

## Introduction

# Other Crosscutting Activities and Policies

Chapters 2 and 3 of this Report summarize NIH research activities on the topics specified in the statute mandating this report. Chapter 2 summarizes research activities on topics that are disease-specific (e.g., those regarding cancer and chronic diseases). Chapter 3 summarizes activities from the perspective of key research approaches and resources (e.g., genomics, clinical and translational research, research training, and health communications). Other activities essential to the mission of the NIH—technology transfer, science education, providing a platform for discovery, improving the management of research, and ensuring responsible research and development—are summarized below.

### Technology Transfer and Sharing

Federal and NIH policy requires that the outcomes of NIH research be made available to the public. Provisions of the Bayh-Dole Act (35 U.S.C. 200 et seq.) and the Federal Technology Transfer Act (15 U.S.C. 1501 et seq.) are intended to stimulate the commercialization of federally funded inventions by ensuring the transfer of federally funded technology to the private sector.

The NIH Office of Technology Transfer (OTT) develops technology transfer policies that are approved by the PHS Technology Transfer Board. Technology transfer and sharing policies, as they apply to extramural research, are developed with and administered by OER. These policies include principles, guidelines, and regulations related to publication, invention reporting, and intellectual property policy matters. [OER policies](#) are designed to enhance access to publications resulting from NIH-funded research; ensure appropriate sharing of data, tools, and research resources; and promote the transfer of technology (in the form of licenses and patents). All recipients of Federal grants or contracts must report details of inventions and patents that have been made through such awards. NIH developed an online Extramural Invention Information Management System (Edison) in 1995 for Bayh-Dole reporting compliance, and now administers the Interagency Edison system (iEdison) through which inventions supported by any of 18 Federal research agencies can be reported.

Intramural [policies](#) and activities are managed by the Office of Technology Transfer (OTT) in the NIH OIR. As mandated by the Federal Technology Transfer Act and related legislation, OTT evaluates, protects, licenses, monitors, and manages the wide range of intramural NIH and U.S. Food and Drug Administration (FDA) discoveries, inventions, and other intellectual property. A large part of OTT's responsibility for technology transfer is carried out by retaining title to inventions developed in NIH and FDA laboratories and licensing these inventions to the private sector entity best suited to conduct the further research and development needed for potential commercialization and public health benefit. The NIH Pipeline to Partnerships (P2P) searchable database is a new resource developed to encourage the development of technologies licensed from OTT or being developed by NIH SBIR/STTR awardees by showcasing them for an audience of potential strategic partners, investors, and licensees. The P2P database provides an additional avenue by which NIH can facilitate more rapid development of products for the benefit of public health.

### Science Education and Literacy

NIH takes an active role in science education and science literacy activities. These activities aim to attract young people to biomedical and behavioral science careers, lay the groundwork for advanced study, enhance public

understanding of health science, and empower the public as consumers of science and health information.

[Curriculum supplements](#) —ready-to-use, interactive teaching units—are one of NIH's most popular and effective science education efforts. Crafted through a unique partnering of NIH scientists, teachers, and expert curriculum developers, the supplements are aligned with State education standards and are consistent with the National Science Education Standards. NIH has shipped nearly 300,000 curriculum supplements to K-12 educators across the Nation. Topics covered include “The Science of Healthy Behaviors,” “Cell Biology and Cancer,” “Sleep, Sleep Disorders, and Biological Rhythms,” and “The Brain: Understanding Neurobiology through the Study of Addiction.”

NIH aims to engage students and the public in the wonders of biology and biomedical research through other thought-provoking programs as well. For those who are interested in a career in the life sciences, NIH provides resources such as [LifeWorks®](#), a career exploration Web site for middle and high school students, their parents, teachers, and career guidance counselors. Lifeworks® includes in-depth career information on more than 100 health and medical science-related careers. Users can search the site and generate a customized list of careers that match their skills and interests. “SciLife” is an annual health and biomedical career planning workshop for parents and high school students. NIH also sponsors a speakers' bureau that provides engaging science professionals to talk to school groups and local and national organizations.

