# Free Executive Summary

## Ethical Considerations for Research Involving Prisoners

Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research

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# Summary

**ABSTRACT** *In the past 30 years, the population of prisoners in the United States has expanded more than 4.5-fold, correctional facilities are increasingly overcrowded, and more of the country's disadvantaged populations—racial minorities, women, people with mental ilnessl, and people with communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis—are under correctional supervision. Because prisoners face restrictions on liberty and autonomy, limited privacy, and often inadequate health care, they require specific protections when involved in research, particularly in today's correctional settings. Given these issues, the Department of Health and Human Services' Office for Human Research Protections commissioned the Institute of Medicine to review the ethical considerations regarding research involving prisoners. The resulting analysis emphasizes five broad actions to provide prisoners involved in research with critically important protections: (1) expand the definition of "prisoner;" (2) ensure universally and consistently applied standards of protection; (3) shift from a category-based to a risk-benefit approach to research review; (4) update the ethical framework to include collaborative responsibility; and (5) enhance systematic oversight of research involving prisoners.*

In many important ways, the U.S. correctional system is different than it was in the 1970s, when current regulations regarding prisoners as research subjects were promulgated. The total correctional population (persons in prisons, jails, probation, and parole) increased more than 4.5-fold between 1978 and 2004, to nearly 7 million individuals (BJS, 2000a, 2005a,b,c; U.S. Census, 1998, 1994). Correctional facilities are increasingly overcrowded (BJS, 2005a), and access to programs, services, and health care has not kept pace with the rising tide of prisoners (Metzner, 2002; Sturm, 1993). More of our country's disadvantaged populations are under correctional supervision: racial minorities, women, persons with mental illness, and persons with communicable diseases such as HIV/AIDS, hepatitis C, and tuberculosis (BJS, 2005c; NCCHC, 2002).

Prisoners have been exploited in the past, carrying a heavier burden of the risks of research than the general population (Hornblum, 1998; Jones, 1993; Murphy, 2005). Although the level of severity varies depending on the correctional setting, prisoners face restrictions on liberty and autonomy, limited privacy, and potentially inadequate health care services. These factors can be barriers to the prerequisites of ethical research, namely the acquisition of voluntary informed consent, protection of privacy, and access to adequate health care such that a choice between research participation and nonparticipation is not simply a desperate action to obtain treatment.

However, research can impart benefits. Responsible research has the potential of improving the health and well-being of prisoners as well as improving the conditions in which they live. Adherence to the highest ethical values, however, is critically important in designing and conducting human research involving prisoners.

Title 45 § 46 of the Code of Federal Regulations (45 C.F.R. § 46) contains Subpart A, the basic DHHS regulations for the protection of human research subjects, also known as the Common Rule. The Common Rule provides requirements and guidance on issues such as review by an institutional review board (IRB), informed consent by subjects, analysis of risks and benefits, protecting privacy, plus further requirements for approval of proposed research. Additional subparts of 45 C.F.R. § 46 provide more specific protections for certain particularly vulnerable populations: pregnant women, fetuses, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). Subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects), the principal focus of this report, was first finalized in 1978 and was developed in response to the *Report and Rec-*

*ommendations: Research Involving Prisoners* by the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research (1976). The general stance of Subpart C is that only research that fits within four or five categories is permitted in prisoner populations.

The committee's review of current research revealed that most research involving prisoners is taking place outside the purview of Subpart C, and many prisoner studies are being conducted without IRB review. There is no ethically defensible reason to exclude certain prisoners from most, if not all, human subject protections afforded by federal regulation. All of these factors point to a population that is more vulnerable and requires stronger protections than those inspired by the national commission in the 1970s.

With these concerns in mind, the Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS) commissioned the Institute of Medicine to review the ethical considerations in research involving prisoners as a basis for updating DHHS regulations to protect prisoners as research subjects.

The committee was charged with the following tasks:

- consider whether the ethical bases for research with prisoners differ from those for research with nonprisoners.
- develop an ethical framework for the conduct of research with prisoners.
- identify considerations or safeguards necessary to ensure that research with prisoners is conducted ethically.
- identify issues and needs for future consideration and study.

***Note:*** *The committee decided to exclude children (unless treated as adults), military personnel, and persons under restricted liberty due to mental illness and outside the criminal justice system, for example those detained under the U.S. Patriot Act. By excluding these groups, the committee emphasizes that they face very similar circumstances and that very strong ethical safeguards are required. However, the committee lacks the expertise to address the needs of these special populations and such an inquiry exceeds the committee's charge. Parallel studies, such as the one undertaken by this committee, may be needed to explore ethical issues of research involving these groups If, however, juveniles are transferred from the original jurisdiction of the family court (or the equivalent, such as a juvenile court) to the jurisdiction of a state or federal criminal court, then they would fall under the provisions of this report.*

## MAJOR RECOMMENDATIONS

The committee developed each recommendation in this report with the interests of prisoners in mind. Throughout its deliberations, the committee was well aware of the dark history of research involving prisoners (Hornblum, 1998; Jones, 1993; Murphy, 2005) and was determined not to permit the exposure of prisoners to the kind of research abuses that occurred before the national commission released its report (NCPHSBBR, 1976). In this report, in fact, the committee adds further protections both by expanding the population of prisoners covered by rigorous ethical rules and by recommending additional ethical safeguards. At the same time, access to research may be critical to improve the health of prisoners and the conditions in which they live, as the committee was told by prisoners during prison site visits. The task was to strike a a balance between potential benefits and risks of specific research protocols. The goal is to ensure rigorous responsible research that improves the well-being of prisoners while taking great care to protect their health, well-being, and human rights.

