

**National Institutes of Health**  
**Advisory Committee to the Director**  
**Long-Term Itramural Research Program (LT-IRP)  
**Planning Working Group Report****

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## WORKING GROUP ROSTER

**Gilda A. Barabino, PhD**  
City College of New York

**Jeffrey Bluestone, PhD**  
University of California, San Francisco

**Arturo Casadevall, MD, PhD**  
Albert Einstein College of Medicine

**Barry S. Collier, MD**  
Rockefeller University

**Diane E. Griffin, MD, PhD**  
Johns Hopkins University

**David Hunter, MBBS, MPH, ScD**  
Harvard University

**Carl H. June, MD**  
University of Pennsylvania

**Cato T. Laurencin, MD, PhD<sup>†</sup>, (co-chair)**  
University of Connecticut

**Philippa Marrack, PhD**  
National Jewish Health

**Robert Nussbaum, MD**  
University of California, San Francisco

**Nicholas A. Peppas, ScD**  
The University of Texas at Austin

**Amita Sehgal, PhD**  
University of Pennsylvania

**Harinder Singh, PhD**  
Cincinnati Children's Hospital Medical  
Center

**Allen M. Spiegel, MD**  
Albert Einstein College of Medicine

**Lawrence A. Tabak, DDS, PhD<sup>††</sup> (co-chair)**  
National Institutes of Health

### **EXECUTIVE SECRETARY**

**Tara A. Schwetz, PhD**  
National Institutes of Health

<sup>†</sup>ACD member

<sup>††</sup>ACD Executive Director

## REPORT – ACKNOWLEDGEMENTS

Many individuals contributed to the development and preparation of the Advisory Committee to the (NIH) Director (ACD) **Long-Term Intramural Research Program (LT-IRP)** planning working group (WG) report. First and foremost, we thank Drs. Michael Gottesman and Richard Wyatt for their assistance in providing much of the data that describe the National Institutes of Health (NIH) Intramural Research Program (IRP) and access to many of the previous reviews of the IRP. These materials were essential to the WG's process and informed much of the WG's deliberations. We also appreciate the efforts of Joe Kleinman and Margaret McBurney in assembling the requested information.

The input received from the Institutes and Centers (ICs) summarized in the *NIH Intramural Research Program: A Synthesis of Opportunities, Issues, and Challenges* report proved very useful. Thanks go to the IC Directors and many NIH staff members who met with subgroups of the ACD LT-IRP WG during two "site-visits." We acknowledge, with many thanks, the outstanding efforts of our team, Drs. Tara Schwetz and Rashada Alexander, for the incredible support they provided to the co-chairs and other members of the WG.

Finally, we are most grateful to and appreciative of the LT-IRP WG members, who devoted much time and effort to this endeavor. Their important observations and insights guided the development and subsequent refinement of the recommendations presented in this report.

Cato T. Laurencin, MD, PhD, Co-Chair, ACD LT-IRP WG

Lawrence A. Tabak, DDS, PhD, Co-Chair, ACD LT-IRP WG

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## REPORT – EXECUTIVE SUMMARY

Since its inception, the National Institutes of Health (NIH) has supported an internal Intramural Research Program (IRP), composed of a federal research workforce whose goal is to (i) conduct biomedical research to further understanding of biology and human disease and (ii) to train the next generation of scientists. Many seminal discoveries have been made within the IRP and numerous scientific leaders received their initial training in IRP programs.

Faced with budgetary challenges and an ever-changing scientific landscape, Dr. Francis Collins, the NIH Director, assembled and charged a working group (WG) of the Advisory Committee to the Director (ACD) to examine the IRP in an effort to guide its long-term planning efforts. Dr. Collins requested that the WG identify areas of opportunity and uniqueness that should be enhanced within the IRP, as well as approaches to ensure the sustainability of the IRP going forward.

WG deliberations were informed by considerable data, as well as interviews with NIH staff. However, due to constraints in time from charge to report issuance and the acknowledged gaps in the scientific expertise of the WG membership, the analysis of the NIH IRP focused on overarching principles rather than the specifics of individual scientific programs. Thus, the recommendations described in the report reflect the central priorities identified by the WG members that could be used as a framework to guide the future planning efforts of the IRP.

The WG envisions the IRP of the future as an environment of people rich in diversity, where a group of highly creative and talented investigators are encouraged and rewarded for using innovative approaches to solve significant scientific questions or address unmet biomedical needs. They do so by collaborating seamlessly with both fellow IRP investigators, as well as those in the extramural community. The IRP should be at the forefront of identifying and addressing areas of important scientific opportunity – “great scientific challenges” – to advance the overall scientific endeavor. This can be accomplished, in part, by creating more opportunities for (i) substantial trans-IRP efforts, and (ii) broader and deeper IRP-extramural collaborations. Particular attention must be directed towards developing a more effective and efficient utilization of the NIH Clinical Research Center (CRC), including enhancing ease of access by those in the extramural community to the unique opportunities that it provides.

The IRP should be the national leader in developing creative approaches to address the paucity of diversity within the scientific workforce. New, testable, strategies must be developed and piloted within the IRP to recruit and retain a highly diverse cohort of individuals at all stages of the metaphorical career “pipeline.” Successful efforts should then be optimized to enable their ready adoption in other research settings. Further, given the rich history of IRP success in training physician-scientists, the IRP should enhance and expand current approaches aimed at increasing the numbers of physician-scientists.

## Recommendations

Although the recommendations that follow are segmented by topic area for ease of reading, they are in fact interrelated and in many instances interdependent. The overarching vision for the IRP requires integration of components from each topic area.

Following analysis of numerous previous reports and provided data (described in detail in the section *Charge to the Working Group and Process*), the WG identified the following recommendations, which are listed in priority order for each section, to strengthen and sustain the IRP:

### **Research Recommendations**

1. *Establish a standing committee to identify “great scientific challenges” and motivate new research initiatives catalyzed by the IRP.*
2. *Bolster support for highly innovative research.*
  - a. *Establish a trans-NIH innovation fund.*
  - b. *Encourage the formation of optional IC innovation funds.*
3. *Encourage interdisciplinary and team science and promote more synergistic intramural and intramural-extramural collaborations through continued development and evaluation of different research structures.*
  - a. *Evaluate the Porter Neuroscience Research Center approach to integrated science.*
  - b. *Develop a mechanism to respond to emergent health crises.*
  - c. *Modify mechanisms to allow for more expansive IRP-extramural interactions.*
  - d. *Host annual scientific meetings at NIH.*
4. *Refocus the mission and function of the Clinical Research Center (CRC).*

### **Research Recommendations**

1. *Establish a standing committee to identify “great scientific challenges” and motivate new research initiatives catalyzed by the IRP* – The WG recommends the formation of a standing committee, comprised of outside experts and scientific leaders within the IRP, to advise the NIH Director on important future research areas, fundamental scientific problems, or national biomedical needs in which the IRP could focus resources – “great scientific challenges.” It is recommended that several annual national and international workshops or meetings be held on campus to facilitate ongoing assessment of these areas, thereby highlighting progress and identifying challenges. These meetings would bolster dialogue in emergent areas and elevate the IRP as a major force for expanding scientific frontiers (*Research Recommendation 3*).

2. *Bolster support for highly innovative research* – NIH should a) establish a trans-NIH innovation fund to reserve approximately 1% of the IRP budget for bold research projects, some of which address the identified “great scientific challenges.” To ensure broad input and encourage a high level of innovation, a substantial fraction of the fund should be used to support competitive research awards based on proposals by individual IRP investigators or collaborative teams that may not be focused on the designated “great scientific challenges,” and b) as a complementary mechanism, urge the Institutes and Centers (ICs) to create optional internal innovation funds of no less than 5% of their non-personnel IRP budget to support highly innovative projects directed toward their focused missions.
3. *Encourage interdisciplinary, team science and promote more synergistic intramural and intramural-extramural collaborations through continued development and evaluation of different research structures* – There are a number of ongoing experiments within the IRP to enhance collaborative efforts with the IRP, including the Porter Neuroscience Research Center. The evaluation of these approaches should be conducted to inform future IRP efforts towards strengthening multi-, inter-, and transdisciplinary activities that address research questions. The WG also recommends reviewing and potentially modifying existing mechanisms for intramural-extramural partnerships, including U01s and the Visiting Scientist program, developing strategies to more seamlessly integrate intramural and extramural funding, and encouraging sabbatical-equivalent experiences for intramural scientists in extramural laboratories to facilitate collaborative opportunities. Development of a mechanism to respond to emergent health crises, with the inclusion of staff scientists and clinicians, is recommended as well. The NIH IRP also should host 4-6 substantial scientific workshops or meetings annually, thereby greatly increasing interactions with the extramural community and addressing the “great scientific challenges” (*Research Recommendation 1*).
4. *Refocus the mission and function of the Clinical Research Center (CRC)* – The CRC has been a leader in the field of rare diseases. While the WG agrees that the CRC should maintain a focus in this research field, the group recommends that there also should be greater emphasis on common public health issues that impact a large portion of the population (e.g., diabetes and heart disease). In particular, the CRC is well positioned to correlate the genotype and phenotype of diseases or conditions using a precision medicine approach (9). The CRC should continue to emphasize research on areas such as vaccine development and mechanisms of drug resistance in the context of pathogens or cancer therapeutics.

## **Workforce Recommendations**

1. *Increase diversity throughout the IRP.*
  - a. *Develop new, innovative models for increasing diversity.*
  - b. *Utilize a central fund to support early-stage investigator recruitment.*
2. *Restructure the review process of IRP Principal Investigators to provide broader, trans-NIH context, and a more stringent evaluation of scientific impact; where appropriate, team science should be included as a review criterion.*
  - a. *Reform the review process to be a trans-NIH effort based on scientific area that incorporates team science.*
  - b. *Institute a rigorous and periodic review process for staff scientists.*
3. *Strengthen recruitment procedures for IRP leadership, Principal Investigators, including Assistant Clinical Investigators, and Staff Scientists and Clinicians.*
  - a. *Expand and publicize current recruitment efforts.*
  - b. *Recruit all Staff Scientists and Clinicians through a national/international process.*
  - c. *Enhance the Assistant Clinical Investigator program.*
4. *Identify the most sustainable size of the IRP workforce.*

## **Workforce Recommendations**

1. *Increase diversity throughout the IRP* – The WG considers the diversity of the IRP workforce a national imperative for success, and recommends that the IRP utilize its unique environment to experiment with approaches identified by the NIH Chief Officer of Scientific Workforce Diversity (COSWD) and the NIH Steering Committee WG on Diversity to recruit, retain, and support individuals from diverse backgrounds. Initially, the COSWD should utilize a newly created central fund to support early-stage investigator recruitment.
2. *Restructure the review process of IRP Principal Investigators to provide, broader, trans-NIH context, and a more stringent evaluation of scientific impact; where appropriate, team science should be included as a review criterion* – The WG recommends restructuring the IC-centric Board of Scientific Counselors (BSC) review process to one in which the review is conducted by a trans-NIH approach that uses a distinguished extramural review panel that spans major scientific fields. The evaluation of IRP investigators should be comprehensive and include their major individual and/or collaborative contributions, and where appropriate, recognition of their contribution to team science. Staff scientists also should undergo a similar matrix-oriented review every 4 years.
3. *Strengthen recruitment procedures for IRP leadership, Principal Investigators, including Assistant Clinical Investigators, and Staff Scientists and Clinicians* – The IRP should recruit more scientists

from the extramural community than is currently done, with a focus on those in the early-stage of their career – those within ten years of completing their terminal research degree or medical residency. All positions, including staff scientists and clinicians, assistant clinical investigators (ACIs), tenure-track, and tenured investigators, should be recruited through national/international searches. Consideration should be given to engaging the BSC or an equivalent review group in the recruitment process. Recruitment incentives unique to the IRP should be highlighted to attract the finest researchers, and the Stadtman mechanism, which was created to do just that, should be evaluated to optimize its efforts.