NIH's [Science Education Partnership Awards](#) (SEPA) funds innovative educational programs, such as collaborations among biomedical and clinical researchers and teachers and schools, museums and science centers, media experts, and other educational organizations that generate educational resources such as curricula; exhibits; films; student, teacher, and parent workshops; after-school and summer hands-on science programs; essay contests; and science fairs. A dedicated [SEPA Web site](#) provides access to the educational materials and expertise produced through these efforts. SEPA enables researchers, educators, and community groups to share their knowledge, expertise, and enthusiasm about health and science research with K-12 students and the general public.

## Providing the Platform for Discovery

### *Buildings and Facilities*

With more than 18,000 employees and 229 government-owned buildings in six locations, the facilities infrastructure maintained by the OD Office of Research Facilities is the literal foundation for a successful research program. The facilities necessary to support 21st century science are far more sophisticated than yesterday's bricks, mortar, pipes, and lines. From biosafety to facilitating team science, the requirements of today's research create greater demands in providing and sustaining a safe, healthy, and functional environment for employees and patients.

### *The Clinical Center*

The Clinical Center is the Nation's largest hospital devoted entirely to research. Here, NIH scientists work to translate laboratory discoveries into better means to improve the Nation's health. Comprising two facilities—the Mark O. Hatfield Clinical Research Center, which opened in 2005, and the original Warren Grant Magnuson Clinical Center, which opened in 1953—the Center houses inpatient and outpatient units as well as research laboratories and features a unique design that locates patient care units in close proximity to cutting-edge laboratories doing related research. This facilitates interaction and collaboration among clinicians and researchers. More than 1,600 intramural NIH laboratories use the Center to conduct research. The Center has more than 100,000 outpatient visits a year and 7,000 inpatient admissions. Approximately 1,200 credentialed physicians, dentists, Ph.D. researchers, 660 nurses, and 570 allied health care professionals such as pharmacists, dietitians, and medical technologists work at the Center. As a research facility, only patients with the precise kind or stage of illness under investigation are admitted for treatment under a protocol, but subjects who are enrolled in clinical studies receive

the benefit of access to cutting-edge technologies and compassionate care.

### ***The Library***

Through the National Library of Medicine (NLM), NIH provides the world's largest medical library. The Library collects materials in all areas of biomedicine and health care. The collections stand at more than 9 million items—books, journals, technical reports, manuscripts, microfilms, photographs, and other images. Housed within the Library is one of the world's finest medical history collections of old and rare medical works. Far more than a physical facility, the Library is responsible for MEDLINE®, a database freely accessible on the Internet through PubMed®, which has more than 16 million journal article references and abstracts going back to the mid-1960s with another 1.5 million references back to the early 1950s. Some 900 million searches of MEDLINE are done each year by health professionals, scientists, librarians, and the public. Links from references to full text articles increasingly are available.

To maintain the currency of its collection, the Library selects, orders, and acquires publications from a wide variety of sources. Each year NLM receives, reviews, and processes approximately 25,000 monographic items for possible addition to the NLM collections, and acquires, licenses, and processes over 22,000 print, non-print, and electronic serial titles.

To manage its collection and maximize accessibility, the Library employs sophisticated cataloging and indexing schemes that in and of themselves are important tools for the Nation's network of medical libraries. These activities include maintaining and developing the online [NLM Classification](#), a scheme for the shelf arrangement of medical literature in libraries, and [MeSH](#), the Library's controlled vocabulary thesaurus. MeSH consists of sets of terms naming descriptors in a hierarchical structure that permits searching at various levels of specificity. The MeSH thesaurus is used for indexing articles from 4,800 of the world's leading biomedical journals for the MEDLINE/PubMED® database. It also is used for the NLM-produced database that includes cataloging of books, documents, and audiovisuals acquired by the Library. Each bibliographic reference is associated with a set of MeSH terms that describe the content of the item. Similarly, search queries use MeSH vocabulary to find items on a desired topic.

