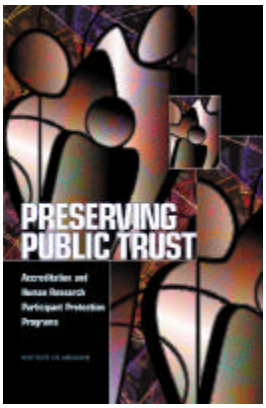
INSTITUTE OF MEDICINE

Shaping the Future for Health

PRESERVING PUBLIC TRUST:

ACCREDITATION AND HUMAN RESEARCH PARTICIPANT PROGRAMS



The protection of individuals who volunteer to participate in research is essential to the ethical conduct of research. Such protections were not explicitly and systematically addressed in the United States, however, until the late 1940s, when scientists and policy makers recognized the need to respond to crimes committed by Nazi scientists during World War II. Since then there has been a growing sensitivity to and acceptance of the need to conduct research involving human participants with regard for their autonomy, privacy, and safety.

The protection of individuals who volunteer to participate in research is essential to the ethical conduct of research.

Over the past 50 years, regulatory policies have evolved to create a system of participant protections involving investigators, sponsors, research institutions, health-care providers, federal agencies, and patient and consumer groups. But with this enhanced system of protections comes concern about whether its complexity and size has rendered it unresponsive to the growing pressures of a constantly changing research environment.

The need to improve protections has become more apparent as report after report has highlighted mounting concerns about the ability of the participant protection system to keep up with the evolving research enterprise. Nearly all of these reports have recommended a reexamination and modernization of the system. In addition, in 1999 the former federal Office for Protection from Research Risks and the Food and Drug Administration took action against several major research universities, suspending their human research programs because of apparent noncompliance with federal regulations. Also in 1999, Jesse Gelsinger, an 18-year-old research volunteer, died in a gene transfer trial not because of his underlying disease but because of the experimental intervention itself. As the circumstances and events leading up to his death emerged, it became apparent that the system intended to protect him from unacceptable research risks instead failed him.

Trust in the human research enterprise… demands that the system responsible for protection be credible and accountable.

Trust in the human research enterprise, embodied in an individual consenting to participate in a study, and thereby assuming risks inherent in that study, demands that the system responsible for protection be credible and accountable. In policy discussions that have occurred in the wake of these

events, many have suggested that one way to improve accountability in the system is through an accreditation process.

In response to a request from the Secretary of the Department of Health and Human Services (DHHS), the Institute of Medicine formed a committee to conduct a two-phase study to examine how to improve the structure and function of human research participant protection programs. This report provides the committee's response to its first task: to review and consider proposed standards for accreditation of programs that aim to protect research participants and to recommend an approach to monitoring and evaluating the total system of human participants protections. The committee's recommendations are presented in Box 1 according to the phases inherent in the development of an accreditation process.

Human Research Participant Protection Programs

In the United States, the system of human research participants protection traditionally has centered on the institutional review board, or IRB, which is charged with independent review of research protocols to assess risks and the adequacy of protections for study participants. In this report, the committee envisions a broader human research participant protection system than just the IRB, with multiple functional elements that in total are referred to as *human research participant protection programs*, or HRPPPs. The many HRPPPs in this country make up a system with four principle functions: 1) to ensure that research design is sound and that a study's promise for augmenting knowledge justifies the involvement of human participants; 2) to assess the risks and benefits of a study independently of the investigators who carry out the research; 3) to ensure that participation in research is voluntary and informed; and 4) to ensure that participants are recruited eq-

BOX 1 Summary of Committee's Recommendations According to the Three Implementation Phases of an Accreditation Process

Development of an Accreditation Program:
Pursue Accreditation Through Pilot Testing as One Approach (Recommendation 1)
Establish a Nongovernmental Accreditation Organization(s) (Recommendation 2)
Accommodate Distinct Research Methods and Models Within Accreditation Programs (Recommendation 5)
Directly Involve Research Participants in Accreditation Programs & HRPPPs (Recommendation 8)