Given concerns about the number of physician-scientists entering the biomedical research workforce and a desire to increase the number of clinician scientists to ensure maximal utilization of the CRC, strong consideration should be given to enhancing the visibility of the ACI program. It is recommended that prioritization of resources is necessary to increase its size. Consideration should be given to approaching recruitment to this program in a trans-NIH manner.

4. *Identify the most sustainable size of the IRP workforce* – Workforce analyses should be conducted to determine the optimal critical mass of the IRP, including a trans-NIH assessment of the current investigator cohort (by years of service), and an evaluation of the desired ratios of basic, translational, clinical, and population-based research.

#### **Training Recommendations**

1. *Enhance the diversity of IRP trainees.*
2. *Expand and enhance support mechanisms for clinical research trainees.*
  - a. *Broaden the MSTP size, support, and opportunities.*
  - b. *Develop a mechanism for MD research training at the NIH CRC.*

#### **Training Recommendations**

1. *Enhance the diversity of IRP trainees* – The WG recommends expanding current diversity efforts targeting the trainee population to include partnerships with additional institutions, and continuing to support and enhance mentorship for postdoctoral fellows.
2. *Expand and enhance support mechanisms for clinical research trainees* – To create a pivotal hub of clinical research training within the IRP, the WG recommends enhancing publicity for the ACI and Lasker Clinical Research Scholars programs to increase the career opportunities in clinical research. The WG also recommends that the current approach to the Lasker Clinical Research Scholars program be evaluated to enhance recruitment. Further, the WG recommends that Medical Scientist Training Program (MSTP) students should be provided with the opportunity to participate in a clinical research experience at the NIH CRC, and the potential of expanding this program should be explored. NIH should develop a mechanism (similar to the K08 and K23 mechanisms) to provide MDs with appropriate research training at the NIH CRC, in combination

with one of the existing eight NIH programs that support physician-scientist trainees or those early in their careers. The WG recommends increasing the awareness of the joint NIH-Duke University Master of Health Sciences in Clinical Research program; interested trainees should be encouraged to participate. Finally, communication and publicity about awards available to IRP trainees should be increased.

#### **Infrastructure/Facility Recommendations**

1. *Develop more robust joint initiatives with the extramural clinical research community.*
  - a. *Evaluate the feasibility of establishing a phase 1 clinical trials unit at the CRC.*
  - b. *Develop joint initiatives with local hospitals, the Department of Defense, and the Department of Veteran’s Affairs.*
2. *All “core” resources (and other unique equipment/facilities) should be accessible throughout the entire IRP community. Review the shared resource cores to provide optimal support and open access.*
3. *Accelerate efforts to identify a solution for pending data and computing issues.*
  - a. *Develop a comprehensive data storage and computing plan.*
  - b. *Partner with PCORI to provide IRP investigators with special access to PCORnet databases.*
  - c. *Expand pilot programs for electronic lab notebooks within the IRP.*
4. *Explore the feasibility of establishing a centralized biobank.*

#### **Infrastructure/Facility Recommendations**

1. *Develop more robust joint initiatives with the extramural clinical research community* – It is recommended that existing mechanisms for collaborating with the extramural community be expanded. In particular, the feasibility of establishing a phase 1 clinical trial unit at the CRC that is open to the extramural community should be determined. The CRC should collaborate with other area hospitals on joint initiatives, particularly focused on pediatric research. Development of additional partnerships with the DoD and VA are also encouraged.
2. *All “core” resources (and other unique equipment/facilities) should be accessible throughout the entire IRP community. Review the shared resource cores to provide optimal support and open access* – To foster an atmosphere of true collaboration and build on current efforts, the WG recommends that all shared resources be accessible to the entire IRP. A catalogue of current resources, criteria for evaluating the shared resources to ensure the sun-setting of unnecessary cores, approaches to better integrate and optimize use and reimbursement among the ICs, and mechanisms for rapidly instituting new cores should be developed.

3. *Accelerate efforts to identify a solution for pending data and computing issues* – The WG is aware of the NIH-wide Scientific Data Council, consisting of NIH leadership and campus experts, that has been charged with developing a comprehensive data storage and computing plan, including best estimates of future needs. The WG encourages that this process be accelerated, given the urgencies surrounding “big data.” Partnership with PCORI to procure special access to the PCORnet databases for IRP investigators also is recommended. The use of electronic lab notebooks should be piloted and expanded amongst intramural researchers as well.
4. *Explore the feasibility of establishing a centralized biobank* – The WG recommends convening an expert panel to determine the feasibility and infrastructure and procedures necessary to develop a centralized biobank to store biological samples and expand collaborations within and among the extramural and intramural communities.

#### **Administrative Recommendation**

1. *Develop an implementation plan that includes periodic reporting.*

#### **Administrative Recommendation**

- *Develop an implementation plan that includes periodic reporting*— A plan for the implementation of the accepted recommendations from this report, including an evaluation component, is recommended; periodic status reports to the ACD should be developed as well.

**While not specifically recommendations, the WG also acknowledges several areas of concern within the IRP and NIH in general that are not within NIH’s control, and recognizes that measures to facilitate progress in these areas would require Congressional action. These areas are highlighted in the body of the report.**

## REPORT – CHARGE TO THE WORKING GROUP & PROCESS

### *Charge to the Working Group*

The last review of the Intramural Research Program (IRP) was undertaken by the Institute of Medicine (IOM), as part of a review of the entire NIH organizational structure, and was completed in 2003(3). Therefore, Dr. Francis Collins, the NIH Director, assembled a WG of the ACD to examine and assess the IRP in an effort to:

- Identify areas of opportunity within the IRP
- Identify methods to enhance the uniqueness of the IRP
- Evaluate the sustainability of current approaches

Dr. Collins charged the group on August 1, 2014 and requested that their recommendations be assembled into a report to be presented at the upcoming ACD meeting on December 11, 2014.

### *Prior Reports*

The ACD LT-IRP WG was provided with the following prior reports, which include both external and internal reports:

Prior Reports of the IRP (1, 6-8):

- [A Healthy NIH Intramural Program: Structural Change or Administrative Remedies? \(IOM, 1988\)](#)
- [National Institutes of Health Intramural Research Program Report of the External Advisory Committee of the Director's Advisory Committee \(1994\)](#)
- [NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research \(2004\)](#)
- [Scientific Management Review Board \(SMRB\) Report on the NIH Clinical Center \(2010\)](#)
- The NIH Intramural Research Program: A Synthesis of Opportunities, Issues, and Challenges (2014; Appendix 1)
- Office of Intramural Training and Education (OITE) Report
- Individual reports from each Institute and Center (IC) on its IRP (2014)
- Internal summaries of how NIH implemented prior recommendations from the NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research
- Timelines for major NIH governance changes as a result of prior external reviews

The group also received three recent workforce reports generated by WGs of the NIH Advisory Committee to the (NIH) Director, the ACD:

- [NIH Advisory Committee to the Director Biomedical Research Workforce WG](#)
- [NIH Advisory Committee to the Director WG on Diversity in the Biomedical Research Workforce](#)
- [NIH Advisory Committee to the Director Physician-Scientist Workforce WG](#)

The WG received information from the Office of Intramural Research (OIR) on the following topics:

- General IRP information
  - Program profile
  - Professional designations
  - Review process information and criteria for tenure
  - Personnel demographics
  - Age distribution of investigators
  - Source of investigators recruitments (intramural vs. extramural)
  - Clinical and laboratory careers flowcharts
  - Sabbaticals
  - Data specific to staff scientists and staff clinicians
  - Major IC IRP accomplishments
  - Awards and honors to IRP Investigators
  
- Trans-IC IRP programs
  - IRP Training Programs
    - IRP diversity training programs
    - Graduate Partnership Programs (GPP) information (see Relationships between IRP and External (Extramural) Community)
  - Shared resource information
  - Technology transfer data
  - Programs to assist human subjects protocol
  
- Relationships between IRP and External (Extramural) Community
  - Collaborations with extramural investigators
  - Graduate Partnership Programs (GPP) information

In addition to extensive email communications, the WG met formally five times between August and November of 2014, including two in-person meetings and three teleconferences, to meet the requested goal of providing recommendations to the ACD in December 2014. In addition, a subset of WG members also conducted site visits to the NIH campus to gain a better understanding of the IRP.

## REPORT – A CURRENT SNAPSHOT OF THE NIH IRP

Since its inception, the NIH has supported an internal Intramural Research Program (IRP), composed of a federal research workforce whose goal is to (i) conduct biomedical research to further understanding of biology and human disease and (ii) to train the next generation of scientists.

Of the 27 Institutes and Centers (ICs) that comprise NIH, 24 support an IRP. The IRP complements the much larger effort that supports research in the extramural community – at universities, research institutes, and hospitals throughout the Nation.

Housed within the NIH Office of the Director, the Office of Intramural Research (OIR), led by Dr. Michael Gottesman, the Deputy Director for Intramural Research, is responsible for coordinating and overseeing the policies related to research, training, and technology transfer activities conducted in the IRP. The office also oversees the process to regularly review all IRP investigators and IC intramural programs as a whole.

The IRP's primary function is to conduct research that reveals new principles of biology, provides a new understanding of human disease, and seeks to change treatment paradigms. The structure and resources of the IRP are designed, in part, to provide support for projects that fall beyond the general scope of the extramural program, such as those requiring long-term support, those where an unusually rapid response is required to meet a new public health need, and those that present unusual scientific opportunities. A second critical function of the unique environment of the IRP is to provide optimal training for biomedical researchers.