The recommendations discussed later (and presented in Box S-1, page 18) will allow research, in limited circumstances, that might benefit prisoners. These limited circumstances cannot be captured by a rigid categorical approach but need to be rooted in an ethically relevant risk-benefit analysis that grapples with the balance between a need for protection and access to potentially beneficial research protocols. During the course of the committee's deliberations, five themes emerged as organizing categories for the committee's recommendations: (1) expand the definition of "prisoner," (2) ensure universal, consistent ethical protection, (3) shift from a category-based to a risk-benefit approach to research review, (4) update the ethical framework to include collaborative responsibility, and (5) enhance systematic oversight of research with prisoners.

### Expand the Definition of Prisoner

Subpart C defines a prisoner as any person who is "involuntarily confined or detained in a penal institution" as a result of violating a criminal or civil statute, detained in other facilities as an alternative to

criminal prosecution or incarceration, or detained pending arraignment, trial, or sentencing (45 C.F.R § 46.303[c]). The present regulation's emphasis on custodial detention is too narrow. Of the nearly 7 million persons under adult correctional supervision in 2004, only 2.1 million were in prisons and jails. The rest—4.9 million—were on parole and probation, groups that do not clearly fit under the definition in the current regulations (BJS, 2005d). The committee, therefore, recommends an expansion of the definition of prisoner to afford protections for a larger population of prisoners involved in human subjects research.

> **Recommendation: Redefine "prisoners" to expand the reach of human subjects protections. The Department of Health and Human Services and other relevant agencies that write, implement, or enforce regulations pertaining to research with prisoners should expand the definition of "prisoner" to include all settings, whether a correctional institution or a community setting, in which a person's liberty is restricted by the criminal justice system.** (*Recommendation 4.1*)

The goal of this recommendation is to expand the reach of the regulatory procedures and oversight mechanisms recommended in this report to the fuller population of individuals whose liberty is restricted by the criminal justice system. These individuals face greater risks than those in the general population. The freedom of a prisoner to make a choice as well as the ability to protect his or her privacy can be hampered in any of the correctional settings that restrict liberty. Throughout this report, the term "prisoner" is used with this expanded meaning in mind. An exclusion, however, was provided by the committee so that prisoners living in a noncustodial community setting could enroll in research that is open to any citizen in the community when his or her status as a prisoner is not relevant or related to enrollment in the study.

## Ensure Universal, Consistent Ethical Protection

The committee was asked to make recommendations regarding research under the oversight jurisdiction of OHRP, but currently OHRP jurisdiction is severely limited by the terms and conditions of Subpart C; its oversight extends only to research funded by 3 of 17 federal agencies.

The Department of Justice's Bureau of Prisons (BOP) has its own set of rules (BOP, 1999, 2005), and other federal agencies and nonfederal entities (e.g., state and private) that support research with prisoners are not required by statute or regulation to offer special protections for prisoner subjects. The committee recommends more uniform application of regulations and oversight of all prisoner research regardless of the source of funding or supervising agency as well as a better accounting of research involving prisoners and greater openness throughout the universe of prisoner research.

> **Recommendation: Establish uniform guidelines for all human subjects research involving prisoners. Congress should mandate a uniform set of guidelines for human research participant protection programs[1] for all research involving prisoners.** (*Recommendation 3.1*)

All human subjects research involving prisoners should be regulated by the same ethical standards irrespective of source of funding, supporting agency, or type of correctional facility (federal, state, local, or private) or program that houses the prisoner. This would mean that all 17 federal agencies that are signatories to the Common Rule, any additional federal agencies, and all nonfederal sponsors of research would be required to comply with a newly drafted Subpart C.[2] All research involving prisoners, therefore, would be under OHRP oversight (see Recommendations 6.5 and 6.6). There is no justification for variability across agencies, sponsors, and facilities regarding their approaches to protecting the rights, health, and dignity of prisoners participating in human subjects research, individuals who are among the most vulnerable human subjects of research.

Establishing uniformity within the research protections systems specific to prisoners would enable a second, important step to be realized.

[1]The term "human research participant protection program" is used throughout this report to mean the network of entities with direct responsibility for the safety of those enrolled in the studies carried out under its purview. The HRPPP most often includes the research organization, the study sponsor, investigator, IRB, and, when relevant, the data safety monitoring board (IOM, 2003). In the contexts described in this report, prison research subject advocates would be an important part of this network as well.

[2]Federal regulation of state and private research would be constitutionally permissible by using, for example, the federal spending power. See, e.g., South Dakota v. Dole, 483 U.S. 203, 211 (1987) (upholding the constitutionality of a federal statute conditioning states' receipt of federal funds on adoption of a minimum drinking age of 21).

