Mr. Peter Lichtenbaum  
Assistant Secretary of Commerce for Export Administration and  
Acting Under Secretary of Commerce for Industry and Security  
U.S. Department of Commerce  
Bureau of Industry and Security  
14th & Pennsylvania Avenue, N.W.  
Room 2705  
Washington, D.C. 20230

Dear Mr. Lichtenbaum:

I am writing to express my concerns regarding the impact of implementing the recommendations of the Department of Commerce (DOC) Inspector General’s (IG) report, as described in the advance notice of proposed rulemaking (ANPR). The proposed changes, while well intentioned, are too sweeping in scope.

NIH fully recognizes that both the Nation’s security and its economic interests must be promoted in order for us to remain in a world leadership position. We are very concerned that the proposed changes, while attempting to address potential security risks, will seriously compromise NIH’s ability both to conduct fundamental research on its own campus and to support fundamental research throughout the Nation and in a number of countries around the world.

The NIH is the primary Federal agency for conducting and supporting biomedical research. Foreign nationals, at both the pre-doctoral and post-doctoral levels, play a critical role in the conduct of this research. Should the IG recommendations be implemented as described in the ANPR, the change would have a profoundly chilling effect on the conduct of fundamental research which involves foreign nationals. The free and broad exchange of ideas and information across borders, upon which the conduct of science depends, would be greatly hampered. The biomedical scientific research community, which has been the crucible for the innovation and creativity that gave birth to and has fueled the growth of the Nation’s biotechnology industry, would lose diversity of perspective, a critical component of its success. Our leadership in science and technology, which is an essential element in our Nation’s economic and physical security, would be seriously compromised.

National security interests are, of course, a high priority for the NIH. On our own campus, we have established and significantly improved resources to secure our facilities and ensure that the materials used in, and the results of, the research that we conduct are not misused to threaten human health. We have implemented the DHHS and USDA Select Agent Rules; we conduct background checks and carefully evaluate visiting
foreign national scientists; we have installed a perimeter fence to secure the NIH campus; and we routinely check IDs for entry. Next week, NIH will host the first meeting of the National Science Advisory Board for Biosecurity (NSABB). The NSABB has been established under the leadership of the Department of Health and Human Services to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from vitally important biological research might be misused to threaten public health or national security. The NSABB is a critical component of a set of Federal initiatives to promote biosecurity in life sciences research. As with the proposed ANPR, the NSABB’s recommendations on national policy for dual-use biological research will have related and broad ranging implications for the conduct of biomedical research in this Country. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported life sciences research for which there is the greatest potential for misuse of its findings and technologies, taking into consideration both national security concerns and the needs of the research community.

NIH suggests that alternative approaches to achieving the aims of the proposed changes be explored. DHHS and other relevant agencies, in consultation with NSABB, will be working with the scientific community to define the areas of technology used in the conduct of fundamental research which pose the greatest risks, and will collaborate on appropriate measures to address these risks. This approach would entail extensive outreach to the scientific community to raise awareness of the risks and provide the tools necessary to manage and eliminate the most critical concerns without implementing cumbersome regulations that would compromise our Nation’s leadership in the conduct of biomedical research.

NIH applauds the DOC for recognizing that these major issues could have significant negative consequences, and thanks the DOC for engaging in a trans-agency discussion of the issues via the subcommittee of the Office of Science and Technology’s Committee on Science (OSTP/COS), under your leadership. NIH also applauds the DOC for engaging, via the ANPR, the science and technology communities that would bear directly the brunt of the impact of the proposed changes.

We appreciate the opportunity to work with you on these important issues and would welcome the opportunity to discuss our concerns in more detail.

Sincerely,

[Signature]

Elias A. Zerhouni, M.D.
Director

Enclosure
Attachment 1: National Institutes of Health Comments in Response to the Department of Commerce’s Advance Notice of Proposed Rulemaking

**Significant revision of fundamental research exemption to the EAR**

The Bureau of Industry and Security (BIS) ANPR suggests that the well-established scope of protection for fundamental research should be narrowed by (a) revising the definition of fundamental research; (b) using a foreign national’s country of birth as a criterion for requiring Deemed Export licensing; and (c) requiring that foreign nationals conducting fundamental research be licensed if in the course of conducting the research they need access to controlled equipment or technology. NIH is very concerned that this narrowing of the exemption will make it impossible to conduct fundamental research in the open manner that has led to critical innovation, and thereby will lose for both the NIH and for the nation, the fundamental value of fundamental research, as recognized by Presidential National Security Decision (NSDD-189).