Development of Standards:
Articulate Sound Goals Within Accreditation Standards (Recommendation 3)
Establish Flexible, Ethics-Based, and Meaningful Standards (Recommendation 4)
Base Standards on Existing Regulations (Recommendation 6)
Incorporate Continuous Quality Improvement Mechanisms into Standards (Recommendation 7)
Use Modified NCQA Standards to Initiate Pilot Programs (Recommendation 9)

Development of an Evaluation Process:
Begin Collecting Data and Assessing Impacts of Accreditation Now (Recommendation 10)
Initiate Federal Studies Evaluating Accreditation (Recommendation 11)

uitably and that risks and benefits are fairly distributed. The HRPPP, which can take many forms in many contexts, is the functional unit that would be the subject of an accreditation process.

…accreditation of HRPPPs should be pursued as *one* promising approach to improve the system.

Accreditation as One Approach to Improving the System

In addition to improving protections, accreditation as a mark of excellence—of achievement well beyond regulatory compliance—might offer a HRPPP a competitive advantage over nonaccredited competitors in seeking support from sponsors or access to participants, researchers, or students. The committee recommends that accreditation of HRPPPs should be pursued as *one* promising approach to improve the system. The first step toward this strategy is the implementation of pilot programs to test standards, establish accreditation processes, and build confidence in accreditation organizations. The committee believes that the ideal accreditation body is a national independent organization that is credible among those seeking accreditation but independent of any particular interest group among them.

Accreditation Standards

The central focus of this report is accreditation standards, the benchmarks by which accreditation programs measure achievement. Any set of standards must be flexible enough to be applicable to a variety of institutions yet rigorous enough to ensure that their enactment enhances protection of participants in human research. In addition, they must be clearly written, relatively straightforward to execute, consistently applicable, and measurable.

At a minimum, standards should address an organization's level of functional performance in specific areas. Some would further argue that the measurement should not just address what the organization is capable of doing but what it actually does. In theory, standards should set forth maximum achievable performance expectations for