Currently, there is no central repository of information about the amount and type of research with prisoners as subjects. For the same reasons that registries of clinical research on drugs and biologics exist and have garnered strong support (DeAngelis, 2004; IOM, 2006), a national database would bring clarity to the currently murky landscape of research involving prisoners.

> **Recommendation: Maintain a public database of all research involving prisoners. The Department of Health and Human Services, in cooperation with the Department of Justice, should systematically and comprehensively document all human subjects research with prisoners.** (*Recommendation 2.1*)

The establishment of a publicly available, national registry of research involving prisoners should include data such as who is conducting research with what support, with what kind of research on what populations, and the nature and extent of ethical oversight provided. A national registry would shed light on the totality of research taking place on prisoners and the quality of ethical oversight provided for each protocol. To enable consideration of questions of justice, it could be used to examine the magnitude and volume of prisoners in different types of research to determine the allocation of benefits and burdens of research among prisoners. A registry would also enhance the application of research findings to prisoner populations.

> **Recommendation: Ensure transparency and accountability in the research enterprise. Human research participant protections programs and prison administrations conducting human subject research should be open, transparent, and accountable.**
> (*Recommendation 6.7*)

A sound, ethical protection program involves an open, transparent research process. It requires that the mechanisms used to protect participants from undue harm and to respect their rights and welfare must be apparent to everyone involved. This transparency requires open communication and interaction with the local community, research participants, investigators, and other stakeholders in the research enterprise. Accountability entails maintaining fidelity to the methodology stipulated in the

protocol as well as accountability to ensure the quality and performance of the protection program itself.

### Shift from a Category-Based to a Risk-Benefit Approach to Research Review

The current categorical approach used in Subpart C to review proposals for research involving prisoners is dependent on narrowly defined stipulated research categories that are subject to various interpretations. If a protocol does not fit a category, it is not allowed. This approach does not provide sufficient or reliable protections for the human subject because it does not consider the potential benefits and risks involved in the study and might disallow research that would be quite acceptable on risk-benefit grounds. In addition, the present structure does not address the actual conditions of confinement or the restrictions on liberty experienced by the prisoner subject (whether incarcerated or subject to restraints on liberty in connection with community-based alternatives to incarceration).

> **Recommendation: Apply a risk-benefit framework to research review. The U.S. Department of Health and Human Services should revise regulations regarding research with prisoners from a model based on categories to a system based on weighing of risks and benefits for the individual human subject, similar to the approach currently used in Subpart D.**
> (*Recommendation 5.1*)

A risk-based approach is preferable because it requires human research participant protection programs (HRPPPs) and OHRP to (1) focus on the potential benefits and harms of each suggested research protocol and (2) identify the particular ethical issues that each protocol raises in the specific context of the correctional setting. As in Subpart D (45 C.F.R. § 46.407), protections should increase as the risk-benefit scale tilts more toward risk (IOM, 2004).

A risk-benefit approach should apply to all types of research: biomedical, social/behavioral, and epidemiological. Ethically permissible research must offer potential benefits to prisoners that outweigh the risks. Under this framework, it is clear that studies offering no potential benefit

to subjects would be precluded (i.e., testing of cosmetic products). Biomedical research in correctional settings would be severely limited. Phase 1 and 2 studies, as defined by the Food and Drug Administration (FDA), for example, would not be allowable because safety and efficacy are not yet clear in these early phases of biomedical research; therefore, risk would overshadow potential benefit.

Biomedical research involving prisoners in two narrow circumstances may be ethically acceptable:

1. In normal circumstances, a biomedical research study may be ethically acceptable if:

   - for research on new therapies or preventive measures, there is already some evidence of safety and efficacy, as in Phase 3 testing for new drugs, as defined by the FDA; and
   - the ratio of prisoner to non-prisoner subjects does not exceed 50 percent.

2. In exceptional circumstances, a biomedical research study may be ethically acceptable even if the benefit of an intervention has not been completely established, or if the research population is disproportionately comprised of prisoners. These two criteria may be waived if the research addresses a condition or behavior that is solely or almost exclusively found in incarcerated populations (e.g., repetitive sexual assaults). Studies of this nature could only proceed, however, with a federal-level review. The protocol must be submitted to a national, specially convened panel of experts, who, in a public process, consider the ethical acceptability of a particular protocol, and make recommendations to the responsible government authority (OHRP) regarding the special circumstances that do or do not provide a basis for research and the safeguards that must apply. This review would be very similar to the process outlined under Subpart D (45 CFR 46.407) that requires DHHS Secretarial consultation for studies that are not otherwise approvable which present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of prisoners (rather than children), except that the panel of experts could be convened by an entity outside DHHS if appropriate."

This approach comports with the committee's risk-benefit approach. Given the history of and continued potential for prisoner exploitation, biomedical research should be permitted only if there is a strongly favorable benefit-risk ratio for the prisoner. The distribution of burdens should also be considered, thus the requirement that at least half of research subjects must come from nonprisoner populations. Research should only involve prisoners to provide a benefit to prisoners, not because they are a convenient source of subjects. This approach would enable fair distribution of potential benefits and burdens to prisoners.

To provide extra protections in the area of biomedical intervention research, which likely carries the greatest risks for subjects, the only benefits that should be considered are the benefits to the subjects themselves. Benefits to prisoners as a class are not a strong enough justification for a biomedical intervention study to proceed. These biomedical inquiries may include drug studies and surgical, radiological, or any interventional study in which the outcome of the biomedical intervention is the question of interest.

