup> (or "Category A"), and research of "prisons as institutional structures or of prisoners as incarcerated persons"<sup>11</sup> (or "Category B"). Research in either one of these two categories is further limited to studies that present "no more than minimal risk and no more than inconvenience" to prisoner subjects (emphasis added).<sup>12</sup>

Under Subpart C, the definition of minimal risk is "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological ex-

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amination of healthy persons" (emphasis added).<sup>13</sup> Importantly, the Subpart C definition of minimal risk, promulgated in 1978 and unchanged since, materially differs from the Subpart A definition of the same term, which was promulgated in 1981 and revised slightly in 1991.<sup>14</sup> Under Subpart A, minimal risk "means that the probability and magnitude of *harm* or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests" (emphasis added).<sup>15</sup> Under the *Belmont Report* – the ethical foundation of the federal regulations pertaining to human subject protection – harms are meant to include psychological, physical, legal, social and economic harms.<sup>16</sup> This interpretation is reflected in the Department of Health and Human Services (HHS) guidance materials, and the Subpart A definition of minimal risk may reasonably be interpreted to encompass all of these types of harms.<sup>17</sup> In sharp contrast, however, the definition of minimal risk under Subpart C is explicitly limited to "physical or psychological harm," and does not include legal, social or economic harms. Why Category A and B research under Subpart C specifically excludes these other harms as a criteria for permitted research involving prisoners as human subjects is inexplicable. Surprisingly, there appears to be no official explanation of the need for these different definitions, although HHS guidance materials are careful to note that the definitions do differ.<sup>18</sup>

### Implications

One obvious implication of the minimal risk restriction in Category A and B research under Subpart C is that research conducted or supported by HHS is not permitted if the probability (i.e., the chance or likelihood of occurrence) and magnitude (i.e., potential severity)<sup>19</sup> of physical or psychological harm posed by research is by any measure greater than the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. Presumably – in light of the lack of explicit HHS guidance on the matter – for purposes of review, research tests or procedures need not be restricted to those tests or procedures actually used in routine medical, dental or psychological examinations, but may include tests or procedures that are equivalent to those routinely used in practice.

There are two less-obvious but nonetheless important, conflicting implications of the minimal risk restriction in Category A and B research under Subpart C that HHS

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has failed to address. These are:

1. category A and B research is not permissible if the research presents any harm other than or in addition to physical or psychological harms; or,
2. category A and B research is permissible if the research presents harms other than those that are physical or psychological, whether or not these other harms are minimal or more than minimal.

Under the first case, the Subpart C definition of minimal risk may be read to prohibit studies in which prisoners are exposed to risks that include social, economic or legal harms. Under the second case, the Subpart C definition of minimal risk may be read to permit studies in which prisoners are exposed to risks that include social, economic or legal harms, which risks may be more or less than minimal. In either case, however, these other types of harms must be carefully evaluated considering the special living conditions of prisoners.<sup>20</sup> For example, certain behavioral research related to violence or drug use history may pose legal or disciplinary harms (compelled or inadvertent disclosure to prison officials), while record research related to prior hospitalization or sexually transmitted disease may pose social harms (breach of privacy or confidentiality, or stigma). While these types of harms may not be included in the Subpart C definition of minimal risk for the express purpose of indicating whether, based upon physical or psychological harm, Category A or B research is permissible, it is clear that the risks of such harms may be present in many types of research that may involve prisoners as human subjects.<sup>21</sup>

Accepting the first case (i.e., that no research of the type described in categories A and B is permitted if the research presents any harm other than physical or psychological harm) would – by categorically excluding prisoner's participation in research that may pose legal, social and economic harms – appear, at least in the name of beneficence, to be most protective of prisoner subjects. However, this may also serve to devalue the complementary principles of respect for persons and justice that are expressed as other basic *Belmont Report* principles. Alternatively, accepting the second case (i.e., research of the type described in categories A and B is permitted so long as physical and psychological harms are minimal, even if other harms are not) would – by not placing any obvious categorical limits upon social, economic or legal risks – appear to devalue the principle of beneficence relative to re-

spect for persons or justice. The second case suggests that the concern for protecting prisoners against these other harms is outweighed by both the interest in maximizing prisoners' autonomy in making decisions about taking part in research, and by ensuring a more equitable distribution of research risks (and benefits) among prisoners and non-prisoners. Interestingly, the second case is arguably somewhat consistent with the National Commission, which observed in making its recommendations related to prisoners as human subjects that "the Commission is not primarily *intending to protect prisoners from the risks of research*," which risks, the Commission further noted, "may be rather small compared to other occupations."<sup>22</sup> Currently, there is no record that serves to indicate where the HHS stands with respect to these conflicting interpretations.

### Proposals

1. Neither Category A nor B research under Subpart C should be interpreted by researchers or research reviewers, including IRB members, to *a priori* prohibit research that may expose prisoner subjects to risks that include social, economic or legal harms; the requirements under Subpart A – to which any research conducted or supported by HHS is subject, including research involving prisoners – should be used to ensure that these social, economic or legal harms are minimized.
2. Researchers should conduct a thorough evaluation of *all* possible social, economic and legal harms – regardless of their magnitude or their chance or likelihood of occurring – to which prospective prisoner subjects may be exposed in proposed Category A and B research under Subpart C. These social, economic and legal harms should, in addition to physical and psychological harms, be explained as part of the informed consent process.
3. Informed consent for Category A or B research under Subpart C that may expose prisoner subjects to risks that include social, economic or legal harms should be conducted such that prospective prisoner subjects' informed consent is *subjective*. That is, researchers and research reviewers, including IRB members, should take steps to ensure that each prospective prisoner subject, given the individual's unique circumstances (e.g., age, educational attainment, literacy skills) understands, comprehends and appreciates the social, economic and legal harms to

which the subject may be exposed by taking part in the proposed research. Such steps might include, for example, post-informational testing of prospective subjects for their actual grasp of the proposed research and related risks.