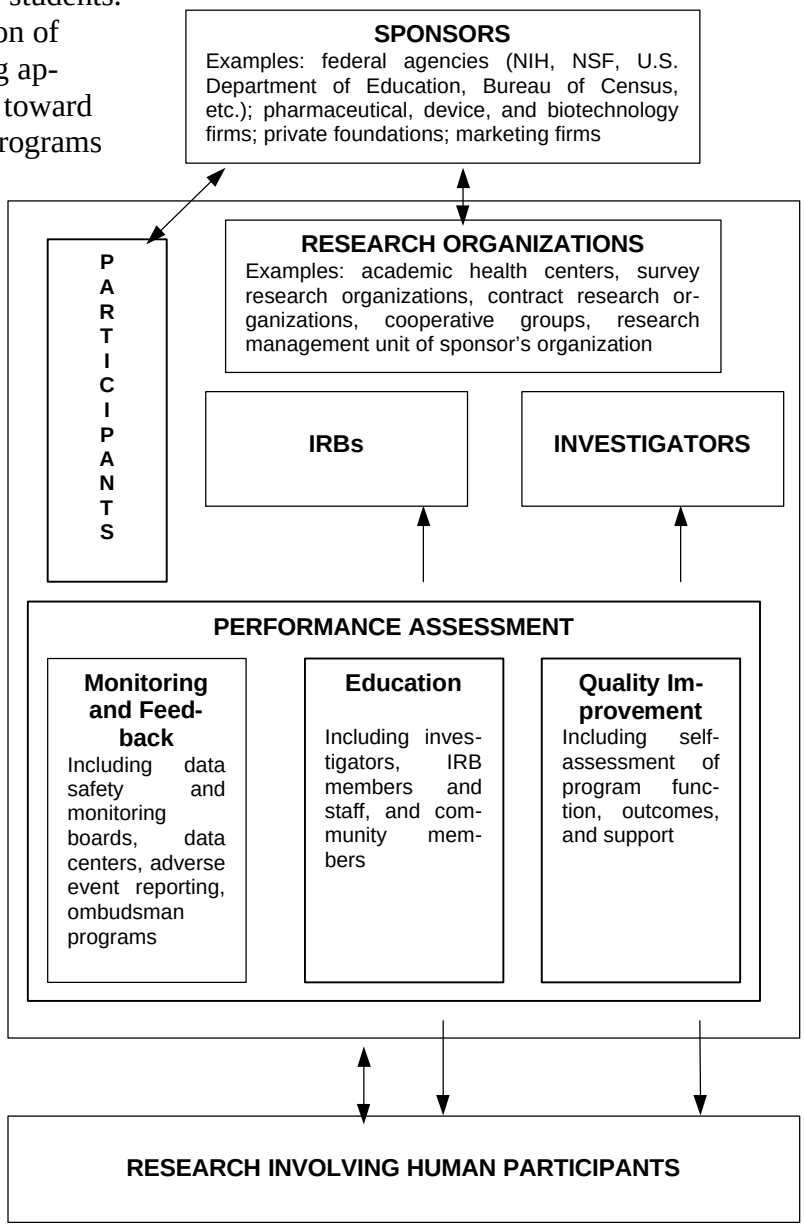


FIGURE 1 Human research participant protection programs. The components in the large box are all parts of an HRPPP. Arrows represent information flow pathways, not organizational responsibilities. All units within HRPPP should have formalized communication procedures.

activities that affect the protection of human research participants. Perhaps most importantly, they should be based on widely accepted ethical principles that form the norms for research behavior.

The committee reviewed available draft standards developed independently by Public Responsibility in Medicine and Research (PRIM&R) and by the National Committee for Quality Assurance (NCQA) under contract to the U.S. Department of Veterans Affairs (VA). The following criteria were used in assessing the standards: 1) their scope and focus; 2) their relationship to the existing regulatory standards; and 3) the extent to which the standards can be consistently implemented, measured, and enforced; as well as their inclusion of various key elements.

Neither set of proposed standards applies readily to the full range of human research or to the diversity of research institutions involved. It is not clear in all cases how the standards should be applied to nonbiomedical research settings, contract management organizations, cooperative clinical trials groups, independent IRBs, site management organizations, or research units within federal agencies and private industry.

Nonetheless, the committee concluded that an accreditation program(s) should be pilot tested and that the NCQA standards are more suitable than those prepared by PRIM&R, not only in VA facilities, but, with modification, for the accreditation of other research institutions. The NCQA standards are the strongest basis for use in the accreditation of other research institutions because they include specific attention to quality improvement, provide flexibility in achieving performance goals (e.g., increased protection of research participants), and are explicit in their grounding in current regulations.

The NCQA standards are the strongest basis for use in the accreditation of other research institutions because they include specific attention to quality improvement, provide flexibility in achieving performance goals (e.g., increased protection of research participants), and are explicit in their grounding in current regulations.

In expanding the draft NCQA standards for use beyond VA facilities, the committee recommends that the standards be strengthened in several specific ways. These include: how investigators will be reviewed, beyond the review of protocols by IRBs; how sponsors will be assessed; how participants will be involved in setting performance standards; and how oversight mechanisms can ensure participants' safety.

The committee makes two additional recommendations regarding standards. First, the formulation of accreditation standards, the accreditation process, and HRPPP operations should directly involve research participants. Second, the accreditation process should accommodate organizations involved in research beyond the traditional research organization models provided by academic health centers and VA facilities. The accreditation process also should be appropriate for research methods other than clinical research.

Evaluating HRPPP Pilot Accreditation Programs

Experience will best guide judgments about the costs and benefits of an accreditation strategy.

