

## About NIH

# Ensuring Responsible Research

NIH recognizes that with public support for research comes an obligation to ensure that research is conducted in a responsible manner to promote the integrity of NIH-supported biomedical and behavioral research and research training, to protect the health and safety of the public, and to conserve public funds. Responsible conduct of research features many interrelated attributes—including objectivity, honesty, accuracy, efficiency, safety, and ethical behavior. NIH addresses these issues through an array of policies, programs, and activities.

### Ethical Conduct

#### *Ethical Conduct for NIH Employees*

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 meet that responsibility. The Ethics in Government Act (5 U.S.C. Appendix) requires each agency to provide an initial ethics orientation to new employees. NIH provides a Web-based training system to meet that obligation, as well as the annual ethics training for all other NIH staff. It is significant to note that, since 2004, NIH has made annual ethics training mandatory for all employees, a standard that far exceeds the government-wide requirement.

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](#). NIH ethics staff members are readily available to answer questions and provide ethics and conflict-of-interest counsel, as needed, and the NIH Ethics Office provides extensive information and resources on its website. 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. For the ethics staff, there are semi-monthly meetings and extensive NIH Ethics Office-sponsored training in selected topics throughout the year. Training opportunities from the Office of Government Ethics also are made available to NIH ethics staff and are well attended.

#### *Financial Conflict of Interest in Extramural Research*

Proper stewardship of Federal funds includes ensuring objectivity of results by protecting federally funded research from compromise by financial conflicts of interest (COIs). Public Health Service (PHS) and HHS regulations (42 CFR 50, Subpart F, and 42 CFR 94), promote objectivity in NIH-funded research by providing standards to ensure that the design, conduct, and reporting of research under NIH-funded awards is not biased by any financial COI. The regulations are applicable to institutions that apply for

PHS<sup>27</sup> funding for research and, through implementation of the regulations by these institutions, to each investigator participating in the research. Each institution receiving NIH research funds is required to have written guidelines on the avoidance of COI (i.e., financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery) and on the management, reduction, and elimination of identified conflicts. Institutions are required to report identified investigator financial COIs to the Grants Management Officer at the funding IC.

The regulations that govern objectivity in research were established in 1995. In the intervening years, the pace of translation of discoveries into interventions has accelerated significantly. Also, the U.S. biomedical research enterprise has grown in size and complexity. Awareness of the increasing complexity of biomedical research and the increased interaction between the government and the private sector in meeting common public health goals led to the question of whether changes to the regulations are needed. NIH recognizes that improvements can be made to its system of oversight, as well as to recipient organizations' management of the financial COI process, but also believes that the complex and controversial issues surrounding financial COI warrant a carefully considered, open dialogue with all affected parties. For these reasons, NIH, on behalf of HHS and PHS, developed an [Advanced Notice of Proposed Rulemaking](#) (ANPRM) to begin a dialogue about broadening the regulations to address institutional COI and to gain public input on all aspects of potential regulation in this area.

The comment period for the ANPRM closed on July 7, 2009. NIH is analyzing the comments received, as well as other related information, to determine how best to move forward in potentially changing the current regulations. If regulatory change is deemed appropriate, a Notice of Proposed Rulemaking would allow for further public comment on any draft regulation. If warranted, the goal would be to have new regulations announced with initial implementation by fall 2010.

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

<sup>27</sup>The PHS comprises all HHS Agency Divisions (of which NIH is 1 of 11) and the Commissioned Corps.

### *Conflicts of Interest in Clinical Research*

COI can be especially problematic in clinical research. For that reason, there is guidance in addition to the policies and regulations noted above. The OHRP guidance, "[Financial Relationships and Interests in Research Involving Human Subjects](#)," covers extramural research and the NIH "[Guide to Preventing Financial and Non-Financial Conflicts of Interest in Human Subjects Research at NIH](#)" ensures both the integrity of research and the safety of subjects in the intramural program.

