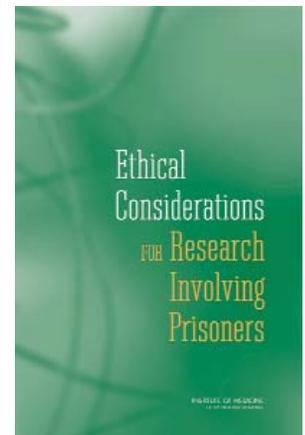


# ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS

The U.S. correctional system is different today than it was in the 1970s, when current regulations regarding prisoners as research subjects were first made known. In 1976, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released a report that resulted in the promulgation of Title 45 § 46 of the Code of Federal Regulations. Subpart A of these regulations serves as the basic Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, also known as the Common Rule. Specific protections for prisoners are found in Subpart C.

Over the past 30 years, the population of prisoners in the United States has expanded more than four-fold. Today, close to seven million individuals are in U.S. prisons, jails, or on probation or parole. In the past, prisoners have carried a heavier burden of the risks of research than the general population. 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. 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. The Office for Human Research Protections (OHRP) of the 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.

In this report, *Ethical Considerations for Research Involving Prisoners*, the IOM committee adds further protections both by expanding the population of prisoners covered by rigorous ethical rules and by recommending additional safeguards. The committee also acknowledges that access to research may be critical to improve the health of prisoners and the conditions in which they live, according to researchers and prisoners, as well as the prisoner liaison panel. However, research with prisoners should be conducted only if it offers a distinctly favorable benefit-to-risk ratio, not because prisoners are a convenient source of subjects. The goal is to ensure rigorous, responsible research that



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improves the well-being of prisoners while taking great care to protect their health, well-being, and human rights.

The committee's recommendations are directed to five distinct objectives: (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**

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 remaining 4.9 million were either on parole or probation—two groups that do not clearly fit under the definition of "prisoner" in the current regulations. By virtue of their restricted liberty, however, they do represent a population with increased vulnerability and deserve similar protections to those who are incarcerated. The committee, therefore, recommends an expansion of the reach of the regulatory procedures and oversight mechanisms recommended in this report to the fuller population of individuals (whether in correctional institutions or community settings) whose liberty is restricted by the criminal justice system.

### **ENSURE UNIVERSAL, CONSISTENT ETHICAL PROTECTION**

Current regulations apply only to DHHS-funded research and to research funded by two other federal agencies (the Central Intelligence Agency and the Social Security Administration). The committee recommends more uniform application of regulations and oversight of all prisoner research. All human subjects research involving prisoners should be regulated by the same ethical standards, irrespective of the source of funding, supporting agency, type of correctional facility (federal, state, local, or private) or program that houses the prisoner.

Today, it is impossible to know how many prisoners are involved in studies because no central database exists of such information. The committee calls for a publicly accessible national registry of research involving prisoners. A registry 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. It would also enhance the application of research findings to prisoner populations.

### **SHIFT FROM A CATEGORY-BASED TO A RISK-BENEFIT APPROACH TO RESEARCH REVIEW**

The protections for prisoners, found in Subpart C of the current research subject regulations, require that proposals for research be reviewed within narrowly defined research categories that are subject to various interpretations. This approach does not provide sufficient or reliable protections because it does not adequately consider the potential benefits and risks involved in the study. Importantly, the present structure does not address the actual conditions of confinement or the restrictions on liberty experienced by the prisoner subject.

A risk-benefit approach, similar to the regulation for children, should apply to all types of research involving prisoners: 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 (e.g., testing of cosmetic products), while studies offering considerable benefit with low risk would be allowed. Biomedical research in correctional set-

tings would be severely limited. Phase 1 (safety) and 2 (effectiveness) 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. But even for phase 3 (after effectiveness is shown) studies, the ratio of prisoner to non-prisoner subjects should not exceed 50 percent, to ensure a fair distribution of research burdens. The Committee believes that a 50 percent rule would minimize the possibility of using prisoners as human subjects because they are a more convenient or accessible population.

