

NBAC Summary of Preliminary Findings:
Adequacy of Federal Protections for Human Subjects in Research

Extending Federal Protections for Human Research Subjects to All Americans

In 1997, President Clinton stated that “science must respect the dignity of every American. We must never allow our citizens to be unwitting guinea pigs in scientific experiments....” That same month, the National Bioethics Advisory Commission (NBAC) resolved, as a matter of ethical principle, that no person should be enrolled in research without the twin protections of informed consent and independent review of the research. NBAC notes with concern that this goal remains unmet.

In particular, the protections of the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, do not extend to all Americans; the Common Rule applies only to subjects in research regulated by the Food and Drug Administration (FDA) or to subjects in research sponsored by some Federal departments and agencies.ⁱ Among the Common Rule’s most important protections are the requirements for informed consent by research subjects and for independent review of the research by a local Institutional Review Board (IRB). Despite the fact that many research institutions voluntarily apply the Common Rule—even to their privately financed research—there are other significant sectors of privately funded research that remain ungoverned either by State or Federal law.

NBAC finds that the absence of Federal jurisdiction over much privately funded research means that the U.S. government cannot know how many Americans currently are subjects in experiments, cannot influence how they have been recruited, cannot ensure that research subjects know and understand the risks they are undertaking, and cannot ascertain whether they have been harmed.

Not only does this prevent the Federal Government from protecting Americans enrolling in research, but it affects the Federal Government’s ability to craft policies governing emerging technologies. While preparing its 1997 report *Cloning Human Beings*, for example, NBAC noted that the Common Rule’s lack of jurisdiction over privately funded research made it impossible to rely on IRBs as the primary mechanism for protecting human subjects against inappropriate uses of those technologies.

Implementation of the Common Rule

Beginning in 1996, Federal departments and agencies responded to NBAC’s request for information pursuant to Executive Order 12975. NBAC is pleased to report that agencies have responded to the Executive Order not only by reporting on their current protections, but by evaluating those protections and taking steps to strengthen them. Based on the agency reports and actions and on its own investigations and contracted studies, NBAC concludes that the Common Rule has significantly reduced, but not eliminated, the

possibility for harm to human subjects. As a result, NBAC also concludes that there is a need for significant improvement, both to enforce Federal protections and to make their implementation less burdensome for Federal agencies and researchers.

Research regulated by the FDA or sponsored by one of the Federal departments or independent agencies that have adopted the Common Rule requires prior approval and continuing oversight by an IRB. NBAC has found that all the Federal departments and agencies that sponsor substantial amounts of biomedical research with human subjects have implemented these requirements. On the other hand, several departments and agencies that sponsor behavioral and other nonbiomedical research have not fully implemented the provisions of the Common Rule, despite the fact that such research may pose serious nonphysical risks, such as loss of insurance or employment, discrimination, incarceration, and invasion of privacy. Although various Federal regulations do provide protections for certain vulnerable populations, these are not incorporated in the Common Rule. In addition, NBAC notes that the Common Rule does not require any special protections for especially vulnerable populations, such as children.

NBAC has identified occasions when nonbiomedical research that posed more than minimal risk was conducted on certain vulnerable populations; in some of these instances, the research was supported or conducted by one of the agencies that has not adopted additional protections, such as those found in Subparts B, C, or D of the Department of Health and Human Services regulations.

Federal departments and agencies do face obstacles in fully implementing the Common Rule. NBAC notes that many agencies find the Common Rule confusing or its provisions too burdensome in light of the type or amount of research they sponsor. Although some agencies have been taking steps to bring themselves into compliance with the Common Rule, nearly all of them agree that increased protection of human subjects cannot be achieved without additional staffing and highly visible statements of commitment from the leadership of their respective departments. Some also have suggested that a central authority governing human subjects research could help to interpret the Common Rule's requirements, create the oversight structures needed for its implementation, and advise on ethically complex protocols.

NBAC also finds that centralized leadership is needed to achieve consistent interpretation of key statutory and regulatory requirements. Lack of a single authority also means that improvement in human subjects protections, such as those specific to vulnerable populations, requires that every affected department independently adopt new regulations. This is inevitably slower and more inefficient than adoption by a central authority.

For example, in its 1998 report *Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity*, NBAC observed that some affected agencies were hard-pressed to reconcile their agency mission of fostering much-needed research into the causes and cures for mental illness with the shared Federal commitment to paying scrupulous attention to the interests of vulnerable human subjects. In addition, the

absence of a single, authoritative Federal office to oversee human subjects protections will make it difficult to ensure that all affected departments will issue regulations implementing NBAC's recommendations; indeed, similar recommendations were made 20 years ago by another national bioethics commission regarding the same population, but they were never adopted.

Ensuring Adequate and Accountable Local Oversight

The decentralized local system is sorely strained by inadequate staffing and education of IRBs; by the explosion in research activity; by emerging ethical issues arising from ethical issues raised by epidemiological and public health research; by the trend toward collaborative, multi-centered research; and by an absence of comprehensive public accountability.

NBAC's work highlights many of these problems and offers some solutions. Its upcoming report on research involving human biological materials, for example, suggests some solutions to the difficult problem of applying current Federal protections to epidemiological research on stored tissue, while its project on international research norms is revealing the dilemmas posed by collaborative research across national boundaries. Its report, *Research Involving Persons With Mental Disorders That May Affect Decisionmaking Capacity*, emphasized the need to maintain the public's trust in the integrity of the scientific endeavor. To that end, NBAC suggested that "IRBs can effectively use the mechanisms of audit (both internal and external) and disclosure to improve accountability and inspire public confidence in their oversight activities."

Conclusion

NBAC finds that the current Federal regulations have served to prevent most recurrences of the gross abuses associated with biomedical research in the earlier part of this century. Nonetheless, some abuses still occur, and the system is in need of significant revision in order to provide clear, efficient, and authoritative guidance to Federal departments and agencies and to ensure that local oversight is effective and accountable to the public. This is essential to improving protections for human research subjects. It is also a necessary first step toward extending these protections to those Americans not yet protected by any State or Federal standards for human subjects in research.

ⁱ As of 1997, 16 departments and independent agencies had formally adopted the Common Rule as signatories. In addition, one other independent agency—the Central Intelligence Agency (CIA)—had adopted the Rule in accordance with Executive Order 12333:

Departments

U.S. Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy

Department of Health and Human Services
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs

Independent Agencies

International Development Cooperation Agency (Agency for International Development)
Consumer Product Safety Commission
Environmental Protection Agency
National Aeronautics and Space Administration
National Science Foundation
Social Security Administration
*Central Intelligence Agency **
*Office of Science and Technology Policy***

* As of 1997, the CIA was not a formal signatory to the Common Rule but had adopted the Rule in accordance with Executive Order 12333. At the time of this report, the CIA is in the process of becoming a formal signatory.

**The Office of Science and Technology Policy is a signatory to the Common Rule, even though it does not itself conduct or support research directly. It has “accepted” the Common Rule, but does not have its own Code of Federal Regulations.