### **Research Integrity**

NIH recognizes that public support for research comes with an obligation to promote integrity in the conduct of that research. Honesty, accuracy, efficiency, and objectivity are important values that characterize what is meant by integrity in research. As defined by regulation,<sup>28</sup> *research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in

reporting research results; it does not include honest error or differences of opinion. Allegations of research misconduct in biomedical and behavioral research or research training supported by NIH tend to be unique rather than routine events at most institutions. However, a research misconduct allegation has the potential for high impact on public health or clinical treatment, the individuals involved, the institution where the alleged misconduct took place, and public trust. (See also, *Ethical Conduct*, above).

OER manages allegations of potential research misconduct that are reported to any member of the NIH extramural staff, and also provides annual training to the IC Research Integrity Officers (RIOs) and extramural staff, through online tutorials and training symposia. Within each IC, a senior official is designated as the IC RIO. Extramural staff is instructed to report immediately any allegation of potential research misconduct to the IC RIO, who then forwards the allegation to one of the Extramural Research Integrity Liaison Officers or the Agency Extramural Research Integrity Officer in OER. A preliminary review of the allegation is conducted then to verify information and assess whether the allegation may be appropriate for an inquiry. On rare occasions, NIH may request an inquiry, but by regulation, the HHS Office of Research Integrity is authorized to request institutions to perform inquiries and investigations related to allegations of potential research misconduct. If a finding of research misconduct is found, the offender may incur administrative actions, including but not limited to: replacement as Principal Investigator on the award; requirement to clarify, correct, or withdraw related publications; suspension or termination of any PHS grant, contract, or cooperative agreement; ban from serving in any advisory capacity to PHS; and suspension or debarment, i.e., exclusion from eligibility for Federal grants, contracts, and cooperative agreements.

The same standards of research integrity and comparable procedures for investigating allegations of scientific misconduct apply to NIH intramural research program. For intramural research staff, the “Guidelines for the Conduct of Research” set forth the general principles governing the conduct of good science. The guidelines cover the responsibilities of research staff in the collection and recording of data, publication practices, authorship determination, mentoring, peer review, confidentiality of information, collaborations, and financial conflicts of interest. NIH employees are required to report suspected or apparent misconduct in science to the Agency Intramural Research Integrity Officer (AIRIO) or Deputy Director for Intramural Research. The AIRIO decides whether the allegation warrants an inquiry to determine whether there is enough evidence behind an allegation or apparent instance of scientific misconduct to warrant moving to the next level of response—an investigation. If the formal investigation determines that misconduct has occurred, NIH sanctions could include removal from a particular project, special monitoring of work, suspension without pay, or termination of employment. The NIH AIRLO decides whether to accept the investigation report, makes a finding of misconduct, and imposes the recommended NIH sanctions. The final step in the process is a review by the HHS Office of Research Integrity, which then makes recommendations on possible PHS sanctions that could include debarment from serving on NIH study sections or receiving NIH grants. The [Intramural Research Program Sourcebook](#) contains all [Policies and Procedures for Investigating Scientific Misconduct](#).

<sup>28</sup>42 CFR Parts 50 and 93. Available at: [http://ori.dhhs.gov/documents/42\\_cfr\\_parts\\_50\\_and\\_93\\_2005.pdf](http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf).

## 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, (4) providing educational materials and programs for investigators and IRBs, and (5) overseeing compliance. Because of the clinical research conducted in the

NIH intramural program, NIH itself has an assurance with OHRP. (See also, *Ethical Conduct*, above for information on OHRP guidance concerning COI in human subject research).

The Office of Extramural Programs (OEP) in the NIH OER conducts activities to ensure the compliance of NIH grantees with HHS regulations and NIH policies regarding the protection of human subjects in extramural research. OEP staff assess the proposed resolution of human subjects concerns identified during peer review of extramural research applications prior to funding, and respond to requests to change human subjects designations of ongoing NIH extramural research projects. OEP also provides training to NIH extramural staff and the extramural scientific community regarding NIH policies on human subject protection and develops and implements policies to ensure that participants in NIH-funded extramural research projects are adequately protected. OER maintains a [grants policy website dedicated to research involving human subjects](#). This comprehensive site provides, in one place, HHS and NIH requirements and resources for the extramural community involved in human subjects research in its roles as applicants/grantees, offerors/contractors, peer reviewers, and institutional officials.

