

I. General Overview

- A half-century of sustained public investment in the National Institutes of Health (NIH) has dramatically advanced the health and improved the lives of the American people and of people around the world.
- NIH has contributed greatly to the United States' global preeminence in research and fostered the development of a biomedical research enterprise that is the envy of the world. As the world's largest supporter of biomedical research, NIH competitively awards extramural grants (which fund researchers at institutions throughout the United States and to some extent outside the U.S.) and supports in-house (intramural) research.

II. Promote Funding For Research

- NIH-supported research represents a dual investment in the future of our nation: (1) helping to assure the health, security and quality of life of our citizens and (2) training the current - and future - scientific and technical workforce needed to maintain our progress.
- Basic research leads to the discovery and understanding of the fundamental workings of nature, which forms the foundation for the translational research and medical advancements that follow. For example, studies of the unusual enzymes in bacteria led to recombinant-DNA technology, sparking the development of modern biotechnology. Industry, which focuses on research that is intended to advance a particular product, relies heavily on the knowledge base developed through publicly supported research.
- History teaches that the visible fruits of our investments in basic research may not be immediate. For example, the Nobel Prize is awarded for research that on average was published more than a decade before the award. Therefore, support of basic science research today is crucial if we want to ensure the new therapies of tomorrow.
- NIH sponsored clinical investigation moves basic discoveries from the laboratory to the patient and tests the human implication of novel compounds and regimens. Not all clinical research is of interest to industry, and the NIH creates a bridge for moving basic science to the bedside.
- NIH is the leading and sometimes only source of funds for certain types of critically important clinical and translational research that are not carried out in the private sector, such as studies designed to understand the mechanisms of disease (including those that seek to understand the genetic underpinnings of disease), combination drug therapies, drug comparison trials, cost-benefit analyses of therapies, and adapting therapies for specific "small market" populations (e.g. pediatric, or rare diseases).
- Because NIH funding is supported by federal tax dollars, it is essential that NIH inform both the public and elected representatives of the value of the research it supports in the long-term battle to overcome human disease and disability. It is also critically important that NIH inform the public and their elected representatives that the path to preventing and curing human disease requires a sustained and long-term investment in basic and clinical research.

III. Use Caution and Follow a Process before Changing NIH's Structure

- FASEB strongly endorses the recommendation of the Institute of Medicine (IOM) to establish a formalized process for creating, consolidating, grouping or eliminating NIH Institutes. FASEB further believes that any decision to create, consolidate, group or eliminate NIH Institutes should take place only after careful study and consideration of the impact of any such change.
- FASEB supports the establishment of a best practices process to conduct periodic reviews of NIH's structure. The review process must involve the relevant stakeholders, including NIH advisory committees, the biomedical research community, patient advocate groups, and Congress.
- FASEB endorses the IOM's observation that "the conceptual or practical case for a wholesale reorganization is not sufficiently compelling to outweigh its potential adverse consequences or risks."
- FASEB also endorses the strengths of the current decentralized structure within NIH. Institute Directors have the expertise in their specific scientific fields. They should retain both scientific and budgetary responsibility. Their autonomy is critical to the ability of NIH to respond knowledgeably to the concerns of diverse groups and constituents.
- FASEB notes that some of the NIH Institutes have become increasingly collaborative. Support of research in shared scientific areas of relevance is now widespread. This should be further encouraged as it enhances the overall program, builds on the individual expertise available within each institute, and encourages multidiscipline-based approaches. One possible mechanism to promote this collaboration is to increase the number of jointly-issued grants to fund research initiatives that address the mission of more than one Institute.
- FASEB believes that the authority currently given to the NIH Director sufficiently enables the Director to advance his/her vision for NIH as well as to ensure collaboration among the Institutes.
- FASEB supports retaining a strong intramural program at NIH; such a program uniquely positions NIH to capitalize on bridging basic research discoveries with new applications to improve the health of our people.

IV. Increase Transparency within the Office of the Director, NIH

- FASEB supports NIH's proposal to establish the Office of Portfolio Analysis and Strategic Initiatives, within the Office of the Director.
- FASEB believes it is important for the NIH Director to have the tools available to evaluate the entire Agency research portfolio to ensure that urgent public health needs are addressed in a timely way.

V. Emphasize Investigator-Initiated Research

- Investigator-initiated, competitive, peer reviewed grants should remain the core mechanism for distributing research funding. This mechanism allows highly skilled scientists to propose the direction and priorities for further research, based on their own expertise and preliminary data. Funding of their proposals occurs only after rigorous reviews. . Such grants have been the foundation for much of the progress to-date in biomedical science.
- By placing most of its resources in investigator-initiated peer reviewed research, NIH ensures that federal taxpayers' dollars support the best science.

VI. Emphasize the Training Component of NIH's Mission

- NIH funding also prepares the next generation of scientists who will be leaders at our nation's universities, professional schools, and commercial enterprises. NIH's commitment to support young scientists has been a long standing priority for both its extramural and intramural programs and should be continued.
- NIH support for the training of clinician scientists (both medical and dental) is especially important for translating basic research to clinical applications. It is equally important for bringing those with clinical expertise into the laboratory so that their perspectives can inform and guide basic research.
- FASEB is especially concerned that the budget pressures caused by flat funding at NIH will disproportionately affect training programs and funding opportunities for young investigators. A budget that does not even keep pace with inflation will limit the entry of new investigators into research careers and adversely affect their ability to compete for research funding.

VII. Protect Competitive Merit/Peer Review:

- In the highly successful peer review system, experienced scientists evaluate applications for NIH funding within their respective fields of expertise and rank those that are most promising. This merit/peer review mechanism identifies the best research proposals within each area.
- Each NIH Institute has an advisory council which complements the peer review system by providing a second-level of review and determines funding of grant proposals.
- The NIH peer review process is the gold standard for determining the quality, importance, and relevance of grant proposals; it should not be subject to subsequent outside influences.
- The process of peer review is crucial to maintaining the quality of NIH research. Any proposed changes should be based on sound criteria and thorough analyses.

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FASEB is composed of 22 societies with more than 84,000 members, making it the largest coalition of biomedical research associations in the United States. FASEB's mission is to enhance the ability of biomedical and life scientists to improve—through their research—the health, well-being and productivity of all people. FASEB serves the interests of these scientists in those areas related to public policy, facilitates coalition activities among Member Societies and disseminates information on biological research through scientific conferences and publications.