### *Workforce Census*

Approximately 1,000 Principal Investigators (PIs; senior investigators [equivalent to professor and associate professors in academic accomplishment], tenure-track investigators, and a small number of assistant clinical investigators [equivalent in some ways to “instructors” in the extramural community]), 1,500 staff clinicians and staff scientists (in some ways equivalent to “research assistant professors” or “research associates” extramurally), and 4,500 trainees, (comprised of nearly 3,200 postdoctoral fellows, 350 predoctoral/graduate students, and 800 post-baccalaureates), conduct research within the IRP (Appendices 2 & 3). In addition, there are smaller numbers of persons in highly specialized/unique roles, including 19 senior clinicians and 45 senior scientists, who do not have tenure, but are responsible for managing large IC programs or departments with substantial resources. Scientific Directors, who are often also PIs, oversee the research within an IC's intramural program and manage intramural resources and administration for their respective IC. The average age of senior investigators and senior clinicians and scientists in the IRP is roughly 60 years, which is slightly higher than the equivalent cohort in the extramural workforce. Over the past decade there has been a steady decline in the number of PIs, with a concomitant increase in the number of staff scientists and staff clinicians.

The diversity within the IRP workforce is extremely limited. The overwhelming majority of PIs, including Scientific Directors, are white males. For example, 80% of senior investigators and 58% of tenure-track investigators are white (not Hispanic). Further, only 1.4% of senior and tenure-track investigators are Black (not Hispanic) and approximately 3.5% of this same cohort is Hispanic. Males also make up 80% and 63% of senior investigators and tenure-track investigators, respectively. In the trainee population, there is a better representation of women, but racial and ethnic diversity is lacking among US Citizens and permanent residents. For instance, Blacks (not Hispanic) and Hispanics respectively represent 2.4% and 3.1% of research fellows and 4.8% and 2.7% of clinical fellows (Appendix 3). There is a rich international diversity with postdoctoral fellows from many countries around the world including China, India, Korea, Japan, and Europe (<https://www.training.nih.gov/trainees/postdocs>).

### *Trans-NIH Training Programs*

The Office of Intramural Training and Education (OITE), which is housed within the OIR, coordinates programs, activities, and resources for the large number of IRP trainees. Basic research trainees can be supported through several award mechanisms, such as the Intramural Research Training Award (IRTA), NCI Cancer Research Training Award (CRTA), and the Visiting Fellows (VF) program. IRTAs and CRTAs are open to postdoctoral and predoctoral fellows, post-baccalaureates, and technical trainees who are US citizens and permanent residents only. The VF program allows those who are citizens of other countries to be funded while they pursue their doctoral degree or seek additional training as a postdoctoral fellow. Further, the IRP supports the training of clinical fellows through programs that include the [Medical Research Scholars Program](#) and training programs in various specialties, such as hematopathology, infectious diseases, and neurological surgery. The NIH, through the Clinical Research Center (CRC), also participates in a collaborative program with Duke University to offer a Master of Health Sciences in Clinical Research for physicians training for careers in clinical research.

### *Technology Transfer Activities*

The NIH maintains an active technology transfer program, which is implemented by its component ICs through the office of their respective Technology Development Coordinators (TDCs) and the central NIH Office of Technology Transfer (OTT). Recently, an extensive review of the OTT resulted in a major reorganization of the distribution of responsibilities to align the full range of technology transfer activities, including patenting and licensing, with a limited number of IC-based technology transfer offices in order to encourage more creative approaches to public-private partnerships at the NIH.

In fiscal year (FY) 2013, sales of NIH licensed products by the private sector were approximately \$7 billion, and the royalties administered by OTT were approximately \$116 million. This includes nearly 600 issued patents and over 175 executed licenses. The royalties received are proportioned in accordance with statutory requirements and NIH policy, and distributed to the inventors, extramural partners that co-own licensed inventions, reimburse patent expenses, and the ICs where the licensed inventions were developed.

### *IRP Budget*

The overall IRP budget is the sum of each IC's intramural program budget, which each individual IC Director determines for his/her Institute or Center. Beginning in FY 2007, NIH was instructed to include nearly 80% of the National Library of Medicine's (NLM) budget to the IRP budget line. A significant portion of these funds support the National Center for Biotechnology Information (NCBI). Other than NLM, the ICs that commit the largest percentage of their budget to the IRP are the National Institute of Environmental Health Sciences (NIEHS), driven largely by the Congressionally mandated National Toxicology Program, and the National Human Genome Research Institute (NHGRI), although the two largest NIH Institutes, the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID), support the largest IRPs in terms of absolute dollars (Appendix 4).

Prior to the inclusion of NLM in FY 2007, the IRP budget was roughly 9.5 percent of the total NIH budget. Currently, approximately 11 percent of the NIH budget, or roughly \$3.4 billion for FY 2014, is allocated to support the IRP. Historically, the IRP budget increased from FY 2000 through FY 2012 (minus NLM); however, once adjusted for inflation using the Biomedical Research and Development Price Index, the budget has been in a steady decline since the peak in FY 2003.

### *Physical Plant*

The NIH intramural program spans seven campuses across the country. The majority of the research within the IRP is conducted on the main campus in Bethesda, MD. The main campus originally was developed beginning in 1938 when 70 acres of land was donated to the federal government. Over the decades, the campus has continued to grow into the 317 acre campus that exists today. Several additional facilities in which intramural research is conducted have arisen across the country, such as the campus in Research Triangle Park, NC and the Rocky Mountain Laboratories in Hamilton, Montana. The intramural programs of the National Institute on Aging (NIA), the National Institute on Drug Abuse (NIDA), and the National Institute of Environmental Health Sciences (NIEHS) are largely off-campus in Baltimore and North Carolina, respectively. In the "off-site" intramural programs, there are 215 tenure-track and tenured PIs, which is approximately 20% of the IRP PIs.

### *IRP Honors*

Over the years, researchers in the IRP have received numerous major awards, including Nobel Prizes, Lasker Awards, National Medals of Science, and Presidential Medals of Freedom. Of particular note, the NIH Clinical Research Center (CRC) was selected as a Lasker Award recipient in 2011. The National Academies, including the Institute of Medicine (IOM), have elected nearly 180 NIH investigators into their ranks, with over 110 members currently in the IRP.

Institution	Nobel Laureates*	NAS <sup>#</sup>	NAE <sup>±</sup>	IOM <sup>¥</sup>	Am. Acad. Arts & Sci. †	National Medals of Science <sup>L</sup>	Presidential Medals of Freedom <sup>‡</sup>
NIH IRP	21 (5)	51	1	61	43	3	2
JOHNS HOPKINS U.	4 (5)	27	6	56	49	4	4
U. of CALIFORNIA, SAN FRANCISCO	5 (4)	40	0	84	58	3	0
U. of MICHIGAN	0	25	27	49	70	2	0
U. of PENNSYLVANIA	? (3)	27	11	74	59	2	0
U. of PITTSBURGH	0 (0)	6	2	24	11	1	1

\*Includes Physics, Chemistry, Medicine; Current faculty (In parentheses, number of Nobel Awards won by people [past & present] while at the university)

<sup>#</sup>[Online membership directory](#); All categories (living); Queried 12/1/14

<sup>±</sup>[Online membership directory](#); All categories (living); Queried 12/1/14

<sup>¥</sup>March 2014 Directory of Members and Foreign Associates

<sup>†</sup>[List of Active Members by Class, November 2013](#); All categories

<sup>L</sup><http://www.nsf.gov/od/nms/recipients.jsp>; (living)

<sup>‡</sup>[http://en.wikipedia.org/wiki/List\\_of\\_Presidential\\_Medal\\_of\\_Freedom\\_recipients](http://en.wikipedia.org/wiki/List_of_Presidential_Medal_of_Freedom_recipients); Medicine and Science Categories

### *Past IRP Report Findings and Implementations*

In 1994, Drs. Paul Marks and Gail Cassell directed a Congressionally-mandated review of the IRP. The [report](#) identified several unique characteristics of the IRP, such as a primarily retrospective review of the investigators and the availability of the CRC's patient investigational facilities. The report also proposed several recommendations, including the creation of a Central Tenure Committee and the improvement of procedures for selecting outside reviewers of intramural research, and put forth the justification for these recommendations and the methods for implementation. These recommendations have remained guiding principles for intramural research at the NIH.

In recent years, more focused reviews of the CRC and clinical research at NIH have been conducted. A [2004 blue-ribbon panel](#), which was co-chaired by Drs. Edward Benz and Joseph Goldstein, reviewed NIH clinical research and developed several recommendations on the governance and oversight, research portfolio, collaborations with the extramural community, and career development opportunities within the IRP's clinical component. The report strongly endorsed the importance of the NIH CRC. In 2010, the [Scientific Management Review Board \(SMRB\)](#) issued a report on the fiscal sustainability and utilization of the NIH CRC. The board recommended that the CRC expand its vision and role, streamline the governance structure, and adopt a stable, adequate budget mechanism to ensure its stability.

### *Recent Workforce Reports*

Three recent reports focusing on the biomedical research workforce have provided guidance to the NIH on issues of import not only to the IRP, but to the extramural community as well. A general report on the overall workforce was released in 2012 by the [Biomedical Research Workforce WG of the NIH](#)

[Advisory Committee to the Director](#), which collected and analyzed data on several aspects of the biomedical research workforce, including graduate and postdoctoral training and staff scientist successes. The WG proposed several recommendations to ensure future US competitiveness by adequately preparing trainees. These recommendations ranged from engaging partners to provide information and experience in sectors other than academia to modifying salary support and benefits. The report identified some issues related to diversity of the workforce and unique issues surrounding the support of MD-PhD physician-scientists; however, these were more thoroughly examined in two separate reports.

The [ACD WG on Diversity in the Biomedical Research Workforce](#) examined the lack of diversity that is prevalent throughout the biomedical research workforce. Specifically, the recommendations developed by the group were designed to enhance the recruitment and retention of those who are from underrepresented groups in the sciences (URG), disabled, or from disadvantaged backgrounds. A third ACD WG, the [Physician-Scientist Workforce WG](#), recently reviewed the composition and size of the physician-scientist workforce and identified several challenges faced by this population of the workforce. Several recommendations were put forth to correct the dearth of physician-scientists, including a variety focused on training programs, as well as incentives to attract physicians to research. The NIH has begun implementing many of the recommendations offered by these three groups, and is committed to achieving progress in each of these important areas.

Although the recommendations that follow are segmented by topic area for ease of reading, they are in fact interrelated and in many instances interdependent. The overarching vision for the IRP will require integration of components from each topic area.

### Research Recommendations

The unique features and attributes of the NIH IRP make it particularly well suited to support projects that fall beyond the general scope of the extramural program. This includes projects that require long-term support, circumstances where an unusually rapid response is required to meet a new public health need, and situations where an unusual scientific opportunity emerges. To ensure that the IRP takes full advantage of its unique makeup and authorities, the WG recommends that a more formal process be put in place to scan the scientific and public health horizons to identify potential areas for the IRP to pursue. The exercise will serve to underscore the unique capabilities of the IRP and provide timely advice for the NIH Director to consider about areas that the IRP could uniquely focus efforts on.