Launching the HRPPP accreditation programs will take some time. Experience will best guide judgments about the costs and benefits of an accreditation strategy. Even as the pilot projects are being planned and implemented, however, forethought about how to evaluate them is in order. The committee recommends that DHHS commission studies to gather baseline data on the current system of protections for human participants in research, that Congress request an evalua-

tion of pilot programs from the General Accounting Office, and that DHHS request a parallel evaluation from the DHHS Office of the Inspector General.

For More Information…

Copies of *Preserving the Public Trust: Accreditation and Human Research Participant Programs* are available for sale from the National Academy Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at www.nap.edu.

This study was funded by the Department of Health and Human Services and the Greenwall Foundation.

The Institute of Medicine is a private, nonprofit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. For more information about the Institute of Medicine, visit the IOM home page at ww.iom.edu.

© 2001 by the National Academy of Sciences. All rights reserved.

Permission is granted to reproduce this document in its entirety, with no additions or alterations.

COMMITTEE ON ASSESSING THE SYSTEM FOR PROTECTING HUMAN RESEARCH SUBJECTS

DANIEL D. FEDERMAN (*Chair)*, Dean for Clinical Teaching, Harvard University, Boston, MA
DANIEL AZARNOFF, President, D.L. Azarnoff Associates, San Francisco, CA
TOM BEAUCHAMP, Professor, Kennedy Institute of Ethics, Georgetown University, Washington, DC
TIMOTHY STOLTZFUS JOST, Newton D. Baker, Baker and Hostetler Professor of Law and Health Services Management and Policy, Columbus, OH
PATRICIA A. KING, Carmack Waterhouse Professor of Law, Medicine, Ethics, and Public Policy, Georgetown University Law Center, Washington, DC
RODERICK J.A. LITTLE, Chair, Department of Biostatistics, School of Public Health, University of Michigan, Ann Arbor, MI
JAMES McNULTY, President, Depressive/Manic Depressive Association of Rhode Island, Bristol, RI
ANNE PETERSEN, Senior Vice President-Programs, Kellogg Foundation, Battle Creek, MI
BONNIE W. RAMSEY, Professor, Department of Pediatrics, University of Washington School of Medicine, Seattle, WA

LYDIA VILLA-KOMAROFF, Vice President for Research, Northwestern University, Evanston, IL
FRAN VISCO, President, The National Breast Cancer Coalition, Washington, DC

Expert Advisers

KAY DICKERSIN, Associate Professor, Department of Community Health, Brown University, Providence, RI
ALBERTO GRIGNOLO, Senior Vice President and General Manager for Worldwide Regulatory Affairs, PAREXEL International, Waltham, MA
MARY FAITH MARSHALL, Professor of Medicine, School of Medicine, Kansas University Medical Center, Kansas City, KS
CAROL SAUNDERS, President, Center for Clinical Research Practice, Wellesley, MA
DENNIS TOLSMA, Director, Clinical Quality Improvement, Kaiser Permanente, Atlanta, GA

Liaisons

RICHARD J. BONNIE, John S. Battle Professor of Law and Director, Institute of Law, Psychiatry, and Public Policy, Charlottesville, VA
NANCY NEVELOFF DUBLER, Director, Division of Bioethics, Montefiore Medical Center; Co-director, Certificate Program in Bioethics and Medical Humanities, Professor of Bioethics, Albert Einstein Medical College, Bronx, NY
ELENA OTTOLENGHI NIGHTINGALE, Scholar-in-Residence, Institute of Medicine and National Research Council, Washington, DC
PILAR OSSORIO, Assistant Professor of Law and Medical Ethics, Associate Director of the Center for the Study of Race and Ethnicity in Medicine, University of Wisconsin, Madison Law School, Madison, WI

Study Staff

LAURA LYMAN RODRIGUEZ, Study Director
ROBERT COOK-DEEGAN, Senior Program Officer
JESSICA AUNGST, Research Assistant
NATASHA DICKSON, Project Assistant

IOM Board on Health Sciences Policy Staff

ANDREW POPE, Board Director
ALDEN CHANG, Administrative Assistant
CARLOS GABRIEL, Financial Associate

Consultant

KATHI HANNA