### ***Information Technology***

Information technology (IT) and computational science increasingly are essential to deciphering the complexity of biological systems. The NIH Center for Information Technology (CIT) provides core IT infrastructure, system security, and services ranging from cable and server acquisition and management, to video conferencing and Web site development, as well as providing the policy framework for IT activities undertaken by other ICs. In addition, CIT and many ICs provide NIH scientists with access to the sophisticated systems, analytic tools, and databases necessary to advance quantitative investigations in fields such as molecular biology and proteomics (for additional information see the section on Disease Registries, Databases, and Biomedical Information Systems in Chapter 3). From supercomputing to management of an Image Processing Facility, CIT also provides the NIH intramural community with invaluable scientific support tools and resources.

### ***Public-Private Partnerships***

The NIH Program on [Public-Private Partnerships](#) was established in 2006 within the NIH Office of Science Policy as a Roadmap initiative to facilitate collaborations to improve public health through biomedical research. As the central NIH resource on public-private partnerships, the program provides guidance and advice to NIH and potential partners on the formation of collaborations that leverage NIH and non-NIH resources to achieve synergy. NIH partnerships can be established directly between NIH (as a whole or through one or more ICs) and any of a wide range of other organizations, including patient advocacy groups, foundations, pharmaceutical or

biotechnology companies, academic institutions, and the Foundation for the NIH (FNIH), an independent, private charitable foundation established by Congress. The Program works with the ICs and OD Offices to review existing partnership mechanisms and recommend policies or legal authorities needed to achieve NIH objectives and manage intellectual property, achieve data access and sharing, and address human subjects protections and other concerns. In September 2007, the Program issued, in the *NIH Manual*, a [reference guide](#) to many of the relevant legal authorities, policies, ethics issues, and other considerations in using the various available mechanisms to create public-private partnerships.

## Improving Research Management

### *Enhancing Peer Review*

In June 2007, NIH embarked on a [trans-NIH effort](#) to examine the two-level NIH peer review system with the goal of optimizing its efficiency and effectiveness, while ensuring that NIH continues to meet the needs of the research community and public at large. The examination involves leaders from across the scientific community through two working groups—one external and one internal. Both groups are seeking broad input. Information collection efforts included a Request for Information published in the *NIH Guide* seeking comments and creative concrete suggestions on how to enhance the system; an internal NIH staff survey; regional meetings around the country; and consultations with professional societies and advocacy groups. After all of the input has been analyzed, both working groups will meet in January 2008 to develop a set of integrated recommendations for next steps.

In parallel with NIH's examination of the peer review system, CSR launched several peer review pilots and initiatives that will inform this ongoing effort. Based on a two-stage pilot test that began early in 2006, NIH shortened the review cycle for new investigators submitting R01 applications. (The R01 is the most common mechanism of grant support for individual investigators.) Before the pilot, on average, it took 10.3 months from the receipt of an application until NIH made an award to support the proposed research. For new applicants, CSR now posts the conclusions of peer review meetings within 10 days. This acceleration gives new applicants opportunity to revise and resubmit amended applications for the next review cycle—4 months sooner than the previous opportunity for resubmission. Since new investigators, by definition, have had no previous R01 support, any delay in their ability to submit an amended application could have a negative impact on their careers. NIH has great interest in the career development of new scientists and this initiative is just one example of NIH's commitment to supporting new investigators in their efforts to obtain R01 research grant funding. NIH is now working toward shortening the review cycle for all applicants.

CSR also has been developing and testing different modes of conducting peer review to enhance the recruitment of the best reviewers. One experiment involves scheduling some study section meetings in areas outside the Washington, D.C., area so meeting sites and travel are more convenient for reviewers.