***Research Recommendation 1: Establish a standing committee to identify “great scientific challenges” and motivate new research initiatives catalyzed by the IRP.***

The WG recommends establishing a standing committee to advise the NIH Director on important research areas or fundamental problems for investment or national biomedical needs that are not being addressed by the extramural community or industry in order to identify areas in which the IRP could focus resources – so called “great scientific challenges.” This committee should be broad-based in composition and include eminent scientists from the IRP, extramural, and industry communities. Stakeholder groups, such as patient advocacy groups should also be included. The committee should meet biennially, and the process should be informed by a series of workshops to be held on the NIH campus that will convene international thought leaders in focused topic areas. The committee will issue a public report with actionable recommendations. Even if these recommendations are not followed by the IRP, highlighting major unsolved biological problems or unmet biomedical issues would have a beneficial effect on identifying areas that need to be addressed by the Nation’s research community, and would help position the IRP as a leader in scientific thought.

***Research Recommendation 2: Bolster support for highly innovative research.***

*a. Establish a trans-NIH innovation fund.*

One stated goal of the IRP has been to support the most innovative research possible. As advances continue to be made at the interface of traditional disciplines, the importance of collaborative, synergistic projects among the NIH ICs has long been discussed, and viewed as essential to enable support for work at the cutting edge of science. Twenty-four ICs have an intramural component in their research portfolio, which can leave the IRP vulnerable to siloed research areas. While the IRP has

promoted collaborative and trans-IC efforts, the WG recommends expanding these activities by creating a resource set to help facilitate their conduct.

The NIH should establish a trans-NIH innovation fund for the IRP, and as a complementary mechanism, urge the ICs to create an optional internal innovation fund to further enable support for highly innovative projects, including some that address the identified “great scientific challenges,” or unique questions that align with multiple IC missions.

The trans-NIH innovation fund should be established within the Office of Intramural Research (OIR) and overseen by the Deputy Director for Intramural Research (DDIR), who will develop a competitive review and selection process. This fund will support independent and collaborative intramural high-risk research that bolsters the goals, issues, and needs of the scientific community, including selected challenges identified by the committee suggested in *Research Recommendation 1*. To ensure broad input and encourage a high level of innovation, a substantial fraction of the fund should be used to support competitive research awards based on proposals by individual IRP investigators or collaborative teams that may not necessarily be focused on the designated “great scientific challenges.” The WG recommends that this fund be sized appropriately (~1% of the IRP budget) to address one or more of the “great scientific challenges” identified by the committee in their biennial report, as well as other investigator-initiated research.

*b. Encourage the formation of optional IC innovation funds.*

Similarly, within each IC, the WG encourages the creation of an optional internal innovation fund. Each IC should reserve no less than 5% of their non-personnel intramural budget to fund highly innovative projects directed toward their focused missions, using a competitive application process and complementing the OIR common innovation fund recommended above. To facilitate such efforts, the OIR should increase communication and transparency of ongoing efforts across the IRP, so that investigators are aware of other research being conducted, regardless of the IC.

***Research Recommendation 3: Encourage interdisciplinary and team science and promote more synergistic intramural and intramural-extramural collaborations through continued development and evaluation of different research structures.***

*a. Evaluate the Porter Neuroscience Research Center approach to integrated science.*

The Porter Neuroscience Research Center is a recent example that reflects the NIH and IRP’s commitment to integrated IC interactions – 80 scientific groups and 10 ICs are located in new, common space. This experiment should be analyzed to determine the benefits and shortcomings of this type of organizational structure. Calculation of the density of PIs (space per PI) may prove valuable in directing this process. If deemed beneficial and effective, this type of collaboration should be broadened to other scientific fields by reorganizing existing physical spaces on the NIH campus to support a critical mass of researchers in related areas in close proximity. As advances in many areas of science are now being fueled by multi-, inter- and trans-disciplinary collaborations, the IRP would be an ideal place to test new models of such activities.

Logistical considerations may make it impractical to provide common space for large numbers of investigators. The Center for Human Immunology Autoimmunity and Inflammation (CHI) represents an excellent example of a collaborative, trans-NIH initiative in which unique core facilities and expertise have been developed, and serve the needs of many investigators spread throughout the NIH campus. It will be important to continue the evaluation of this Center's impact, as it will offer important insights into how other "core" facilities could be developed (and also see *Facilities/Infrastructure Recommendation 2*).

The IRP should consider lessons learned from the extramural population sciences community, where many cost-efficient large-scale studies serve the needs of multiple disease-based investigators. Examples include the Women's Health Initiative (US) and the UK Biobank (UK). Intramural examples include the Framingham Heart Study (currently supported by NHLBI), the NCI AARP cohort, and the PLCO intervention trial. Studies such as these also can serve as distinctive team science "signature" projects for the IRP. Every effort should be made to make these population studies serve the purposes of investigators from multiple institutions to encourage collaboration, as well as cost-efficiency. This will require the design of such studies (and presumably the initial funding) to be collaborative among multiple ICs.

*b. Develop a mechanism to respond to emergent health crises.*

One unique feature of the IRP is its ability to coordinate resources in a relatively timely manner to start short or long-term research projects when the scientific opportunity or public health need arises; the most recent example is the NIH's response to the Ebola crisis. To build upon this capability, the IRP should develop a mechanism to facilitate this process on a trans-NIH level to enable staff scientists and clinicians, or other investigators, to assemble seamlessly to solve either an emergent public health crises or to seize upon areas of scientific opportunity as they arise. This approach could expand staff scientists' and clinicians' experiences beyond their traditional roles in the lab or clinic, and allow them to engage with other labs in multi-IC collaborations. Given the relative flexibility of funding, the IRP should continue to be prepared to respond as the Nation's "first line of research" for rapidly emergent health threats.

*c. Modify mechanisms to allow for more expansive IRP-extramural interactions.*

In addition to these overarching model approaches, the IRP should also develop a mechanism whereby intramural investigators are encouraged to participate in sabbatical-like experiences in IRP research groups and, if feasible, extramural labs.

The IRP should further support and enhance intramural-extramural collaborations in addition to fostering intramural interactions. Partnering with those in the extramural community, including industry, will allow the IRP to broaden its reach, and diversify and bolster its research portfolio. Therefore, the following is recommended:

- Review existing mechanisms for intramural-extramural partnerships
- Effectively utilize the Visiting Scientist program
- Merge intramural and extramural funding to facilitate collaborative opportunities

While many exist across the IRP, collaborations between the intramural and extramural community are perceived as being difficult to establish. There are some mechanisms, such as the Transfer Agreement Dashboard (TAD) and U01s, available to investigators wishing to expand their partnerships with the extramural community. Additionally, Cooperative Research and Development Agreements (CRADAs) are a mechanism often used to collaborate with industry and academic institutions. The WG recommends a review of current intramural-extramural collaborations to determine the extent of the use of these mechanisms and to provide insight into what types of collaborations are formed. One existing pathway that may be utilized more effectively is the Visiting Scientist program, which provides opportunities for foreign scientists to train and conduct collaborative research in the IRP. This program should be emulated or expanded to provide similar opportunities for those domestic scientists who wish to conduct research within the IRP for relatively short time periods (5 years max), and publicized to increase awareness. If necessary, additional mechanisms also should be developed to reinforce the interactions between the IRP and extramural institutions and industry.

Currently, intramural research at the NIH is supported within an IC's budget separately from extramural research. As a means to bolster intramural-extramural collaborations, the WG recommends creating focused mechanisms that allow combining funds from these two budgets, where appropriate. This could include, for example, creating a granting mechanism to support collaborative opportunities between the intramural and extramural communities or allowing the comingling of an extramural investigator's R01 funds with resources available to an intramural investigator to achieve a specific scientific goal.

*d. Host annual scientific meetings at NIH.*

To increase exposure and interaction with the extramural community, the WG recommends that the IRP partner with scientific associations and societies to host 4-6 substantial scientific workshops or meetings annually. These meetings should be focused on identifying approaches to address the "great scientific challenges" identified by the committee in *Collaboration and Research Recommendation 1*. By doing so, IRP investigators will be provided with additional opportunities to interact with their counterparts in the extramural community, thereby increasing the likelihood of collaborative science in emergent areas of science and elevating the IRP as a major force for expanding scientific frontiers.

***Research Recommendation 4: Refocus the mission and function of the Clinical Research Center.***

The NIH CRC is renowned for its research on rare and undiagnosed diseases. While the WG agrees that the CRC should remain a leader in this research field, the group recommends that there also should be a larger emphasis on common public health issues that impact a large portion of the population (e.g., diabetes and heart disease). Selecting such challenges and organizing teams to address them will be challenging, but will have the benefit of encouraging investigators to think creatively on a large scale and the WG believes that this will result in many great ideas.

One area identified by the WG and highlighted in a 2011 National Academies of Science report as a critical component of current research is the correlation between the genotype and phenotype of diseases or conditions, especially those that are rare, using a precision medicine approach (9). The WG

suggests that the IRP utilize the CRC's strengths to build the framework for this burgeoning area of science and designate this as a hallmark of the CRC. Deep phenotyping, with greater granularity than is likely to be obtained from ICD9/10 codes in electronic health records, is required for analyzing gene-gene and gene-environment interactions, especially when considering the influences of multiple genes rather than a single gene. Developing instruments for standardizing the collection and analysis of phenotypic data, backed by ontologic structures and made available through online databases, is an important contribution that the IRP and CRC can make to the scientific community and to its own research studies. Such tools would allow for aggregating data from multiple sites and collectively could form the basis of an "Electronic Research Record" to complement and augment research done using Electronic Health Records (EHRs).

Areas such as vaccine development and mechanisms of drug resistance in the context of pathogens or cancer therapeutics should continue to be emphasized within the CRC. Historically, the IRP has contributed to approximately half of all FDA-approved vaccines currently in use. This strength should be targeted and built upon to expand the CRC's efforts. Antibacterial resistance is among the greatest existing public health threats, and the CRC should focus a portion of its efforts on identifying novel targets for highly drug-resistant pathogens and cancers through in-depth genetic and physiological analysis.

## **Workforce Recommendations**

The number of PIs within the IRP has been declining in recent years, with a net loss of 2-3% of PIs annually, maintaining the current state does not appear desirable or tenable (Appendix 5). Budgets have declined or remained flat, while research costs have increased and likely will continue to do so over the coming years. Based on current budget expectations, the WG recommends altering the current hiring, recruitment, review, and retention policies to stabilize the PI population at an optimal level and ensure the research vitality and distinction of the IRP.

### ***Workforce Recommendation 1: Increase diversity throughout the IRP.***

#### *a. Develop new, innovative models for increasing diversity.*

The diversity of the IRP workforce is a national imperative for success. NIH will not be successful in attracting the most creative minds to biomedical research if we fail to actively engage members of all groups within the Nation. Diverse groups show enhanced problem-solving ability and productivity. A workforce comprised of a diverse array of individuals may be more likely to tackle research questions related to health disparities and inequities or aid in recruitment of individuals from underrepresented groups into clinical trials.