As noted above, because of the clinical research conducted in the NIH intramural program, NIH itself has an OHRP-approved Federal-Wide Assurance (FWA) of compliance with the HHS regulations for the protection of human subjects. The [Office of Human Subjects Research](#) (OHSR) in the NIH OIR—functioning under the assurance and in cooperation with the ICs—implements the policies and procedures of the [NIH Human Research Protection Program](#). With the responsibility to protect the rights and safeguard the welfare of human subjects who participate in intramural NIH research studies, OHSR establishes and maintains the 11 NIH IRBs that are linked to the FWA, provides training for researchers and IRB members, and manages the Human Subjects Research Advisory Committee. In turn, the 11 NIH IRBs are responsible for the prospective and continuing review of NIH intramural research that involves human subjects. The Human Subjects Research Advisory Committee advises the DDIR on policies and procedures regarding the conduct of human subjects research. The importance of this advisory role is underscored by the fact that, under the FWA, the DDIR is the institutional official responsible for human subject investigations at NIH. An additional body, the NIH Intramural Clinical Research Steering Committee, also serves as a forum for trans-NIH governance and policy development in the area of human subjects research. The Committee coordinates efforts and ensures clear communications about goals, progress, and future directions. 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, and is available as a source of advice to the NIH IRBs.

NIH also is working to enhance the safety, efficiency, and effectiveness of the clinical research enterprise by promoting greater consistency in the rules and policies governing the conduct and oversight of clinical research. In addition to the regulations administered by OHRP, clinical investigators are subject to FDA regulations. Moreover, differences in the HHS and FDA regulations can be compounded through policy interpretation. In addition, policies and practices of the NIH ICs can lead to other complications for clinical investigators supported by NIH. Recognizing that the inconsistencies in the oversight system can hamper the efficiency and effectiveness of the clinical research system, NIH created the Clinical Research Policy Analysis and Coordination (CRpac) Program to promote greater consistency in human subject protection policies and requirements. Launched as an NIH Roadmap initiative, CRpac aims to advance the development of clear, effective, and coordinated rules for clinical research to achieve maximally effective human subject protections. For example, CRpac has led major efforts to improve understanding and compliance with adverse event reporting requirements and standardize the reporting of adverse event data,<sup>29</sup> and to develop draft guidelines for human specimen and data collections funded by NIH. (See also the section on *Clinical and Translational Research* in Chapter 3.)

<sup>29</sup>An adverse event is an unfavorable medical occurrence associated with the subject's participation in research.

## Animal Care and Use in Research

The [Office of Laboratory Animal Welfare](#) (OLAW) in the NIH OER oversees the use of animals in NIH-supported biomedical and behavioral research conducted by extramural institutions. OLAW provides guidance and interpretation of the [PHS Policy on Humane Care and Use of Laboratory Animals](#); monitors compliance with the policy; evaluates all allegations or indications of noncompliance with Federal animal welfare requirements; 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, and committing the institution and its personnel to full compliance. OLAW negotiates and approves these assurances as required by Pub. L. No. 99-158, HHS acquisition regulations, and the PHS policy, and holds institutional officials, Institutional Animal Care and Use Committees (IACUC), researchers, and other agents of the institution accountable for ensuring conformance with the institution's Assurance.

OLAW maintains a comprehensive website 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 2008, two online seminar series were launched to focus educational outreach to institutional officials at grantee institutions and to IACUC members. The webinar format enabled invited speakers to communicate timely, relevant information through an interactive forum with constituents at worksites across the Nation, at no expense to the viewers. The feedback on the seminars has been extremely positive, and the process has been fine-tuned to enhance the experience and extend the number of attendees to more than 300 institutions.