There may be research proposals, most likely within social/behavioral and epidemiological categories, that carry very low risks for the prisoner subjects but no personal benefit for the subjects. Instead, the potential benefits may be for prisoners as a class (e.g., studies to identify factors that predict recidivism or that seek to understand the effects of prior trauma on antisocial behavior). Applying a risk-benefit analysis may determine that, because the risks are very low and important knowledge or benefits may accrue for prisoners as a class, the research is ethically acceptable. The same may hold true for epidemiological studies that require analysis of biomedical samples, such as tissue, blood, or urine, but are not designed to assess outcomes of an intervention.

For all studies under consideration, the greater the risk and the more restrictive the correctional setting, the stronger the design and monitoring safeguards need to be.

## Update the Ethical Framework to Include Collaborative Responsibility

In the Belmont Report (NCPHSBBR, 1979), the national commission identified respect for persons, justice, and beneficence as the fundamental ethical principles that should guide the conduct and regulation

of research with prisoners. These three principles should continue to anchor discussions of research with prisoners. However, ideas about ethical research have evolved over the past three decades, leading the committee to suggest that collaborative responsibility be added as a derivative of the principle of justice to give attention to the needs and responsibilities of all parties who will be involved with or affected by a research endeavor.

> **Recommendation: Use a collaborative research approach. Under an ethic of collaborative responsibility, investigators should find ways to obtain input from prisoners and other stakeholders on the design and conduct of any research protocol involving prisoners.** (*Recommendation 5.2*)

Collaborative responsibility is intended to convey the idea that, to the extent feasible, all aspects of research (design, planning, and implementation) should include the active participation of relevant institutional stakeholders (prisoners, correctional officers, medical staff, administrators). A focus on collaboration would help cope with the reality that each institution has its own unique conditions and may facilitate openness of the research environment. The responsibility for collaboration lies with investigators, who need to make the effort to engage prison administration and prisoners themselves for their input, and with the other components of the HRPPP, which must determine that the effort was made.

This report contains two additional recommendations that are part of the updated ethical framework aimed at protecting prisoners:

> **Recommendation: Ensure adequate standards of care. Human research participant protection programs, together with the prison administration and prison health care professionals, are responsible for ensuring that research with prisoners occurs in an environment that is appropriate to the health and well-being of prisoners, including access to existing medical and mental health care that is adequate, protection from inmate attempts to coerce or manipulate participation or nonparticipation in research, and prompt access to decent health care services in case the research causes physical or mental harm.** (*Recommendation 5.3*)

Justice requires more than the protection of prisoners from harm caused by the research itself. Ethical research carries with it a responsibility to grapple with the fact that potential harm is ubiquitous in everyday prison life, creating an environment for research in which the choice to participate in a study can be inherently coercive and potentially dangerous. Thus, in order for research to be ethical, justice requires that it must be done in a setting in which there is an adequate standard of health care in place.

Ethical research requires an environment that is humane and provides reasonable access to supportive care, particularly when human subjects are exposed to physical or psychological risks. Without adequate medical or psychological care, subjects may be vulnerable to undue inducements to participate in research in order to gain access to medical care or other benefits they would not normally have. Finally, researchers have an ethical obligation, if they expose subjects to risk, to rapidly and professionally remedy any harms caused by the research.

> **Recommendation: Support critical areas of correctional research. Government agencies should fund and researchers should conduct research to identify needed supports to facilitate prisoners' successful reentry into society, reduce recidivism, and inform policy makers about the most humane and effective strategies for the operation of correctional systems.** (*Recommendation 5.4*)

Society creates a correctional system for clear purposes such as deterrence to future crime and rehabilitation of those who are convicted of committing offenses. It is of utmost social importance to better understand how best to achieve the purposes of incarceration, including reduction of recidivism and successful introduction back into the community. Perhaps unavoidably, the criminal justice system inflicts some harm on those it punishes. As ethical people, we strive to develop and use corrective measures that are effective and humane without causing unnecessary physical or mental harm to prisoners. However, prisoners are a vulnerable population subject to abuse and exploitation. Indeed, several subclasses of prisoners are some of society's most vulnerable populations, such as young people, persons with mental disabilities, racial minorities, women, and people with diseases (addiction, hepatitis, HIV, hypertension, diabetes) that may or may not be treated during imprisonment. It is,

therefore, especially important to better understand how to protect and promote the welfare and well-being of this large and growing segment of our society. Scientific knowledge and information about best practices gained from high-quality research are critically important to understanding how best to achieve all of the legitimate purposes of the criminal justice system.

## Enhance Systematic Oversight of Research Involving Prisoners

If limited opportunities for research are to be allowed, safeguards and oversight must be strengthened, made consistent, and applied in relation to the levels of study risk and liberty restrictions experienced by the prisoner population. Informed consent must be obtained and privacy protected in the context of the correctional setting.