While the NIH has long acknowledged the importance of achieving diversity in the biomedical and behavioral research workforce, the current census of the IRP clearly shows a lack of diversity throughout the ranks (Appendix 3). There is a paucity of Blacks, Hispanics, and American Indian/Alaska Natives

throughout the IRP workforce. Also problematic is the lack of diversity observed among scientific leaders; for example, only 15% of all IC scientific directors are female. In addition, there is poor representation of Asians in leadership positions as well. As a federal research facility, the NIH should be a leader in workforce diversity. A courageous first step has already been taken – NIH has acknowledged that current policies for increasing the diversity of the workforce are insufficient (see [ACD WG on Diversity in the Biomedical Research Workforce](#))(5). The IRP leadership, together with the [NIH Chief Officer for Scientific Workforce Diversity \(COSWD\)](#), Dr. Hannah Valentine, and the NIH Steering Committee WG on Diversity, should develop new models to encourage young people from diverse backgrounds to pursue careers in biomedical research. Moreover, more effort must be directed towards developing new approaches to the recruitment, retention, and support of persons from diverse backgrounds into independent scientific positions (i.e., ACI, tenure track, and tenured PI) within the IRP. The unique environment afforded by the IRP make it ideal to serve as a test-bed for the Nation. As strategies are developed, they may be tested for their generalizability in the extramural program.

*b. Utilize a central fund to support early-stage investigator recruitment.*

As an initial step, given the urgency to act rapidly, the WG recommends that the COSWD use a newly created central fund to support the recruitment of early-stage scientists – those within ten years of completing their terminal research degree or medical residency – into existing labs. The review of the candidate applications by the mentor for this program should be expedited and the program should be widely publicized. This will jump-start the process and provide a cadre of excellent early-stage investigators who can assume leadership roles over time. Another related opportunity that could be seized by the IRP is to develop a program whereby early-stage investigators, and potentially mid-career investigators, from diverse backgrounds are both mentored and sponsored by senior investigators. By doing so, the IRP would assume a leadership role in identifying solutions that are different from previous efforts, and could become a testing ground for piloting novel programs within the unique setting of the IRP.

***Workforce Recommendation 2:*** *Restructure the review process of IRP Principal Investigators to provide, broader, trans-NIH context, and a more stringent evaluation of scientific impact; where appropriate, team science should be included as a review criterion.*

*a. Reform the review process to be a trans-NIH effort based on scientific area that incorporates team science.*

The NIH BSC review process for IRP investigators, which employs a retrospective approach, has been lauded extensively as an excellent method by which to judge those in the scientific community (Appendix 6). Notably, this review structure has been adopted and modified by the Howard Hughes Medical Institute (HHMI), which utilizes a parallel methodology to support an outstanding group of research scientists at various universities and research institutes. Enhancements to this review process will ensure the most appropriate and thorough review of investigators, including both basic and clinical scientists.

The WG recommends restructuring of the IC-centric BSC review process to ensure that the IRP is uniformly comprised of outstanding investigators. All investigators within the IRP should be reviewed every 5-7 years by a trans-NIH and extramural review panel, overseen by the OIR and coordinated with the associated IC, that spans major scientific fields (e.g., structural biology, neuroscience, and immunology). This review should be performed by wide-ranging and highly accomplished scientific peer groups, similar to those assembled by the HHMI. Restructuring the review process to better assess the quality of each investigator across a particular program may help identify redundancies and opportunities across NIH, as well as aid in ascertaining the appropriate critical mass of the IRP (*Workforce Recommendation 4*).

The impact of IRP investigators should be based on their major individual and/or collaborative contributions. Since team science (interdisciplinary research teams focused on innovative approaches to answer critically important research questions or problems) has become an essential component of biomedical research in recent years and likely will continue to play an ever increasing role, it is important that, where appropriate, it be assessed and recognized in the amended review process. This should not, however, be misunderstood as requiring that all investigators participate in teams. Those who choose not to participate in teams should be evaluated based exclusively on the merits of their contributions. The current NIH criteria, as revised in 2005, do in fact recognize collaborative contributions, but it is not clear if investigators feel confident that team-oriented criteria are being employed in the promotion and evaluation process. If those investigators have hesitated to engage in multi- and interdisciplinary research in the past because of concerns about recognition, emphasizing a commitment to team-based review criteria for promotion and tenure, as appropriate, may enhance the likelihood that investigators will commit to collaborative projects when opportunities arise.

*b. Institute a rigorous and periodic review process for staff scientists.*

Currently, staff scientists undergo a quadrennial review that is conducted by the IC in which they are appointed; therefore, the standards and rigor of the review process vary from IC to IC. To ensure a more thorough and uniform review, the WG recommends that the IRP institute a rigorous, standardized trans-NIH review process for all staff scientists appointed within the IRP, regardless of their hiring mechanism. This review should occur every four years and should involve investigators and leadership from multiple ICs. Similar to the review process for investigators, it should also be performed by scientific area or discipline. A thoughtful and rigorous review of all non-trainee researchers should ensure that precious resources are being used to support only highly meritorious research.

***Workforce Recommendation 3: Strengthen recruitment procedures for IRP leadership, Principal Investigators, including Assistant Clinical Investigators, and Staff Scientists and Clinicians.***

*a. Expand and publicize current recruitment efforts.*

Over the previous five years, 53% of tenure-track investigators were recruited to the IRP from outside institutions, and 75% of tenure appointments were made from the NIH tenure-track pool – those tenure-track investigators currently within the IRP (Appendix 7). The WG considers continual

recruitment from the extramural community essential to maintaining a vibrant and innovative IRP, and this applies not only to the recruitment of PIs, but also to the leadership within the IRP. While the IRP trains many excellent candidates for PI positions, the extramural community offers a much larger and more diverse pool of individuals with a wide range of talents that can bring an added depth and breadth to the IRP. Thus, to enhance the recruitment of highly talented investigators from a broader international pool, the WG recommends the approaches outlined below.

The IRP should recruit more scientists from the extramural community than is currently done. All positions, including staff scientists and clinicians, assistant clinical investigators (ACIs), tenure-track, and tenured investigators, should be recruited through national/international searches. Consideration should be given to engaging the Board of Scientific Counselors (BSC) or an equivalent review group in the recruitment process. Given the tremendous experience of those serving on BSCs, the WG suggests augmenting the recruitment and hiring processes to involve select members of the modified BSCs (described in *Workforce Recommendation 2*) in the search committees. In addition to opening a new pool of reviewers for competed positions, those serving on these review groups also can provide additional extramural perspective and meaningful assessment of potential recruits. The WG also recommends the involvement of leadership or investigators from ICs other than the hiring IC as a means to broaden input and increase collaboration in recruitments and transparency across the NIH.

Recruitment incentives unique to the IRP should be highlighted to attract the finest candidates. For example, the tuition loan repayment plan offered by the NIH, which provides up to \$35,000 per year with no overall cap, and the excellent success rate for IRP applicants should be publicized. Enhancing mentoring by senior-level investigators for early-stage investigators should also help in recruiting pioneering scientists. It is especially important that salaries of tenure-track researchers remain competitive with those in the extramural community, since IRP restrictions on travel and conflict of interest policies are potential deterrents to recruitment of extramural scientists.

The WG recommends that the IRP particularly focus on scientists in the early-stage of their career – those within ten years of completing their terminal research degree or medical residency. One successful example of broadening recruitment of early-stage investigators has been the [Stadtman Tenure-Track Investigators](#) mechanism, which seeks to identify talent through a broad search that can focus on specific areas of science or enable the candidates to bring their ideas to the IRP. The WG recommends that this program be evaluated, modified as needed, and enhanced to optimize its efforts to attract investigators from outside the IRP.

*b. Recruit all Staff Scientists and Clinicians through a national/international process.*

The WG views the over 1500 staff scientists and clinicians, including those who are shared resource core directors, to be a vital component of the IRP's research endeavor. Currently, these highly coveted positions are selected by the IC through which they are appointed. As such, external recruitment procedures should be utilized to fill these positions through a trans-NIH national and/or international search process, similar to that for senior and tenure-track investigators. In this way, the IRP will be provided an additional mechanism through which to increase the diversity of the IRP, as recommended

in *Workforce Recommendation 1*. The recruitment of extramural scientists to these positions is also likely to stimulate new ideas based on the new investigator's experiences at other institutions.

*c. Enhance the Assistant Clinical Investigator program.*

Given concerns about the number of physician-scientists entering the biomedical research workforce and a desire to increase the number of clinician scientists to ensure maximal utilization of the clinical center, strong consideration should be given to enhancing the visibility of the ACI program, which is a competitive temporary PI position in which clinicians receive advanced mentoring and build an independent research portfolio; prioritization of the resources necessary to increase the ACI program's size also should be reviewed. Consideration should be given to approaching recruitment to this program in a trans-NIH manner. While still in its infancy, the [Lasker Clinical Research Scholars Program](#) is designed to support exceptional early-stage clinical researchers and foster their development into fully independent investigators. This program can complement the ACI effort; indeed, several ACIs have successfully competed for the Lasker Clinical Research Scholarship. The WG was disappointed to learn that the number of applications to the Lasker program was lower than expected for such a seemingly attractive program and encourages a detailed analysis of how to improve recruitment into the program. The Stadtman and Lasker mechanisms have the potential to both increase extramural recruitment and attract early-stage investigators, thus invigorating the IRP as it ushers in a new era of scientific discovery at the NIH. Further, the Stadtman and Lasker programs could be used to redouble efforts to increase diversity in the IRP (*Workforce Recommendation 1*).

***Workforce Recommendation 4: Identify the most sustainable size of the IRP workforce.***

While the number of PIs in the IRP has steadily declined over the past 20 years, the number of staff scientists and staff clinicians has increased gradually to its current level of over 1500 (Appendix 5) during this same time period. With the budget constraints that all federal agencies are navigating and the complexities of the current IRP workforce makeup, the issue of the workforce size and balance requires careful consideration. This WG recommends a review and evaluation by the OIR and external advisors in conjunction with the ICs (which could include BSCs) to determine the appropriate critical mass for the IRP, including the CRC, and the correct balance among investigators, staff scientists and clinicians, and trainees. This analysis should include consideration of:

- Trans-NIH evaluation of the current investigator cohort – ICs, in collaboration with the Office of Human Resources, should ascertain the years of service (stratified by decade) of the current pool of IRP investigators, and using various assumptions about separations and hires, model workforce dynamics to help inform the determination of the most sustainable size of the IRP workforce. This approach should play close attention to demographic gaps and opportunities that may be illuminated for targeted recruitment, and may help to address the diversity of the IRP workforce. The comprehensive evaluation of the workforce also will inform any planning processes to address the impending and anticipated efflux of baby boomer aged investigators from the workforce, as this will provide an opportunity to substantially impact the future of the IRP.

- An articulation of the optimal distribution of each IC's support of scientific areas supported in the extramural portfolio versus the IRP.
- The identification of the scientific areas of strength and weakness within the IRP and the workforce required to achieve stated scientific goals in the IRP over the next decade.
- The desired ratio among basic, translational, clinical, and population-based research within the IRP.