To provide extra protections in the area of biomedical research, which likely carries the greatest risks for subjects, the only benefits that should be considered are the benefits to the subjects themselves. There may be social/behavioral and epidemiological studies, however, that carry very low risks for the prisoner subjects but little or no personal benefit. In this case, if risks are very low and important knowledge or benefits may accrue for prisoners as a class, the research may be considered ethically acceptable if all of the ethical safeguards recommended by the Committee are in place.

### **UPDATE THE ETHICAL FRAMEWORK TO INCLUDE COLLABORATIVE RESPONSIBILITY**

The same two ethical considerations that guided the National Commission in 1976—respect for persons and justice—should still be the basis for the conduct and regulation of research involving prisoners today. The IOM committee recommends, in addition, that collaborative responsibility be added as part of the principle of justice. Collaborative responsibility is intended to convey the idea that, to the extent feasible, all aspects of research (design, planning, and implementation) should include the input of relevant stakeholders (e.g., prisoners, correctional officers, medical staff, administrators). For research to be truly ethical, it must be tailored to the individual setting, which presents its own unique challenges and concerns. A focus on collaboration may facilitate openness of the research environment and would help researchers create ethical conditions that are favorable for respect and unfavorable for exploitation.

### **ENHANCE SYSTEMATIC OVERSIGHT OF RESEARCH INVOLVING PRISONERS**

There is no national system of oversight for research involving prisoners. 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. Voluntary informed consent must be obtained and privacy maximized in the context of the correctional setting.

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. 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. 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 maintain independence and ensure credibility among the prisoner-subjects.

In addition, while OHRP's capacity to provide systematic oversight should be strengthened, its jurisdiction is limited. 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.

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### **FOR MORE INFORMATION...**

Copies of *Ethical Considerations for Research Involving Prisoners* are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, <http://www.nap.edu>. The full text of this report is available at <http://www.nap.edu>.

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### **COMMITTEE ON ETHICAL CONSIDERATIONS FOR REVISIONS TO DHHS REGULATIONS FOR PROTECTION OF PRISONERS INVOLVED IN RESEARCH**

LAWRENCE O. GOSTIN (Chair), Georgetown University Law Center, Washington, DC

HORTENSIA AMARO, Northeastern University, Boston, MA

PATRICIA BLAIR, University of Texas Health Center at Tyler, Tyler, TX

STEVE J. CAMBRA, Jr., Cambra, Larson & Associates, Elk Grove, CA

G. DAVID CURRY, University of Missouri-St. Louis, St. Louis, MO

CYNTHIA A. GÓMEZ, University of California, San Francisco

BRADFORD H. GRAY, The Urban Institute, Washington, DC

MICHAEL S. HAMDEN, North Carolina Prisoner Legal Services, Inc., Raleigh, NC

JEFFREY L. METZNER, University of Colorado School of Medicine, Denver, CO

JONATHAN MORENO, University of Virginia, Charlottesville, VA

LARRY I. PALMER, University of Louisville, Louisville, KY

NORMAN G. POYTHRESS, Jr., University of South Florida, Tampa, FL

WILLIAM J. ROLD, New York City, NY

JANETTE Y. TAYLOR, University of Iowa, Iowa City, IA

WENDY VISSCHER, RTI International, Research Triangle Park, NC

BARRY ZACK, Centerforce, San Quentin, CA

### **EXPERT ADVISOR AND LIAISON, BOARD ON HEALTH SCIENCES POLICY**

NANCY DUBLER, Montefiore Medical Center, Bronx, NY

### **CONSULTANTS**

BEN BERKMAN, Georgetown University Law Center, Washington, DC

SARAH SHALE, Bondurant, Mixson & Elmore, LLP, Atlanta, GA

CORI VANCHIERI, Silver Spring, MD

### **INTERN**

JASON E. FARLEY, The Johns Hopkins University, Baltimore, MD

### **IOM STAFF**

ANDREW POPE, Study Director (from August 2005)

ADRIENNE STITH BUTLER, Senior Staff Officer (from August 2005)

TRACY G. MYERS, Study Director (through August 2005)

EILEEN SANTA, Research Associate (from August 2005)

SUSAN MCCUTCHEN, Research Associate

VILIIJA TEEL, Senior Project Assistant