### *New Investigators*

New investigators are the innovators of the future—they bring fresh ideas and technologies to bear on biomedical and behavioral research problems and they pioneer new areas of investigation. Entry of new investigators into the ranks of NIH-funded researchers is essential to the health of this country's research enterprise. Because of that, NIH interest in the training and funding of new investigators is deep and longstanding. NIH exceeded its target of 1,500 new investigators attaining project grant support in FY 2007. In addition, NIH established two new programs to help new investigators in their quest to become independent research scientists—the [Pathway to Independence Award](#) and [NIH Director's New Innovator Award](#). The Pathway to Independence Program, announced in January 2006, offers a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. This new award mechanism is a bridge that will accelerate the transition of

new, creative scientists from research dependence to research independence. The NIH Director's New Innovator Award, announced in March 2007 as a component of the NIH Roadmap, supports exceptionally creative scientists who take highly innovative, even unconventional, approaches to major challenges in biomedical or behavioral research. New Innovator Awards are reserved for investigators who have not yet received a regular research (R01) or similar grant.

### ***Aligning Grant Applications with Team Science***

In February 2006, NIH announced a pilot initiative to alter a longstanding policy and allow more than one principal investigator (PI) on a grant application. This multiple-PI model enables investigators to share the authority, responsibility, and credit for leading and directing a project—intellectually and logistically—and encourages collaboration among equals, when a “team science” approach is the most appropriate way to address a scientific problem. This policy change began as a 2005 Roadmap initiative to stimulate interdisciplinary science. In 2006, NIH and the White House Office of Science and Technology Policy solicited advice and comments on this topic from the scientific community. On the basis of the NIH pilot and received advice, all Federal research agencies are preparing to formally implement policies and procedures allowing multiple PIs on research awards. NIH released its implementation [guidance](#) to the community in November 2006 and most electronic applications were modified to accept multiple PIs beginning with January receipt dates in 2007. On June 25, 2007, NIH released a Federal Register [Notice of Proposed Rule Making](#) to solicit input on the change in definition to accommodate multiple PIs. A notice addressing those comments is being prepared.

### ***Streamlining Grant Management***

NIH constantly strives to make the process of receiving and reviewing grants more efficient. To understand the importance of this streamlining, consider the fact that NIH receives nearly 80,000 applications per year. Moving from a paper-based to an electronic submission process is central to the streamlining effort. NIH recently passed the mark at which over 75 percent of all grant applications are submitted electronically, via the Web portal of Grants.gov. Simultaneously, NIH is phasing out the Public Health Service grant application form and replacing it with a federal-wide application. This represents a significant reduction in burden for applicants who otherwise have to contend with a variety of forms and information requirements depending on the agency to which they apply. The advent of electronic receipt of grant applications has improved the clarity of application materials delivered to reviewers. It also will enable the use of artificial intelligence software to automate referral to NIH Institutes and review committees. The expanded use of Internet Assisted Review allows reviewers to electronically submit critiques and initial priority scores before review meetings as a means of streamlining the review as well as shortening review meetings. These changes will make the review process more effective and less onerous and eventually will lead to a reduction in the time from receipt to award.

The “[NIH Guide for Grants and Contracts](#)” is NIH's primary means of communication with the extramural community. The “Guide” publicizes policy changes, research solicitations, and other notices. Because many funding announcements are trans-NIH solicitations, drafting announcements can involve considerable collaboration. NIH is in the process of developing an Automated Guide System to serve as a document/content management system in support of the “Guide” publication process. This solution will supplant the current manual process of collaboration and review that goes into publishing funding announcements. The management system will facilitate communications and the exchange of data between and among ICs and within the Office of the Director. It also will provide a more efficient and cost-effective means of publishing NIH funding opportunity announcements. A pilot of the system was launched during summer 2007 and a final application will be released in spring 2008.

A first-ever NIH Division of Extramural Activities Support (DEAS) started operations in October 2004. This new organization—the largest A-76 activity at NIH—provides support services for grants management, peer review, and

scientific program management functions. The reorganization of extramural support services into DEAS represents a major change in NIH business practices, from a decentralized operation to a centrally managed unit using standardized operating procedures. Experience with the new organization demonstrated that improvements are needed in its efficiency and effectiveness to best meet IC needs. NIH reengineered the organization to better align staff skills with required responsibilities, be more cost-effective, enable DEAS staff to achieve career growth, and foster better working relationships between DEAS and its IC customers. A new organizational structure was implemented in September 2007.