The WG also supports the utilization of newly reinstated programs that allow long-standing members of the workforce to partially retire from federal service. In this way, resources may be made available to increase the number of early- or mid-stage investigators, while still ensuring continuity of institutional domain knowledge and experienced mentorship of the IRP workforce. A complementary approach should be explored in which funds may be made available to departing IRP investigators to ease their transition to the extramural community.

## Training Recommendations

The IRP has maintained a strong focus on training of individuals throughout the career pathway – summer students (high school through professional school), post-baccalaureates (those who have completed an undergraduate degree), predoctoral students, and postdoctoral research and clinical fellows. In 2013, a census of the training population identified approximately 3,200 postdoctoral fellows of a total of roughly 4,500 trainees in the IRP (Appendix 3).

In recent years, the percentage of MD investigators conducting biomedical research has declined<sup>(4)</sup>. The [ACD Physician-Scientist Workforce WG](#) report, which analyzed a wide array of data on the current physician-scientists workforce, emphasized the importance of bolstering investment in and training of physician-scientists. The ACD Physician-Scientist Workforce WG also developed several recommendations to facilitate support of clinically-trained investigators within the IRP and the extramural community, which this WG believes should be considered to create a pivotal hub of clinical research training within the IRP. Given the identified need to enhance entry of physicians into the biomedical research workforce, the WG recommends that the IRP:

### ***Training Recommendation 1: Enhance the diversity of IRP trainees.***

Although the diversity within the IRP trainee population is slightly better than the overall IRP investigator workforce, there is a need for increased representation of groups from diverse backgrounds within the trainee population. As per a 2013 survey, the majority of research and clinical fellows are white (not Hispanic) or Asian/Pacific Islander. The number of female trainees is comparable to the number of male trainees. Within NIH, efforts are underway to expand the IRP [Graduate Partnership Program](#), in which the IRP partners with institutions that have a track record for training students from groups that are traditionally underrepresented in the sciences to coordinate the training of PhD students. Additionally, a supplement program is under development to provide a competitive pool of

funds for postdoctoral trainees from underrepresented groups within the IRP. This WG commends these efforts and recommends that these programs be expanded to include partnerships with additional institutions, support for more postdoctoral fellows, and support for early-stage investigators and staff scientists and clinicians.

Additional partnerships should be created with institutions that mirror those currently being supported by the extramural [BUILD program](#) (which target under-resourced institutions with highly diverse student populations). This will raise awareness about the many training opportunities that NIH offers. The IRP and COSWD are encouraged to strengthen trans-NIH approaches to recruiting postdoctoral and clinical fellows to ensure that selections are made from the broadest possible pool.

Effective mentors have repeatedly been found to play a significant role in the future success of early career trainees. The IRP should continue to encourage focused mentoring and provide resources for both the mentors and the mentees. For example, the Individual Development Plan (IDP) for all postdoctoral trainees was first introduced within the intramural program and is now recommended for all extramurally supported trainees. The WG strongly recommends that the IRP enhance collection of outcomes data on the successes of IRP graduates at all levels using a standardized tool that collates all of the relevant data in a manner that allows data aggregation across the entire IRP. The data should be evaluated and analyzed every 3-5 years to identify areas for improvement and program strengths.

OITE assists trainees in enhancing their postdoctoral experience by providing an array of educational and career development opportunities, including those beyond the laboratory bench (e.g., science policy, science communication, intellectual property law). These excellent programs should be encouraged and actively publicized.

***Training Recommendation 2: Expand and enhance support mechanisms for clinical research trainees.***

*a. Broaden the MSTP size, support, and opportunities.*

To create a pivotal hub of clinical research training within the IRP, the WG recommends that the current approach to the Lasker Clinical Research Scholars program be evaluated to enhance recruitment. It also is recommended that Medical Scientist Training Program (MSTP) students be provided with the opportunity to participate in a clinical research experience at the NIH CRC to further complement the efforts to recruit early stage investigators via the ACI and the Lasker programs. In addition, NIH should explore increasing the number of positions it supports for the MSTP program by broadening its support beyond NIGMS. While there is no guarantee that these “undifferentiated” trainees will emerge as oncologists or cardiologists, the potential virtue of such a program would be to increase the overall pool of physician-scientists.

*b. Develop a mechanism for MD research training at the NIH CRC.*

NIH should develop a mechanism (similar to the K08 and K23 mechanisms) to provide MDs with appropriate research training at the NIH CRC, in combination with one of the existing eight NIH programs that support physician-scientists trainees or those early in their careers. The WG recommends

increasing the awareness of the joint NIH-Duke University Master of Health Sciences in Clinical Research program; interested trainees should be encouraged to participate. Finally, there should be increased communication and publicity about awards available to IRP trainees, particularly loan repayment programs.

## **Infrastructure/Facility Recommendations**

The main NIH campus, which spans 317 acres, is situated in Bethesda, Maryland and houses most of the research activities of the IRP. However, the WG views the IRP and, in particular the CRC, as a national resource, which unfortunately is accessed by relatively few members of the extramural community due to various administrative challenges. To address this concern, the WG has identified several recommendations.

***Infrastructure/Facilities Recommendation 1: Develop more robust joint initiatives with the extramural clinical research community.***

*a. Evaluate the feasibility of establishing a phase 1 clinical trials unit at the CRC.*

Currently, the CRC is supported by a contribution of funds from each IC that is proportional to its overall budget. This funding structure, often referred to as the “school tax,” was implemented in 2000 and was designed to be budget neutral – that is, contributing ICs would not incur additional budgetary costs. However, this mechanism has proven unsustainable because of fiscal uncertainty, budgetary constraints, and rising operating costs. A previous intensive, internal feasibility review of the CRC determined that instituting a third-party payment system was not practical. The [2010 Scientific Management Review Board \(SMRB\) Report](#) reviewed several possible funding mechanisms for the CRC and suggested incorporating it as a line item in the Office of the Director’s appropriations (8), which would require Congressional approval and has a number of disadvantages associated with it.

One potential means of raising revenue for the CRC that should be explored is to capitalize on its strengths by establishing a phase 1 clinical trial unit that can be utilized by the extramural community. Units to coordinate phase 1 clinical trials, which are a hallmark of the CRC, are costly to maintain extramurally. If the NIH CRC could utilize its existing infrastructure to manage and run phase 1 clinical trials in conjunction with extramural institutions, this could enhance utilization of the facility allowing economies of scale to be fully taken advantage of and could provide some offset for budgetary shortfalls driven by inflationary pressures. The WG recommends that the Clinical Center Governing Board (CCGB) evaluate this approach and determine whether it is likely to address the budgetary problems and the feasibility of the appropriate measures needed to implement this activity.

- b. Develop joint initiatives with local hospitals, the Department of Defense, and the Department of Veteran's Affairs.*

The existing mechanisms for collaborating with the extramural community, including the Bench to Bedside and U01 cooperative agreement programs, should be strengthened by insuring that they have stable support. In addition, efforts should be made to expand and broaden these partnerships. In particular, the CRC should collaborate with other area hospitals to become a specialized, focused center for clinical research.

The committee also was impressed with the ambitious plan NIH put forth to target neonatal pediatric research, since this is an area that has not received the focus it deserves relative to the health needs and both medical and scientific opportunities. Therefore, the WG recommends that the IRP develop joint initiatives on pediatric research to capitalize on the ongoing activities in the extramural community and expand the CRC's capabilities. The IRP should partner with local pediatric hospitals in the Washington, DC area, such as Children's National Medical Center, to build the research portfolios of the organizations involved.

In addition to partnering with local pediatric hospitals, the IRP and the CRC should strengthen collaborations with the Department of Defense (DoD) and the Department of Veterans Affairs (VA). The Walter Reed National Military Medical Center is located directly across the street from the NIH main campus and is adjacent to Uniformed Services University of the Health Sciences, providing an optimal opportunity for collaboration between these institutions. To increase utilization of the CRC, the IRP should explore partnerships with the DoD and VA to capitalize on opportunities for economies of scale with these federal agencies.

***Infrastructure/Facilities Recommendation 2:*** All "core" resources (and other unique equipment/facilities) should be accessible throughout the entire IRP community. Review the shared resource cores to provide optimal support and open access.

The IRP currently has over 20 shared resources, services, and facilities available to investigators (Appendix 8). However, access to some of these shared resources is limited to select ICs. To foster an atmosphere of true collaboration, the WG recommends that all shared resources should be accessible to the entire IRP. A catalogue of current resources, criteria for evaluating the shared resources to ensure the sun-setting of unnecessary cores, approaches to better integrate and optimize use among the Institutes and Centers (ICs), and mechanisms for rapidly instituting new cores should be developed.

To foster an atmosphere of true collaboration within the IRP and build on existing efforts, the IRP should open access to all of these resources, including all other unique equipment or facilities (e.g., Cryo-EM), to the entire IRP – every IC with an intramural component – and adjust the funding accordingly. As research interests change and the scientific community as a whole advances, some of these resources may no longer be needed. Therefore, a retrospective and prospective review of the shared resource cores should be undertaken to identify those that are no longer needed and anticipate those that may be needed in the near future. The IRP also should generate guiding principles, including reimbursement

policies, for the operation and management of the shared resources on a recurring basis. These principles should include developing a catalogue of current resources, criteria for periodically evaluating the shared resources to insure the sun-setting of unnecessary cores, and approaches to better integrate and optimize use among the ICs. Similarly, a mechanism should be developed for rapidly instituting new cores when scientific opportunities become apparent, with a focus on assuring access to early-stage investigators to sustain their scientific competitiveness.

***Infrastructure/Facilities Recommendation 3: Accelerate efforts to identify a solution for pending data and computing issues.***

*a. Develop a comprehensive data storage and computing plan.*

The shift toward studies involving large volumes of data requires a tremendous amount of data storage and processing capability. While the IRP is actively engaged in enhancing big data approaches and computation capacity with its NIH partners, this WG recommends that the newly formed Scientific Data Council, led by the [NIH Associate Director for Data Science \(ADDS\)](#) and the Chief Information Officer, in consultation with campus experts, such as NCBI, develop a comprehensive data storage and computing plan, including a prediction of future needs. The path identified by these experts should be integrated into current planning efforts and implemented to ensure computing demands and restrictions do not hinder scientific progress; access to the extramural community also should be considered.

*b. Partner with PCORI to provide IRP investigators with special access to PCORnet databases.*

While intramural and extramural investigators will be granted similar access to the PCORnet databases, the IRP should partner with PCORI to provide IRP scientists with special access to the wealth of data stored in these databases. In addition, researchers should be provided the resources to utilize the PCORnet databases appropriately, thus expanding the potential for additional innovative findings as a result of these large projects. Additionally, the Common Fund Collaboratory databases are open to all and the IRP and NIH in general should enhance their efforts to publicize this accessibility to a rich pool of data.