A workgroup led by OER developed a new comprehensive [Animals in Research website](#) in 2008. The website provides information for the general public about the benefits of medical research with animals, alternatives to animal research, advances in animal research, and animal health and welfare. For researchers and institutions, the website provides information about emergency preparedness and crisis communication, up-to-the-minute policy and guidance, grants resources, funding opportunities, and training and education, as well as answers to frequently asked questions.

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, which reviews and approves (or disapproves) requests to use animals in research, and has a senior veterinarian who directs its animal care and use program. An Animal Research Advisory Committee meets monthly to discuss trans-NIH topics and provide advice to the NIH DDIR, 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.

## Bioethics Research, Training, and Translation

NIH has a long history of engagement with bioethics—the study of ethical issues and controversies resulting from advances in biology and medicine. NIH was a pioneer in the development of independent ethical review of clinical research studies. In 1996, NIH established the Department of Bioethics within the NIH Clinical Center to conduct conceptual, empirical, and policy-related research into bioethical issues; offer training and educational programs in bioethics; and provide ethics consultation to clinicians, patients, and families. In the 1990s, NIH began a dedicated investment in the study of the ethical, legal, and social implications of genome research through a novel set-aside, as part of the Human Genome Project. And,

in the last two decades, NIH has supported many additional bioethics research and training projects, ranging from short-term courses in research ethics regarding minority participation in AIDS research to studies addressing the ethical, social, and legal issues of human microbiome research. Nonetheless, advances in science and medicine have been accelerating at a rapid pace and, more than ever, NIH needs the foresight and vision to understand the ethical and societal implications of discoveries in biomedical, behavioral, and technological research and the knowledge arising from these advances. In the last 3 years, there also have been calls for NIH to make a greater and wider commitment to addressing the ethical, legal, and social issues—such as, privacy, safety, commercialization, and COI—raised by the research it supports—including biotechnology, tissue engineering, nanomedicine, and synthetic biology. NIH's commitment to the support of bioethics helps maintain and enhance public trust and confidence as NIH explores new frontiers in science.

Integrating bioethics across the entire NIH research portfolio is a long-range agency goal that requires mid- and long-term planning and strategies. As a first step, a trans-NIH task force was formed in early 2009 to develop a research agenda for FY 2010 and FY 2011 and to develop a long-range plan. Additional support for bioethics research was provided through the FY 2009 ARRA Challenge Grant initiative. Support also has been requested in FY 2010 through NIH's regular appropriations process.

The long-range plan will identify research and training gaps and opportunities and formulate a strategy for addressing them over the next 5 to 10 years. It also will include consideration of the optimal administrative approach for sustained support for, coordination of, and accountability for NIH bioethics efforts. Finally, the long-range plan will include the design of an evaluation to assess the value and impact of the investments. Altogether, the plan will provide a framework that will enhance the integration of ethical inquiry and practice into the conduct of research across the entire spectrum, from the most basic projects to the most applied; help maintain the academic discipline of bioethics and expand bioethics investigators and scholars; and develop curricula and ethics training programs. The goal is to facilitate the early identification and deliberation of complex bioethical issues and generate knowledge needed for responsible conduct of science that takes into account its broader societal impact.

## **Promoting Responsible Research through Policy Development**

NIH has a vested interest in promoting research at the cutting edge of science and technology—for example, gene transfer, infectious agents, stem cells, nanomedicine—research that has potential benefits but often unknown risks for which little or no guidance exists. For example, the protection and enhancement of public health, agriculture, and the food supply is a national priority and has led to increased Federal funding for research on infectious agents, especially those that pose a severe threat to human, plant, and animal health. At the same time, concerns have been voiced by the public, scientific community, Administration, and Congress regarding biosafety and biosecurity in research laboratories that work with the most dangerous pathogens and toxins. Concerns also have been raised about the risks that certain information from life sciences research could be misused to threaten public health and other aspects of national security. NIH has a responsibility to anticipate the evolution of issues such as these, and to provide leadership and support for efforts at the NIH, HHS, and national levels that are designed to promote research, assure safety, address ethical concerns, and enhance public understanding and trust, through the development of sound public policies.