Approval of research by the IRB is a critical step, but it is not sufficient. Research involving prisoners must be monitored throughout the course of the study to verify that procedures are being conducted as approved and to detect adverse events or unanticipated problems in a timely manner. The monitoring process may need to differ depending on the setting or study type. Studies that take place in closed institutions, where liberty restrictions are the greatest, require more proactive monitoring than studies within community settings, where subjects can more easily pick up the phone to express concerns or complaints. Similarly, higher risk or more intrusive studies (e.g., research that involves medical, pharmaceutical, or biological interventions) would likely require more intrusive monitoring than social/behavioral studies of nonsensitive issues (e.g., involving questionnaires). The committee suggests that monitoring be accomplished by a prison research subject advocate (PRSA) who is familiar with the local correctional setting but not an employee of the facility to ensure credibility among the prisoner-subjects and maintain independence. The IRB should have free access to the PRSA and be able to meet with the PRSA separate from the investigator and correctional staff.

**Recommendation: <u>Strengthen Monitoring of Research Involving Prisoners</u>. Institutional Review Boards that review and approve research involving prisoners should establish an on-site, ongoing moni-**

**toring function through a prison research subject advocate (PRSA).** (*Recommendation 6.3)*

The activities of the PRSA go beyond the routine annual reviews that IRBs currently conduct. The PRSA's activities are study specific (although a single person could be a PRSA for more than one study) and are "on the ground" activities, involving varying degrees of direct observation of specific research activities (depending on the type & risk level of the research).

**Recommendation: Modify IRB considerations for independent ethical review of research protocols. Institutional Review Boards (IRBs) should focus on the particular ethical issues that each protocol raises in the specific context of the correctional setting. IRBs would no longer be required to forward research proposals to OHRP for certification, except for those rare proposals that require federal-level review.** (*Recommendation 6.4)*

IRBs should:

1. review studies at the local level, make the initial assessments of risk and potential benefits, and approve or reject individual studies based on detailed information about the protocol and correctional setting;
2. determine if a study requires federal-level review;
3. evaluate investigator efforts to obtain input from prisoners and other stakeholders on the design and conduct of the protocol;
4. evaluate the proposed research environment in terms of adequacy of existing health services;
5. calibrate the extent of safeguards and monitoring to the level of restrictions imposed upon prisoners in the particular correctional setting and the degree of risk involved in study participation;
6. receive monitoring reports directly from PRSAs and researchers, at a scope and frequency determined during study review.

The committee recommends that, although IRBs should retain the bulk of the approval and monitoring functions to keep these at a local

level, a national independent body is also needed as an additional safeguard.

> **Recommendation: <u>Enhance OHRP's capacity to provide systematic oversight of research involving prisoners</u>. The Department of Health and Human Services should strengthen the capacity of the Office for Human Research Protections to provide systematic oversight of research involving prisoners that is within its purview.** (*Recommendation 6.5*)

Four necessary functions are currently lacking in whole or in part in oversight of research involving prisoners:

- maintain a national registry of all prisoner research that is conducted,
- make determinations if a study requires federal-level review,
- enforce compliance with the regulations, investigate reports of possible problems, intervene to curtail abuses, and impose sanctions for noncompliance, and
- serve as a national resource for HRPPPs to promote a uniform understanding and consistent application of the regulations.

OHRP is designed to perform three of the four functions above, but does not currently have the funding or personnel to adequately carry out the tasks. OHRP needs to be revitalized and refocused to carry out the three functions already within its purview. In addition, it should be charged with the task of creating and maintaining a national registry of research involving prisoners. This recommendation, however, covers only research supported by DHHS and two other federal agencies. The majority of research involving prisoners is being conducted in the absence of any obligation to provide safeguards or oversight. To remedy that inadequacy and ensure that these protections apply to all research involving prisoners, the enhanced OHRP model must be replicated for all agencies and privately funded research.

> **Recommendation: <u>Establish systematic oversight of all research involving prisoners</u>. Congress should establish a national system of oversight that is applied uni-**

**formly to all research involving prisoners.** (*Recommendation 6.6*)

To expand prisoner protections beyond the narrow jurisdiction of DHHS, Congress should establish a national system of oversight that is applied uniformly to all research involving prisoners, performing all of the functions listed in Recommendation 6.5. The vast majority of research involving prisoners does not fall within OHRP overview jurisdiction. Strengthening the safeguards provided for all prisoners involved in research, regardless of funding source, will facilitate safe and ethical research across the full range of research involving prisoners. These functions could be performed by the revitalized and properly funded OHRP if OHRP's jurisdiction were extended to the entire range of research involving prisoners regardless of funding source (i.e., federal or nonfederal, public or private). An alternative is to compose a national entity to perform the necessary oversight functions. Placing the functions within OHRP may be more feasible and less disruptive, but it must be done with serious attention to the extra support needed within OHRP to undertake those tasks fully and much more broadly than its current limits to Common Rule agencies. The committee is calling for substantial improvements to the existing system of oversight, and if a new entity is necessary to make it happen, then it should be created.