*c. Expand pilot programs for electronic lab notebooks within the IRP.*

Electronic lab notebooks, in which experimental protocols, data, and notes can be uploaded, saved, and shared electronically, are gaining popularity throughout the scientific community. The WG commends the existing programs to pilot the use of electronic lab notebooks within the IRP, and recommends that these programs be continued and expanded to incorporate the use of this new method of recording notes and data throughout the IRP, in part, as a means of enhancing the rigor and reproducibility of science reporting. Results of these pilots should be shared broadly and exported to the extramural communities.

***Infrastructure/Facilities Recommendation 4: Explore the feasibility of establishing a centralized biobank.***

Many studies, especially those using the newest genetic techniques, require access to numerous varied samples from carefully phenotyped individuals. NIH has been at the forefront of conducting such studies and utilizing these technologies, and should continue to maintain this lead role. To support both the intramural and extramural communities, the IRP should convene an expert panel to determine the feasibility of developing a centralized biobank, as well as its associated computational infrastructure, with rigorous standardized operating procedures to store biological samples and expand collaborations within and among the extramural and intramural communities. This biobank could be housed in the NIH CRC to increase its potential for interactions with extramural institutions, particularly those in close proximity to the CRC. Analogous to the UK Biobank, this biobank also could function as a key resource to aid in the creation of large-scale population-based studies. Biorepositories, such as the one suggested, can be quite costly to maintain; therefore, if capacity is ample, the IRP could amortize a portion of the costs by offering the service to nearby academic centers that do not wish to or cannot feasibly commit to a full biobank program. In addition to recouping some of the costs of maintaining the biobank, opening access to extramural investigators may stimulate collaborations.

## **Administrative Recommendation**

The 1994 review of the IRP performed by the group led by Drs. Marks and Cassell included an implementation plan to address the recommendations that arose from the report. Unfortunately, the WG assembled here was limited in time, and unable to thoughtfully develop such a path forward. Therefore, the WG recommends the following:

***Administrative Recommendation 1: Develop an implementation plan that includes periodic reporting.***

The recommendations outlined in this report will be presented to the NIH Director at the December 2014 ACD meeting and, following the meeting, the NIH Director will determine which recommendations are approved for adoption. The WG suggests that a plan for implementation of the accepted recommendations, including metrics to evaluate the progress and efficacy of the plan, be developed. To provide transparency, the NIH should provide periodic reports on the status of the implementation plan.

## ***Recognition of Structural or Administrative Problems***

Throughout the provided materials and in discussions with NIH leadership and investigators, several administrative issues arose consistently. Unfortunately, as a government agency, the NIH has no or little control over many well-intentioned, but inadvertently problematic, policies. As such, the WG has identified several areas that it feels should be addressed; however, they require legislative action to do so.

Currently, the NIH as a whole receives a one year budget appropriation that expires at the year's end – if the funds are not obligated by the end of the fiscal year, the money is returned to the US Treasury

through a process referred to as “use or lose.” Most other federal agencies are funded in such a way; however, this becomes quite problematic for scientific agencies in particular. Biomedical research takes years to develop and yield results, and the short budget cycle combined with the inability to transfer funds over into the next fiscal year makes long-term planning approaches difficult. Currently, some agencies have much more flexibility; e.g., most of the Department of Energy’s (DOE) appropriations are multi-year or no-year (DOE can request reallocation of unobligated funds indefinitely), while the Department of Justice (DOJ) has special authority to transfer unused budgets to an account for future use(2, 10). This added flexibility would greatly benefit the NIH as a whole, as well as the IRP. To alleviate some of the burden and uncertainty of a one year funding appropriation, the WG supports the establishment of a two year budget for NIH. In providing appropriations for a two year period, in which funds can be rolled over from the first to the second year, the NIH will have more flexibility and stability to fund outstanding science, both extramurally and intramurally. Additionally, the WG considers the current budget for the IRP, which is roughly 11% of the entire NIH budget, an appropriate level for funding the IRP, and suggests that it remain at this percentage for the foreseeable future.

Conflict of interest (COI) and travel restrictions are well-intentioned to eliminate waste and potential biases in the federal government. However, they are inadvertently posing undue burden on the scientific activities of those in the IRP and hindering recruitment of top-tier investigators. For example, attendance at conferences and scientific meetings allows investigators to present their material to a wide scientific audience. Often, new ideas are developed and collaborations are formed as a result of direct communication with others in attendance, particularly those collaborations that would not have been formed otherwise (e.g., discussions at a poster from a lab a PI was unaware of or did not realize had a shared interest). Due to burdensome restrictions on conference attendance and travel, scientists are either unable to attend meetings or are notified of their approval just days in advance. This current system results in increased costs in travel fees and added administrative processes that syphon resources from the central mission – biomedical research. Thus, the WG supports amendment of federal conference and travel legislation to exclude the NIH and other scientific agencies. At a minimum, the unit for determining attendance should be the NIH rather than HHS so as to avoid the complexity of interagency communication and reconciliation. Additionally, complex and restrictive COI policies also inhibit recruitment and hiring of senior level investigators. Many scientists who may be the best fit for open positions within the IRP (and NIH as a whole) either do not apply or must sever ties with companies or other organizations that pose a potential conflict. Additional administrative burdens also are imposed to comply with these COI regulations, which are mandated by the Department of Health and Human Services (DHHS). Therefore, changes to these policies must be made and implemented at the departmental level to allow for the NIH to attract the best talent, while maintaining an appropriate atmosphere of scientific integrity.

There is strong support from the WG and many of the IRP scientists to facilitate opportunities for intramural and extramural investigators to collaborate on a common research goal since this will speed the project and increase the likelihood of success. It would also result in a much needed infusion of funds to support the CRC. It is unclear whether federal rules prohibit this activity, but it is clear that

there is sufficient legal concern to prevent the development of such arrangements on a regularized and expedited basis. If this problem requires new legislation to assure NIH that it is acceptable, then it should be added to the list of challenges requiring legislative remedy.

### ***Administrative Barriers***

As a federal agency, the NIH recognizes the need for transparency and adequate communication with the public, Congress, and other agencies; therefore, the WG does not foresee any objections to the reporting of the implementation plan and periodic status updates. The largest barrier to addressing the items identified as areas to be considered is the requirement of action above the level of the NIH administration. Particularly, amending the budget structure and travel policies necessitate Congressional amendments to current legislation. Further, the logistics of redressing the co-mingling of intramural and extramural resources are unclear. The WG recognizes that these policies and laws will be very difficult to change, but urges their consideration by those in Congress and DHHS.

## REPORT – IMPLEMENTATION CONSIDERATIONS

The IRP is a vital component of the US biomedical research enterprise. To ensure that it remains a robust, productive program, this WG has recommended several changes be made to the overall program, as well as particular components. In times of fiscal constraints, it is not realistic to assume or suggest that IRP budgets increase to cover additional costs associated with implementing these recommendations. Thus, difficult decisions must be made to solve these complex problems. Several barriers to achieving the goal of a more efficient and sustainable IRP exist, and the WG acknowledges the complexity involved, particularly with those items that require Congressional or departmental action.

## REPORT – RECOMMENDED FUTURE REVIEWS

- Review and evaluation of the Porter Neuroscience Center organization and structure
- Analysis of current intramural-extramural collaborations
- Feasibility evaluation of the CRC serving as a phase 1 clinical trial unit for extramural
- Evaluation of the appropriate critical mass of PIs for the IRP
- Shared Resources
  - Separate review of the animal program
  - Separate review of the shared facilities and cores to inform maximization of resources
- Comprehensive data storage and computing plan
- Feasibility study to determine the infrastructure and procedures necessary to develop a centralized biobank

## REPORT – CONCLUDING REMARKS

The primary areas of concern identified by the WG are addressed in the recommendations described within the report. The WG considers identifying emergent scientific priorities and providing support for the most highly innovative research to be of the utmost importance. Equally important is the need to increase the diversity of the IRP workforce to ensure the continued competitiveness of the IRP. The path to do so begins with recruiting and mentoring trainees and extends to retaining and supporting early- and mid-stage investigators. The unique environment of the IRP allows for it to become a test bed to experiment with pioneering pilot projects, which can be shared with and emulated in the extramural community if successful.

This report's recommendations also emphasize the need to more effectively integrate and increase trans-NIH efforts and collaborations, as well as those with the extramural community. The IRP should pilot novel approaches to support interdisciplinary and team science, and administrative barriers should be addressed that hamper both intra-IRP and extramural-IRP interactions.

Additional important workforce issues surrounding the recruitment and subsequent review of IRP scientists were identified. The recommendations offer pathways to infuse the IRP with the most capable, innovative researchers, and more effectively evaluate their performance. Support of trainees, particularly those conducting clinical research, is an essential component to guaranteeing a stable route forward for the IRP and its CRC.

Additional areas of concern that hinder scientific progress within the IRP were identified and included in this report to increase awareness of these issues. Unfortunately, the NIH is unable to address these issues alone, as they require legislative action to remedy; however, the WG maintains that changes to the identified issues, including travel restrictions, conflict of interest policies, and stability in budget appropriations, must be addressed for the IRP to retain its competitive standing.

The WG envisions enormous opportunities for the IRP to capitalize on its distinctive features. The WG is optimistic about the future of the IRP and its ability to build on its extraordinary scientific and training reputation as the US government's premier biomedical research institution.

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1. The NIH Intramural Research Program: A Synthesis of Opportunities, Issues, and Challenges (No Appendices)
2. Personnel Designations
3. Personnel Demographics
4. IRP Budget
5. Workforce Trends
6. Review Process
7. Principal Investigator Pathways
8. Shared Resources

**The NIH Intramural Research Program:  
A Synthesis of Opportunities, Issues, and Challenges**

**Contributors:**  
NIH IC and Scientific Directors  
NIH Institute and Center Long-term Planning Groups  
Chairs, IC Boards of Scientific Counselors  
NIH Deputy Director for Intramural Research

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## **Executive Summary**

The NIH-supported biomedical research enterprise faces severe resource constraints, and the NIH Intramural Research Program (IRP) is not immune. The approach of the IRP to manage these constraints is to form a healthy balance between investigator-driven and collaborative team science in a collegial culture that accommodates world-class basic, translational, population-based, and clinical research. These research areas should be mission-related, innovative, and of high quality and impact on improving human health. This strategy can be sustained if the ICs define and fund scientific priorities in the IRP and make optimal use of the NIH Clinical Center and other distinctive features of the IRP.

This document contains a synthesis of issues, challenges, and opportunities for the NIH IRP for the next five to ten years. The assessment reflects a yearlong effort with broad input from the NIH community, including the Institutes' Boards of Scientific Counselors, the IC Directors, the NIH Scientific Directors, and the Deputy Director for Intramural Research. The content of this document was driven by the charge by the NIH Director and is intended to inform the Working Group of the Advisory Committee to the Director that will give advice to the Director on future directions for the IRP.