Much of the leadership and support regarding new and evolving policies about responsible conduct of research is vested in the NIH Office of Science Policy (OSP). Within OSP, the [Office of Science Policy Analysis](#) (OSPA) coordinates NIH responsibility for the interpretation, development, and implementation of policies regarding human embryonic stem cells. In addition, OSPA coordinates action on nanotechnology policy issues. This includes providing management and analytic support for the Trans-NIH Nanotechnology Task Force. The [Office of Biotechnology Activities](#) (OBA), also within OSP, monitors scientific research and progress in the areas of recombinant DNA,<sup>30</sup> genetics technologies, and dual-use research<sup>31</sup> to anticipate future developments, including potential safety, ethical, legal, and social

concerns. OBA also manages the CRpac program, discussed above, which promotes greater consistency in human subject protection policies and requirements.

<sup>30</sup>Recombinant DNA is DNA created by combining genetic material from different sources to create a new genetic sequence.

<sup>31</sup>Dual-use research is defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security.

### *Stem Cell Research*

NIH is responsible for the interpretation and implementation of legislation, Executive Orders, and Administration policies relating to stem cell research. OSPA advises NIH, Congress, the scientific community, and the public on current stem cell policies and specific research activities allowable under current policies and regulations. The office plays an integral role in developing guidelines for research involving human pluripotent cells of all types.

On March 9, 2009, President Barack Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. The Executive Order states that the Secretary of HHS, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

The NIH Guidelines for Human Stem Cell Research were published on July 7, 2009, and are available at <http://stemcells.nih.gov/policy/2009guidelines.htm>. The Guidelines implement the Executive Order as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. In addition, on July 30, 2009, the President directed all Federal departments and agencies that support and conduct stem cell research to adopt the Guidelines. For hESCs derived from embryos donated in the United States on or after the effective date of the Guidelines (July 7, 2009), specific provisions regarding the embryo donation and informed consent process apply and are detailed in Section II of the Guidelines.

On September 21, 2009, NIH Director Francis S. Collins announced that NIH is accepting requests for human embryonic stem cell lines to be approved for use in NIH-funded research. Dr. Collins also announced the members of a new working group of the Advisory Committee to the Director (ACD)—the Working Group for Human Embryonic Stem Cell Eligibility Review. After considering the analysis done by the Working Group, the ACD makes recommendations to the NIH Director regarding the eligibility of particular human embryonic stem cell lines for use in NIH-funded research. hESCs that meet Section IIA requirements are considered through NIH administrative review.

The NIH Director makes the final decisions regarding the eligibility of all hESCs. Those lines deemed eligible are listed on the NIH Human Embryonic Stem Cell Registry. Once a human embryonic stem cell line is listed on the Registry, there is no need for further submissions requesting review of that particular line. The first hESCs were listed on the Registry on December 2, 2009.

### *Recombinant DNA, Genetic Technologies, and Dual Use Research*

OBA manages a range of activities related to responsible use of recombinant DNA, genetic technologies,

and dual use research including:

- Administration of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, which address the safe and ethical use of basic and clinical research involving recombinant DNA molecules at institutions that receive any NIH funding for recombinant DNA research;
- Management and analytical support for the NIH Recombinant DNA Advisory Committee (RAC);
- Operation of the NIH Genetic Modification Clinical Research Information System (GeMCRIS), an electronic resource for information and adverse event reporting on gene transfer trials, which also is used by FDA;
- Outreach and education to stakeholder communities regarding biosafety and biosecurity; and
- Management and analytic support for the National Science Advisory Board for Biosecurity (NSABB).

The RAC reviews all proposals for human, gene transfer, and 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, enabling 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 [RAC website](#) to enhance their accessibility to the scientific and lay publics. As new issues are identified, the RAC helps NIH develop safety symposia and policy conferences to engage the scientific and public communities in thoughtful dialogue regarding emerging issues and concerns.