**Recommendation: Ensure voluntary informed consent. Human research participant protection programs should ensure that voluntary informed consent is obtained from subjects in all research involving prisoners.** (*Recommendation 6.1*)

Informed consent is vital to autonomous decision making and respect for persons and is considered a bedrock of ethical research. Informed consent is an interactive and ongoing process to ensure that participants are voluntarily participating in research and that they understand the level and nature of the risks and the uncertainty of potential benefits. The written consent form—one part of the process—is the mechanism for documenting that communication with the participant regarding relevant considerations to enrollment in a protocol has taken place. The informed consent process must help the prisoner to exercise autonomous decision making. The process poses special challenges in the correctional setting, where autonomy is incompatible with institutional order and judicially

imposed limitations on liberty. In a correctional setting, a prisoner's capacity to exercise independent judgment may have atrophied. The consent process and discussion must focus on the risks and potential benefits of the research in the context of confinement and the nature of restrictions imposed on the prisoner's liberty. This would include the impact of research data on a prisoner (e.g., how would testing positive for a communicable disease impact housing, work opportunities, medical treatment, family visiting). There is no question that, within correctional settings, it is more difficult to provide integrity to the process of informed consent, but this does not remove the obligation. If it is determined that voluntary informed consent is not obtainable, then a research proposal should not go forward.

> **Recommendation: Protect the privacy of prisoners engaged in research. Human research participant protections programs should collaborate with prison officials, probation officers and other staff relevant to the correctional setting to protect the privacy of subjects in prisoner research.** (*Recommendation 6.2*)

Privacy is considered one of the necessary prerequisites for ethical research. In most circumstances, this means nondisclosure of the identity of the research subject and ensuring confidentiality of the specific data collected. Privacy is exceedingly difficult to attain in prison settings, however, because of the inherently coercive and institutionalized contexts and the controlled and public nature of physical movement. Maximizing privacy within a correctional setting will require collaborative planning efforts specific to the particular correctional setting that involve potential subjects and staff from the correctional setting to consider the impact of participation on privacy issues.

Given that it may not be possible to guarantee absolute privacy in some situations, researchers and IRBs should consider the extent to which core privacy issues can be protected from disclosure through realistic and practical approaches. For instance, it may be clear to prisoners and staff that medical research is being conducted, but the specific nature of the study or the characteristics common to human subjects need not be generally known or discernible. These measures, and their limits, should be discussed in detail with prospective participants in the context of the consent process.

## CONCLUDING REMARKS

The recommendations offered within this report are intended to encourage the development of a uniform system that provides critically important protections for prisoners involved in research. Research has the potential to help society better understand how to protect and promote the welfare and well-being of this large and growing segment of our society. For any research to go forward, however, it must offer more benefits than risks to prisoners, and the setting in which the prisoners are consigned must allow for the ethical conduct of research, including autonomous decision making, voluntary informed consent, and privacy protection. Strengthening systems of oversight and requiring collaboration at every level of the research process will require substantial commitments from every stakeholder (Table ES-1). The committee acknowledges that the collaboration model, for example, will be new within most correctional settings and among many researchers. However, if research is to be supported to improve the welfare of prisoner populations, which the committee recommends, it must be done with rigorous safeguards and under a comprehensive HRPPP. The hallmark of a decent society is to ensure humane, respectful treatment of all prisoners. Responsible, ethically appropriate research is one important aspect of the kind of society to which we aspire.

**BOX S-1**
**Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research**

Recommendations

Expand the Definition of "Prisoner" Redefine "prisoner" to expand the reach of human subjects protections. (4.1)

Ensure Universal, Consistent Ethical Protection

- Establish uniform guidelines for all human subjects research involving prisoners. (3.1)
- Maintain a public database of all research involving prisoners. (2.1)
- Ensure transparency and accountability in the research enterprise. (6.7)

Shift from a Category-Based to a Risk-Benefit Approach to Research Review

- Apply risk-benefit framework to research review. (5.1)

Update the Ethical Framework to Include Collaborative Responsibility

- Use a collaborative research approach. (5.2)
- Ensure adequate standards of care. (5.3)
- Support critical areas of correctional research. (5.4)

Enhance Systematic Oversight of Research Involving Prisoners

- Strengthen Monitoring of Research Involving Prisoners (6.3)
- Modify IRB considerations for independent ethical review of research protocols. (6.4)
- Enhance OHRP's capacity to provide systematic oversight of research involving prisoners. (6.5)
- Establish systematic oversight of all research with prisoners. (6.6)
- Ensure voluntary informed consent. (6.1)
- Protect the privacy of prisoners engaged in research. (6.2)

**TABLE S-1** Impact of Committee Recommendations on Stakeholder Responsibilities

| Stakeholders | Current Duties | Proposed Duties Based on Committee Recommendations |
|---|---|---|
| Congress | | 1. Mandate uniform guidelines<br>2. Adequately fund OHRP to strengthen its capacity to provide uniform oversight<br>3. Establish national oversight entity (OHRP or other) to provide same OHRP oversight functions for the larger universe of research involving prisoners that is not within DHHS jurisdiction. |
| DHHS/OHRP | 1. DHHS agencies follow Sub-part C, OHRP also has oversite for research involving prisoners for two other agencies (CIA, SSA) that signed on to Subpart C.<br>2. For above mentioned studies involv- | 1. Expand definition of prisoner.<br>2. Support critical areas of correctional research.<br>3. Revise Subpart C regulations to reflect a risk benefit approach to research review similar to Subpart D.<br>4. Establish a system of safeguards to be applied uniformly. |