## Ensuring Responsible Research

NIH is committed to promoting scientific progress in a transparent and responsible manner. Several OD offices have, or share, responsibility for the development and implementation of policies and procedures to ensure that research is conducted safely, ethically, and securely.

### *Biotechnology Activities*

The [Office of Biotechnology Activities](#) (OBA) within the OD Office of Science Policy continually monitors scientific research and progress in the areas of recombinant DNA and genetics technologies in order to anticipate future developments, including potential ethical, legal, and social concerns. In accord with these responsibilities, OBA manages the operation of, and provides analytical support to, the NIH Recombinant DNA Advisory Committee (RAC) and the HHS Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS). OBA also manages the National Science Advisory Board for Biosecurity, which is addressed in Chapter 2 in the section on *Infectious Diseases and Biodefense*, and the NIH/FDA Genetic Modification Clinical Research Information System (GeMCRIS), a comprehensive information resource and analytical tool for scientists, research subjects, sponsors, institutional oversight committees, Federal officials, and others with an interest in human gene transfer research.

[RAC](#) reviews all proposals for human, gene-transfer clinical research (often referred to as “gene therapy”) at institutions receiving NIH funds for recombinant DNA research. RAC review occurs before biosafety review at the institution where the research will be conducted. This enables RAC review to inform local review. As a Federal advisory committee, RAC issues recommendations to the NIH Director. RAC proceedings and reports are posted to the OBA Web site to enhance their accessibility to the scientific and lay publics. As new issues are identified, RAC helps NIH develop safety symposia and policy conferences to engage the scientific and public communities in thoughtful dialogue regarding emerging issues and concerns. RAC has been a vital national forum promoting critically important scientific progress in a transparent, responsible, and safe manner and enhancing public trust in the science.

SACGHS provides policy advice to the Secretary, HHS, on the broad array of complex medical, ethical, legal, and social issues raised by the development and use of genetic technologies. In 2006, SACGHS began an in-depth fact-finding process on the U.S. system of oversight of genetic testing. The Secretary's charge for this inquiry is to undertake the development of a comprehensive map of the steps needed for evidence development and oversight for genetic and genomic tests, with improvement of health quality as the primary goal. In November 2007, SACGHS issued a [draft report for public comment](#).

### *Human Subjects Protections in Research*

The HHS [Office for Human Research Protections \(OHRP\)](#) implements the Federal regulations governing the protection of human subjects [45 CFR 46](#) for all HHS agencies, including NIH. OHRP is responsible for (1) negotiating assurances with each institution that conducts HHS-sponsored human subjects research, (2) registering local Institutional Review Boards (IRBs), which assess risk, benefit, and many other matters with respect to proposed and ongoing studies involving human subjects, (3) issuing policy and guidance that clarifies the regulations, and (4)

providing educational materials and programs for investigators and IRBs, and overseeing compliance. Because of the clinical research conducted in the NIH intramural program, NIH itself has an assurance with OHRP.