The 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. For example, in March 2009, NIH published in the *Federal Register* a proposal for comment to expand the scope of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* to include nucleic acid molecules that are synthesized rather than being made by recombinant techniques. The proposal represents the first major expansion to the document’s scope since it was first written more than 30 years ago. This action was in response to a recommendation made in the December 2006 report of NSABB, *Addressing the Biosecurity Concerns Related to the Synthesis of Select Agents*. NSABB recommended to the HHS Secretary that the language and implementation of current biosafety guidelines be examined to ensure that such guidelines and regulation provide adequate guidance for working with synthetically derived nucleic acids. NIH was tasked with conducting the assessment. OBA also consulted with the RAC, which noted that the biosafety risks are related more to the product being produced than the technique being used, and recommended expanding the scope of the *NIH Guidelines* to specifically cover synthetic nucleic acids. The public comments generally have been supportive of the proposal. NIH also held a public consultation about the proposed changes in a day-long meeting in June 2009. A revised version of the proposal was reviewed by the RAC at its quarterly meeting in December 2009. A *Federal Register* notice requesting comment on a revised proposal was published on April 22, 2010. OBA anticipates a final proposal will be published by the end of 2010.

[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. SACGHS is charged with undertaking 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 April 2008, SACGHS submitted its report on the [U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services](#). The report is the culmination of extensive fact finding, analysis, expert consultation, outreach to the public, and deliberation by the committee, and highlights gaps in the oversight system for genetic testing and provides recommendations to maximize the benefits of genetic testing and minimize harms.

OBA also is a focal point for the development of policies addressing biosafety and biosecurity. This includes the development of policy regarding dual use research (life sciences research that yields information or technologies with the potential to be misused to threaten public health or endanger other

aspects of national security). NIH was a key participant in the HHS Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, which was established in FY 2008 in response to concerns about the risks associated with the proliferation of high- and maximum-containment laboratories in the United States. The Task Force reviewed the current systems of biosafety oversight and made recommendations to improve biosafety and biocontainment oversight at U.S. laboratories. NIH also participated in the Working Group on Strengthening Laboratory Biosecurity in the United States, established in January 2009, by Executive Order 13486, *Strengthening Laboratory and Biosecurity in the United States*. The Working Group is charged with reviewing and evaluating laboratory operations regarding the use, handling, storage, or transport of biological Select Agents and toxins.<sup>32</sup> The Working Group developed a report, which included recommendations for new legislation, regulations, guidance, and practices for enhancing laboratory security and reliability of personnel at all Federal and nonfederal facilities working with biological Select Agents and toxins. NIH also has developed new, comprehensive biosafety recommendations for work with potentially pandemic flu viruses<sup>33</sup> that have the ability to infect humans. The guidance was developed to ensure that important research on pandemic influenza is carried out using biosafety containment and practices that will protect laboratory workers and the public.

[NSABB](#), managed by OBA, is a Federal advisory committee established to advise the Federal Government on ways to minimize dual use biological research risks and inform the development of Federal and institutional oversight guidelines. In response to heightened security concerns surrounding the potential misuse of dangerous pathogens within research settings, NSABB was charged with recommending strategies for enhancing the reliability of personnel who have access to Select Agents and toxins. The challenge was to identify policies aimed at mitigating the risk of misuse of Select Agents by individuals who have legitimate access to them as part of their jobs, without unduly hindering the pace of life sciences research. The NSABB issued its findings and recommendations in May 2009, and they are being considered at various levels of the Federal Government, along with those of the Executive Order Working Group and other groups that have focused attention on these important issues.

<sup>32</sup>Select Agents are biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The possession, use, and transfer of Select Agents and toxins are regulated by HHS and the U.S. Department of Agriculture.

<sup>33</sup>Examples include 1918 H1N1, human H2N2 that circulated in 1957-68, and strains of HPAI H5N1.