The fundamental research exemption is based on principles set out by NSDD-189, which has been in place and relied upon by the research community since 1985 (http://www.aaau.edu/research/ITAR-NSDD189.html). These principles were reaffirmed by the current administration in November 2001 (http://www.aaau.edu/research/Rice11_1_01.html). NIH feels that the proposed new regulatory restrictions on fundamental research involving foreign nationals contradict the principles set out by NSDD-189. NSDD-189 unequivocally states that “No restrictions may be placed upon the conduct … of federally-funded fundamental research that has not received national security classification.” NSDD-189 recognizes that our nation’s leadership in science and technology is an essential element of our economic and physical security, and that the strength of American science requires a research environment conductive to creativity in which the free exchange of ideas is a vital component.

**Country of birth**

The BIS ANPR proposes a change to basing need for licensure on a foreign national’s country of birth rather than country of current citizenship. NIH opposes this proposed change. The proposed change creates great potential for discrimination and presumes national allegiances that may have no basis whatsoever. Furthermore, it will add to the growing perception that this nation of immigrants, and its premier biomedical research institution, does not welcome foreign scientists – the very foreign scientists that have helped make the nation’s scientific enterprise the most successful in the world.

The recent report “Policy Implications of international Graduate Students and Postdoctoral Scholars in the United States’ issued by the Committee on Science, Engineering, and Public Policy (COSEPUP) of the National Academy of Sciences, documents the long-standing, continuing, and profoundly positive impact of international graduate students and post-docs on the advancement of U.S. science, education, economy
and national security. This report also cites the increase in international competition to recruit the best students and scholars. The U.S. will be severely limited in this critical competition if we implement requirements that are perceived as making training in the U.S. an "unwelcoming" environment. If the DOC IG’s recommendations are implemented without considering these factors, our nation’s ability to attract the best and the brightest will be seriously harmed, which in turn, will harm our ability to retain world leadership in the field of biomedical research.

While the security rationale for this change is evident in the ANPR, we understand that there are no documented examples of a violation that would have been addressed had this proposed change been in place. Since country of birth is considered in the approval of visas, we suggest this is the appropriate venue to address such security concerns. This would avoid placing NIH and other research institutions in the position of considering national origin as a condition of employment thereby potentially violating Federal anti-discrimination laws against such practices.

**Burden of compliance**

NIH believes that a change in the definition of fundamental research will impose a tremendous regulatory burden on NIH and on the institutions that receive awards from NIH. The EAR places responsibility for determining whether an export license is required on the institution conducting the research. To assure compliance with the EAR as recommended in the IG report, institutions are very likely to take a conservative approach because it would be safer to be over-inclusive and apply for a license that is ultimately not required than to fail to apply for a required license and incur the consequences.

As an example of potential impact of a change to the fundamental research exemption, one can look at the NIH’s intramural research program – the scientists who perform research at NIH. In calendar year 2004, NIH’s intramural research benefited from the services of almost 3,760 foreign nationals working under temporary visas – approximately 62% of the scientific staff who conduct research at NIH. Virtually all of this activity is covered by the fundamental research exemption, and therefore is currently exempt from export control regulations. The majority of NIH support for research however, goes to research institutions throughout the U.S. and around the world. In FY 2004, NIH made 45,312 domestic awards (less contracts, fellowships, research career awards) to 30,451 individuals[SRA]. Scientists and research personnel supported by NIH awards is estimated at 212,000 people nationwide, many of whom are foreign nationals. Extrapolation from the intramural program, even conservative, suggests that potentially thousands of foreign nationals will require licensing. Should the IG recommendations be implemented, significant additional controls and procedures will have to be instituted to ensure institutional compliance with these recommendations. For example, institutions would have to (a) implement processes and systems for determining and verifying the country of birth of their foreign research personnel; (b) identify controlled equipment and technology and subsequently devise and implement processes and systems to track which foreign nationals need access; (c) develop and implement an internal process for assisting
foreign nationals in applying for licenses, which is reported to be a labor intensive and time consuming process. The DOC would also have to develop processes and systems to handle the potentially thousands of applications that the definition change would elicit – orders of magnitude more applications than the DOC currently receives and processes.