Although 45 CFR 46 is called the “Common Rule” and some 17 Federal agencies, including the National Science Foundation, Department of Defense, and Department of Veterans Affairs are governed by the rule, implementation policies vary and parallel regulations, e.g., for FDA, compound the differences in agency human subject protection practices. In fact, variability exists even across NIH ICs. Recognizing that this variability can hamper the efficiency and effectiveness of the clinical research system (because it requires the research community to understand and fulfill multiple requirements that may be redundant or even conflicting), NIH created a Clinical Research Policy Analysis and Coordination (CRpac) Program to serve as a focal point for harmonizing, streamlining, and optimizing human subjects protection policies and requirements. Launched as an NIH Roadmap initiative, CRpac aims to develop clear, effective, and coordinated rules for clinical research to achieve maximally effective human subjects protections. High on CRpac's list of problems to tackle is the variation in requirements for reporting adverse events. (An adverse event is an unfavorable medical occurrence associated with the subject's participation in the research). Investigators and IRBs face multiple requirements regarding the content, format, and timing of adverse event reports that must be made to different agencies and oversight bodies. Working closely with the preexisting Federal Adverse Event Task Force (FAET), CRpac gathered and analyzed adverse event terms, definitions, and rules contained in a wide array of regulations, policies, and guidance documents across many agencies; documented the workflow for reviewing and using adverse event information; and developed a draft Basal Adverse Event Report (BAER)—a single core report that PIs could send to multiple agencies for consideration. In addition, CRpac formed a Trans-NIH Adverse Event Steering Committee to analyze NIH-specific needs and requirements for adverse event information and propose ways to coordinate and streamline the reporting policies of the ICs. In addition, to launch a dialogue on the characteristics and relative benefits of various models of IRB review, in November 2006, CRpac helped sponsor a National Conference on Alternative IRB Models.

The [Office of Human Subjects Research](#) in the NIH OIR manages human subject protection activities in the intramural program. Functioning under the assurance NIH filed with OHRP, and in cooperation with the ICs, the Office implements [NIH policy](#), establishes and maintains the 14 NIH IRBs, and provides training for researchers and IRB members. In addition, the Office manages the Human Subjects Research Advisory Committee, which advises the Deputy Director for Intramural Research—who is the Institutional Official responsible for human subjects investigations at NIH—on policies and procedures regarding the conduct of human subject research.

Within the NIH Clinical Center, the site of most NIH intramural human subjects research, the [Department of Bioethics](#) provides a center for research, training, and service related to bioethical issues. The Department conducts conceptual, empirical, and policy-related research into bioethical issues; offers comprehensive training and educational programs in bioethics; provides ethics consultation services to clinicians, patients, and families; and is available as a source of advice to the NIH IRBs.

### ***Animal Care and Use in Research***

The [Office of Laboratory Animal Welfare \(OLAW\)](#) in the Office of Extramural Research (OER) oversees the use of animals in Public Health Service (PHS)-supported biomedical and behavioral research. OLAW provides guidance and interpretation of the *PHS Policy on Humane Care and Use of Laboratory Animals* ([PHS Policy](#)), monitors compliance with the PHS Policy, and supports educational programs that further the humane care and use of research animal subjects. As a condition of receiving PHS support for research involving laboratory animals, institutions must provide a written Animal Welfare Assurance (Assurance) to OLAW describing in detail the means they will use to comply with the PHS Policy and Federal statutes and regulations relating to animals. OLAW

negotiates and approves these Assurances as required by HHS acquisition regulations and the PHS Policy. The assurance commits the institution and its personnel to full compliance with the PHS policy. OLAW holds accountable and depends upon institutional officials, Institutional Animal Care and Use Committees, research investigators, and other agents of the institution to ensure conformance with the institution's Assurance. This includes evaluating all allegations or indications of noncompliance with Federal animal welfare requirements.

OLAW maintains a comprehensive Web site with links to relevant laws, policies and guidance, an online tutorial, and a variety of other training materials and resources regarding laboratory animal welfare. In 2006, when OLAW published "[What Investigators Need to Know About the Use of Animals](#)," it added a significant new brochure to the materials it offers. Humane care and use of animal subjects in biomedical and behavioral research is monitored by several Federal agencies and regulated by numerous guidelines and regulations. The brochure provides a complete, concise overview of all the regulations that apply to PHS-funded investigators. Response to the brochure from the research community has been overwhelmingly positive and OLAW has distributed more than 60,000 copies.

A new source of information on the need for animals in research is in development by NIH<sup>10</sup>. Animals in Research will be a Web-based resource for the public, grantee investigators and institutions, and NIH staff. The OER Web site will provide information on the critical role of this research for improving human and animal health, the latest breakthroughs in animal-based research, new funding opportunities, up-to-the-minute policy and training information, and guidelines for grantee institutions' emergency preparedness and crisis communication.