| Stakeholders | Current Duties | Proposed Duties Based on Committee Recommendations |
|---|---|---|
| DHHS/OHRP (con't) | ing prisoners, OHRP must certify that IRB has followed Subpart C.<br>3. If a protocol does not fit within one of five catargories, regardless of risk benefit, it is not approved. | 5. Revitalize OHRP to enhance its capacity to provide uniform oversight.<br>6. Maintain a national registry of all prisoner research.<br>7. OHRP no longer certifies all studies, although it still oversees process of "exceptional" study review.<br>8. OHRP focus shifts to national oversight, data collection, compliance, enforcement, and technical assistance role. |
| Other federal agencies | Only CIA, SSA follow Subpart C. | 1. All federal agencies follow Subpart C.<br>2. Support critical areas of correctional research. |
| Nonfederal and private sponsors | Not required to follow Subpart C. | Must follow revised Subpart C. |
| Correctional settings | 1. No clear, standard expectations for providing input in design or access for onsite monitoring.<br>2. May or may not require IRB review for research at their facility. | 1. Be open to providing input to investigators regarding the design and conduct of research protocols involving prisoners.<br>2. Require that research be approved by an IRB before it is conducted at their facility.<br>3. Assist in protection of subject privacy.<br>4. Provide for timely and adequate medical response to adverse events experienced by the research subjects.<br>5. Ensure that PSRAs have open access to monitor research activities. |
| HRPPP/IRB | 1. Protocol review is based on categories.<br>2. For DHHS- | 1. Review shifts from category-based to risk-benefit approach, with focus on the |

| Stakeholders | Current Duties | Proposed Duties Based on Committee Recommendations |
|---|---|---|
| HRPPP/IRB (con't) | supported research involving prisonersm submit to OHRP for certification, and if necessary, federal-level review.<br>3. Wait for OHRP certification before study can be approved.<br>4. Ensure informed consent.<br>5. Protect subject privacy.<br>6. Include prisoner representative as voting member of IRB | particular ethical issues that each protocol raises in the specific context of the correctional setting.<br>2. Only "exceptional" studies are submitted to OHRP for federal-level review.<br>3. Evaluate investigator efforts to obtain input from prisoners and other stakeholders on the design and conduct of research protocols involving prisoners.<br>4. Evaluate the proposed research environment in terms of adequacy of existing health services to ensure that prisoner participation is truly voluntary and assess existing capacity to provide for timely and adequate medical response to adverse events experienced by the research subjects.<br>5. Ensure informed consent.<br>6. Protect subject privacy.<br>7. Include prisoner representative as voting member of IRB<br>8. Be open, transparent, and accountable. |
| Investigators | 1. Present studies to IRB and await IRB approval and OHRP certification.<br>2. No standards for getting input or ensuring adequate medical response.<br>3. Obtain informed consent. | 1. Present study to IRB for approval. Only requires OHRP review for "exceptional" studies<br>2. Demonstrate efforts to obtain input on study design and implementation from stakeholders, including prisoners.<br>3. Demonstrate to the IRB that the proposed research environment provides for timely and adequate medical |

| Stakeholders | Current Duties | Proposed Duties Based on Committee Recommendations |
|---|---|---|
| Investigators (con't) | | response to adverse events experienced by the research subjects.<br>4. Obtain informed consent.<br>5. Be open, transparent, and accountable. |
| PRSAs | Do not exist. | Provide assurance, via ongoing, onsite monitoring, such that research subjects within a specific facility or program are protected.<br>Multisite studies would likely have more than one PRSA.<br>Duties expand as potential risks to participants increase. |
| Prisoners | 1. Provide informed consent. | 1. Provide informed consent.<br>2. Provide input, on request, on study design and implementation. |

NOTE: OHRP, Office for Human Research Protections; DHHS, Department of Health and Human Services; CIA, Central Intelligence Agency; SSA, Social Security Administration; IRB, institutional review board; PRSA, prison research subject advocate.

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# Ethical Considerations for Research Involving Prisoners

Committee on Ethical Considerations for
Revisions to DHHS Regulations for
Protection of Prisoners Involved in Research

Board on Health Sciences Policy

Lawrence O. Gostin, Cori Vanchieri, and Andrew Pope, *Editors*

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# Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Neil R. Powe,** Welch Center for Prevention, Epidemiology and Clinical Research, Johns Hopkins Medical Institutions, and **Elena O. Nightingale,** Scholar-in-Residence at the Institute of Medicine. Appointed by the National Research Council and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

# Preface

The Committee's task—to review the ethics regarding research involving prisoners—was as challenging as it was important. Research is critically important in providing knowledge needed for informed and enlightened prison policy, as well as for affording health benefits to prisoners. At the same time, research could impose unacceptable risks on prisoners, complicated by serious concerns about the potential for coercion in the prison environment. The history of prisoner research is plagued with illustrations of unconscionable abuses. Getting the balance right between scientifically rigorous research and ethically appropriate treatment of prisoners is vital in a decent, humane society. It was a difficult task in which the Committee had to take account of history, demography, vulnerability, and the restrictions of prisoner life.