4. Evaluation of proposed Category A and B research under Subpart C should be referenced against available regulatory materials pertaining to research for which review may be expedited – in which risk is presumed minimal – *with consideration of related harms to include the specific context of a prison setting*. Examples of research that may be reviewed by an IRB through an expedited review procedure that may be relevant to Category A and B research includes, for example, collection of blood samples by finger stick; prospective collection of biological specimens for research purposes by noninvasive means; research involving materials (e.g., data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes; and research on individual or group characteristics or behavior or research employing survey, interview, or focus group methodologies.<sup>23</sup> Consideration of harms posed by these types of research activities within the prison context should include an evaluation of whether a prisoner's status as an incarcerated person or the prison environment serves to materially increase the chance or likelihood that such harms will occur, or increases the potential severity of such harms.

5. A "catalogue" of examples of minimal risk research relevant to prisoners or to prisons – based upon the types of research for which expedited review may be conducted that are described in paragraph 4 above – should be developed by research reviewers, including IRBs. The catalogue should include more precise descriptions of the types of research that are specific to the study of prisoners or of prisons, in which such research is considered to present minimal risk of social, economic and legal harms, as well as minimal risk of physical or psychological harms. For example, such a catalogue might distinguish anonymous survey from focus group research of drug use history, or record research involving prior hypertension treatment from record research involving prior history of suicide attempt or ideation. Such a cat-

alogue might also be used in the review of Category C and D research under Subpart C, as well as review of research involving non-prisoners as well.

While certainly not exhaustive, taken together, the above proposals provide an alternative to the regrettable lack of specific HHS guidance pertaining to minimal risk as applied to research involving prisoners. The proposals also represent a departure from the usual resignation to the ambiguity created by awkward regulatory language or the absence of meaningful guidance, or even worse, to entirely foreclosing Category A and B research under Subpart C simply because such research might present a risk of harm other than those that are physical or psychological. In essence, this article's broader interpretation of the restrictions on research under Subpart C serves to acknowledge the value placed upon providing prisoners with the opportunity – with appropriate review – to take part as subjects in research in which prisoners' participation might otherwise not be permitted. This may in turn permit research that may not only address some of the most intractable issues related to criminalization or incarceration that haunt our society, but may be most pertinent to prisoners' own circumstances.

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#### References

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3. 45 Code of Federal Regulations §46.302 (2003).
4. 45 CFR §46.306(a)(2)(A).
5. 45 CFR §46.306(a)(2)(B).
6. 45 CFR §46.306(a)(2)(A), (B).
7. National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (Bethesda, Maryland: National Bioethics Advisory Commission, 2001): at 69-96; National Human Research Protections Advisory Committee, *Report: Clarifying Specific Portion of 45 CFR 46 Subpart D that Governs Children's Research* (Bethesda, Maryland: National Human Research Protections Advisory Committee, 2003): at 1-4.
8. 45 CFR §§46.101-124 (2003).
9. 45 CFR §§46.301-306 (2003).
10. 45 CFR §46.306(a)(2)(A).
11. 45 CFR §46.306(a)(2)(B).
12. 45 CFR §46.306(a)(2)(A),(B). Note that the other two categories of permitted research involving prisoners as human subjects, "research on conditions particularly affecting prisoners as a class..." [45 CFR 46.306(a)(2)(C)] and "research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject" [45 CFR 46.306(a)(2)(D)], are not limited to minimal risk studies.
13. 45 CFR §46.303(d).
14. 43 FR 53655 (1978); 56 FR 28003 (1991). The 1991 revision has no relevance to the discussion of minimal risk.
15. 45 CFR §46.102(i). The Subpart A definition of *minimal risk* is identical to that used in regulations of the Food and Drug Administration that pertain to, respectively, the protection of human subjects, and institutional review boards. 21 CFR §50.3(k); 21 CFR §56.102(i).
16. National Commission, *supra* note 2, at page 7.
17. Office for Protection from Research Risks ("OPRR"), *Protecting Human Research Subjects: Institutional Review Board Guidebook* (Washington, D.C.: U.S. Government Printing Office, 1993): 3-3 to 3-5.
18. *Id.*, at 6-33; Office for Human Research Protections, *OHRP Guidance on the Involvement of Prisoners in Research* (Rockville, Maryland: Office for Human Research Protections, U.S. Department of Health and Human Services, May 23, 2003).
19. National Commission, *Supra* note 2: at 7 (describing "probability" and "magnitude"); *see also* E. D. Prentice and B. G. Gordon, Institutional Review Board Assessment of Risks and Benefits Associated with Research, in National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (Vol. II: Commissioned Papers) (Bethesda, Maryland: National Bioethics Advisory Commission, 2001), at I-7.
20. The Belmont Report further states that "[w]hile the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked." Belmont Report, *supra* note 2: at 7. The OPRR has described the risks to which subjects may be exposed as "physical, psychological, social and economic." OPRR, *supra* note 17: at 3-3 to 3-5; *see also* R. J. Levine, *Ethics and Regulation of Clinical Research* (2d ed.) (New Haven, Connecticut: Yale University Press, 1998): 42-51 (describing the same taxonomy of risks).
21. Of course, these other risks are still subject to other 45 CFR 46 provisions, including that these other risks be "commensurate with risks that would be accepted by nonprisoner volunteers" (45 CFR §46.305(a)(3)), and that, importantly, "risks to subjects are minimized..." (45 CFR §46.111(a)(1)).
22. *Id.* (emphasis added).
23. 63 FR 60364 (1998).