The [Office of Animal Care and Use](#) (OACU) in the NIH OIR administers the intramural program of animal care and use. OACU develops [guidelines and policies](#) for the responsible care of laboratory animals and the proper operation of NIH animal facilities and offers a variety of training courses and health and safety information for personnel who work with animals. Each NIH component that uses animals in research has an Animal Care and Use Committee that reviews and approves requests to use animals in research. In addition, each component's animal care and use program is directed by a senior veterinarian. An Animal Research Advisory Committee meets monthly to discuss trans-NIH topics and provide advice to the NIH Deputy Director for Intramural Research, who is the NIH institutional official accountable for animal care and use. All components of the intramural NIH animal care and use program are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International.

### ***Ethical Conduct***

The fundamental Federal principles of ethical conduct hold that conscientious performance of duty is placed above private gain, that employees shall not have financial interests that conflict with that duty, and that employees will avoid any actions creating the appearance that they are violating the law or the standards of ethical conduct. It is the responsibility of every NIH employee to abide by the [statutes and regulations, including the supplemental standards of ethical conduct](#) for HHS employees, and the implementation policies and procedures of NIH. Significant ethics training resources at NIH help employees to meet that responsibility. The [NIH Ethics Program](#) consists of a central NIH Ethics Office located organizationally within the NIH OD and an ethics office in each IC, managed by a [Deputy Ethics Counselor](#) and an [Ethics Coordinator](#). Attorneys from the HHS Office of the General Counsel, Ethics Division, maintain an office at NIH to provide legal advice and assist IC ethics counselors and coordinators as needed.

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<sup>10</sup> When the Animals in Research Web site goes live in June 2008, the URL will be: <http://grants.nih.gov/grants/policy/air/index.htm>

The Ethics in Government Act (5 U.S.C. App.) requires each agency to provide an initial ethics orientation to new employees. NIH provides a Web-based training system for completing this requirement and the mandatory annual training. Also, NIH ethics staff is readily available to answer questions and provide ethics and conflict-of-interest counsel, as needed, and the central Ethics Office provides extensive information and resources on its Web site.

Prudent stewardship of public funds requires that appropriate steps be taken to ensure objectivity in research and freedom from financial conflicts of interest. Therefore, each institution receiving NIH research funds must have written guidelines on the avoidance of conflicts of interest. These guidelines must cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. They also must indicate how outside activities, relationships, and financial interests are reviewed by the responsible and objective institution official(s). Institutions that identify research investigator financial conflicts are required to report the conflicts to the NIH Grants Management Officer at the funding IC.

The most recent edition of the "[Guidelines for the Conduct of Research \(2007\)](#)" sets forth the general principles governing the conduct of good science as practiced in the NIH IRP, including the responsibilities of research staff in the collection and recording of data, publication practices, authorship determination, mentoring, peer review, confidentiality of information, collaborations, human subjects research, financial conflicts of interest, and animal care and use.

NIH also has established [conflict of interest, confidentiality and nondisclosure rules](#) for reviewers of grant applications and R&D contract proposals. The [rules](#) require reviewers to identify and certify real or apparent conflicts of interest both pre- and post-meeting. Employment, financial benefit, personal relationships, professional relationships, or other interests may be a basis for a conflict of interest, and any one condition may serve to disqualify a reviewer from participating in the review of an application or proposal.

Conflicts of interest are especially problematic in clinical research. For that reason, the [HHS Office for Human Research Protections](#) issued specific guidance on "[Financial Relationships and Interests in Research Involving Human Subjects.](#)" Moreover, in February 2007, NIH updated its "[Guide to Preventing Financial and Non-Financial Conflicts of Interest in Human Subjects Research at NIH.](#)" "The Guide," directed at the intramural community, aims to ensure both the integrity of research and the safety of subjects in the intramural program.