The charge of our Committee, the Institute of Medicine Committee on Ethical Considerations for Revisions to the DHHS Regulations for Protection of Prisoners Involved in Research, was to explore whether the conclusions reached in 1976 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research remain appropriate today. The Commission's path-breaking report on the ethical values of human subject research resulted in regulation of all human subject research funded by the U.S. Department of Health and Human Services (DHHS). The provisions regarding research on prisoners are contained in Subpart C of the regulations.

Specifically, the Committee was asked to: (1) consider whether the ethical bases for research with prisoners differ from those for research with non-prisoners, (2) develop an ethical framework for the conduct of research with prisoners, (3) based on the ethical framework developed, identify considerations or safeguards necessary to ensure that research

with prisoners is conducted ethically, and (4) identify issues and needs for future consideration and study.

Past abuse in biomedical research in prisons has engendered deep distrust among prisoners and their advocates. It is impossible to ignore the historical exploitation of prisoners and their current misgivings about the biomedical research enterprise. The prison population, moreover, has markedly changed since 1976. It is vastly larger in number with disproportionate representation of African Americans, Latinos, persons with mental illness, and other historically disenfranchised populations. Many women and children are also incarcerated in American prisons today. Prisoners are particularly vulnerable to exploitation not only because of their low socioeconomic status, but also due to the realties of prison life. Although conditions are widely variable, overall prisoners are subjected to high levels of coercion (explicit and implicit). The prison environment makes it difficult to assure even minimal standards for ethical research such as voluntary informed consent and privacy.

Given these realities, the easiest thing would have been to recommend a virtual ban on human subject research involving prisoners. Yet, the Committee felt that this would be a mistake. Research affords the potential of great benefit as well as burden. It can help policymakers to make correctional settings more humane and effective in achieving legitimate social goals such as deterrence and rehabilitation. Research can also help policy makers better understand and respond to the myriad health problems faced by prisoners such as HIV/AIDS, tuberculosis, hepatitis C, mental illness, and substance abuse. Respect for prisoners also requires recognition of their autonomy. If a prisoner wants to participate in research, his or her views should be taken into account. The overall goal, then, is to permit scientifically rigorous research to the extent that it confers significant benefit without undue risk and in accordance with the prisoner's wishes.

The critical question facing the Committee was whether, given all these factors, current federal regulation is ethically sound and has achieved an appropriate balance between scientific knowledge and prisoner vulnerability. Our answer, after an exhaustive study, was an emphatic "no." Although the ethical principles articulated by the National Commission are still largely apt, the Committee found that the federal system of human subject protection is deficient.

The Committee was surprised and disappointed to find that there were no systematic data sources on the quantity and quality of prisoner research in the United States. Committee members searched the literature

and determined there is a great deal of research involving prisoners taking place that appears to be largely unregulated. The most glaring problem is that the federal rules cover only a small fraction of the research being undertaken in prisons. This is because the regulations (45 C.F.R. § 46) do not cover human subject research unless it is funded by a few federal agencies, or the sponsoring institution has voluntarily adopted Subpart C. Much of the research supported through other sources (e.g., federal, state, or private) is outside the scope of regulatory protection. Subpart C also only applies to narrowly defined "prisoners," not including individuals who are under state imposed limitations of liberty but not in traditional prison settings. There appears to be no morally defensible reason for excluding a large number of prisoners from human subject protection, as is currently the case.

The Committee boldly recommends five paradigmatic changes in the system of ethical protections for research involving prisoners. First, expand the definition of "prisoner" to include a much larger population of persons whose liberty is restricted by virtue of sentence, probation, parole, or community placement. Second, ensure universal, consistent standards of protection so that safeguards based on sound ethical values apply to prisoner research irrespective of the source of funding. Third, shift from a category-based to a risk-benefit approach to defining ethically acceptable research so that prisoners are never exposed to research risks unless there is a distinctly favorable benefit-to-risk ratio. Fourth, update the ethical framework established by the National Commission to include collaborative responsibility—the concept that research should be conducted in meaningful collaboration with the key stakeholders notably prisoners and prison staff. Finally, enhance systematic oversight of research involving prisoners so that human subject protections are more rigorous and more reliable than those that exist under the existing Institutional Review Board (IRB) mechanism.

The treatment of prisoners (both respect for their rights and concern for their health and well-being) is a principal measure of a decent and civilized society. Therefore, the committee strongly encourages the executive and legislative branches to give due consideration to the proposals in this report.

Finally, and importantly, I express my sincere gratitude to the DHHS Office for Human Research Protections (OHRP) for commissioning this project, the Institute of Medicine (IOM) leadership for its support and insights, and to my fellow Committee members for their exceptional wisdom and service. Committee members worked hard and long in de-

vising solutions to apparently intractable problems. The Committee is particularly grateful to the 10 members of the prisoner liaison committee who educated us about prison life. Without their involvement, we could not have fully understood the problems or solutions. Cori Vanchieri and her team (Ben Berkman and Sarah M. Shalf) wrote extraordinarily incisive drafts for the Committee to review. Andrew Pope is not only the Director of the IOM Board on Health Sciences Policy, but also brilliantly assumed the position of Study Director of our Committee. His leadership is warmly appreciated.

Lawrence O. Gostin, *Chair*
*Committee on Ethical Considerations*
*for Research Involving Prisoners*

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**APPENDIXES**