Some of the ideas in this assessment are enhancements or extensions of changes and processes already in place to respond to the challenges currently faced by the IRP, and some represent new directions that will support the dynamic mission of the IRP for years to come as it strives to be both stable and competitive. These items include an articulation of possible areas of scientific opportunity for the IRP as well as ideas for some critical process changes to create the best possible research environment including:

- Sustaining the Clinical Center and aligning IC scientific priorities with CC resources
- Developing innovative recruitment strategies to assure the presence of outstanding entry-level researchers, including joint recruitments and appointment of scientists and clinicians by partnering with neighboring research institutions and hospitals
- Promoting diversity and inclusion in the biomedical research workforce
- Creating funding mechanisms within existing resources to energize trans-NIH recruitment, innovative investigator-initiated research, and form teams to tackle important scientific problems and public health emergencies
- Developing new mechanisms for partnerships and sharing, including internal sharing of valuable resources among ICs and new ways to improve intramural-extramural interactions.
- Assuring the most efficient operation of the IRP, including the idea of authorizing carry-over funds for NIH research.

## I. The Intramural Research Program: Background, Mission, and Vision

The NIH is the primary U.S. federal agency for conducting and supporting medical research. Since the 1950s, the vast majority of this federal investment has been directed, in the form of grants, to the extramural research community, where scientists work at universities, institutions, and organizations. Currently, approximately 11 percent of the NIH budget supports research within federal laboratories located in Maryland, North Carolina, Montana, Arizona, Massachusetts, and Michigan; this constitutes the Intramural Research Program (IRP). Of the 27 NIH Institutes and Centers (ICs), 23 have an intramural component to which they allocate a variable portion of the IC budget ([Appendix 1](#)).

The IRP has been shaped by many insightful and highly useful outside reviews over the past decades, and the results and implementation of those reviews are summarized in the attached documents ([Appendices 2-6](#)). The current mission and vision of the NIH IRP have been influenced by these reviews.

**Mission statement:** The IRP works within the framework of the NIH mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The IRP's mission is to 1) conduct distinctive, high-impact laboratory, clinical, and population-based research; 2) facilitate new approaches to improve the public health through prevention, diagnosis and treatment; 3) respond to public health emergencies; 4) train the next generation of biomedical researchers; and 5) maximize the impact of IRP discoveries through information sharing and partnerships with academia, industry, and other government agencies.

**Vision statement:** The NIH IRP seeks to be a dynamic research environment for new generations of imaginative scientists to conduct fundamental research that:

- reveals new principles of biology,
- provides new understandings of human disease, and
- changes treatment and prevention paradigms.

This research environment also is designed to attract and train a highly-talented and diverse cadre of scientists who will lead biomedical research in the 21st century.

## II. Defining the Intramural Research Program

Many characteristics of the Intramural Research Program are embedded in the special ways the IRP funds, reviews, staffs, and organizes a constellation of technology and talent, and fosters intellectual freedom. The main focus of the IRP is on people rather than projects, a model that other scientific organizations and programs have emulated. To that end, the IRP recruits outstanding researchers and assigns them relatively stable, state-of-the-art resources to conduct original and primarily investigator-initiated research. In most ICs, the Principal Investigators (PIs) with independent resources are clustered together by research theme into Laboratories and Branches, under the leadership of carefully chosen

Laboratory and Branch Chiefs. The research of all PIs is reviewed regularly, rigorously, and mainly retrospectively by outside experts in the form of its Boards of Scientific Counselors. To facilitate translation of laboratory findings into new approaches to prevent and cure human diseases, the IRP promotes interactions among laboratory, population-based, and clinical scientists.

The IRP has evolved with certain distinctive features that, when fully exercised should enable the scientific opportunities in Section III of this document. These include:

- A people-oriented funding process in which a critical mass of highly talented, carefully-selected PIs are allocated funds that are under their control to support high-impact, innovative, and where required, long-term research. This results in a diverse portfolio of laboratory, population-based, and clinical research.
- A prospective assignment of resources determined by Scientific Directors chosen and regularly reviewed for their ability to recognize innovative, high-impact projects. IRP leadership and individual PIs can redirect resources and change directions quickly in response to new ideas, research opportunities, and public health emergencies. Therefore, researchers are not trapped by their successes; pursuing new directions and research areas are common and encouraged.
- The NIH Clinical Center as a key element in the application of basic science to clinical challenges and responses to public health emergencies as well as a venue for fostering first-in-human clinical trials, long-term natural history studies, and the study of rare diseases.
- The embedding of the NIH IRP in the overall NIH enterprise, enabling scientific leaders to interact directly with PIs and trainees and facilitating fact-finding from leaders of other government branches and non-governmental organizations.
- An emphasis on rigorous but mainly retrospective peer review that recognizes high-impact research with appropriate adjustments of resources over time.
- An established and stable infrastructure, including cutting-edge research facilities and equipment.
- Essential services to the extramural community, such as the databases produced by the National Library of Medicine (NLM) and its National Center for Biotechnology Information (NCBI), e.g., PubMed, PubMed Central, and GenBank.
- Stringent controls on consulting and equity holdings among IRP scientists to create an environment free of financial conflicts of interest and make the NIH a trusted source of advice on biomedical research matters of national importance.
- A PI focus on research as well as mentoring of laboratory and clinical staff.
- A large population of trainees at all levels, with the major emphasis on postdoctoral training.

### III. Developing Scientific Opportunities for the Future

Although each IC has specific areas of scientific strength, the following scientific opportunities represent a subset of cross-cutting proposals made by the ICs in their long-term planning processes for the IRP (see [Appendix 7](#) for more detailed descriptions). Most of these opportunities are also being funded by various extramural mechanisms. Within the IRP, they would benefit from the scope and diversity of IRP resources, including personnel, funds and facilities.

***Precision medicine and disease prevention:*** The IRP can systematically collect multi-parameter molecular data (genomic, transcriptomic, epigenomic, proteomic, metabolomics, and microbiomic) from patient populations; identify molecular features associated with health disparities, disease progression, outcome, treatment response, and susceptibility in a shared phenotype resource; develop preventive, prognostic, and therapeutic tools based on mined data; and tap into cohorts to molecularly define disease and inform mechanisms for treatment and prevention. This endeavor capitalizes on the shared repository of phenotypic information on all of the patients seen in the Clinical Center; proximity to NCATS facilities to more quickly develop therapies with high-throughput drug and small-molecule screens for the identification of disease pathways; and proximity to numerous, world-class population studies housed within the IRP. The new emphasis on preventive medicine that will result from development of more precise predictive tools will require increased collaborations to involve pediatric patients by partnering with pediatric hospitals and programs.

***Cell-based therapies:*** The IRP can usher a new wave of cell-based therapies by combining established and maturing scientific disciplines such as immunobiology, genome engineering, and cell engineering. The IRP will expand its infrastructure for cell- and vector-production laboratories and enhance its GMP facilities, develop point-of-care stem cell harvesting technologies; and enhance stem cell differentiation and tissue regeneration with modified scaffolding. The focus will be on approaches and disease types perceived as not being commercially viable given scientific challenges or limited market potential.

***Microbiome:*** The IRP can lead mechanistic studies of microbiome function — inflammation, signaling, immune function — by building on strong and complementary strengths across the NIH IRP in immunology, immunotherapy, microbial and human genomics, cohort studies, animal model systems, and on access to well-defined patient populations in the Clinical Center. This strategy includes increased investment in germ-free facilities and the use of whole genomic sequencing of microbes to track the spread of pathogenic and drug-resistant organisms.

***Drug resistance:*** Antimicrobial resistance is among the greatest threats to public health facing us today. The IRP is well positioned to take on this public health emergency, and indeed the program already has mobilized its talent to respond to and manage an outbreak in the Clinical Center of carbapenem-resistant *Klebsiella pneumoniae*, for which IRP scientists used genome sequencing to quell the spread. Through in-depth genetic and physiological analysis to identify novel targets, and high-throughput screening at NCATS to

find new antibiotics and anti-cancer drugs, the IRP will create next-generation antibacterial drugs that target the Achilles' heel of highly drug-resistant pathogens and cancers. The IRP's genomic and proteomic diagnostic tools already in development will help hospitals that have outbreaks of multidrug-resistant organisms by enabling the use of organism-selective antibiotics rather than the broad-spectrum agents in current use.

***RNA biology and therapeutics:*** The IRP can take a leadership role in the development of a comprehensive program for the investigation and therapeutic exploitation of RNA, including antisense therapy, RNA interference, and RNA silencing. The goal is to capitalize on the IRP's solid foundation in genetics and molecular biology to (a) systematically map the RNAome in health and disease — that is, perform genome-wide sequencing of mRNAs and unconventional RNAs and combine this with the IRP's "genomic medicine" data collection, and (b) elucidate RNA structures to develop new clinical targets.

***Vaccines:*** The IRP has contributed to about half of all FDA-approved vaccines currently in general use, possessing expertise across the broad spectrum of the vaccine development process, including basic immunology, molecular and structural biology, immunopathogenesis, bioinformatics, genomics, preclinical testing, vaccine production, and conduct of clinical trials. The IRP will continue to develop an effective vaccine or other immune modulator for prevention and treatment of HIV/AIDS and other high-burden diseases, such as respiratory syncytial virus, dengue, malaria, and tuberculosis, as well as biodefense threats and emerging and re-emerging infectious diseases including influenza, filoviruses (Marburg and Ebola), chikungunya, and MERS coronavirus.

***Neuroscience:*** In this era of the Presidential BRAIN initiative for brain research, the NIH IRP is properly positioned to combine the forces of all its neuroscience-related programs: neurogenetics, aging, addiction, mental health, neurodevelopmental and neurodegenerative diseases, infectious diseases, sensory organs, pain perception and modulation, environmental science, and cancer. There likely will arise core-enabling themes, such as neuroscience of non-human primates, big data, brain bank, human genetics, PET imaging (including radiotracer development), neuroplasticity of chronic pain, sleep, and the neurobiology of obesity and appetite.

***Inflammatory diseases:*** Most of the NIH ICs are involved in studies for which inflammation is a common denominator. With its deep trove of immunologists, rheumatologists, and cancer biologists, the IRP continues to make major contributions to the characterization and control of inflammatory processes. The NIH Center for Human Immunology (CHI), a consortium of several NIH institutes, already has begun to make inroads on detailed molecular definition of conditions that affect the immune system, and we will continue on this successful path.

***Clinical and molecular imaging:*** The IRP has invested in infrastructure to diagnose and stage diseases utilizing nucleotide technologies, spectroscopy, and NMR in the Clinical Center's Laboratory Medicine and PET departments. The IRP also has shared IC facilities in neuroimaging and optogenetics, including investment in new cutting-edge imaging technology- scanners, high-field MRI for human brain imaging, combined PET/fMRI, large

MRIs for obese patients, and additional capacity for the development of new radioligands for PET. In its 10-year vision, the IRP will develop targeted probes, new bioengineering approaches for brain imaging, new methods for imaging as a surrogate biomarker, new non-invasive measurements, and fast, 3D microscopic imaging. The IRP has a world-class cohort of investigators who are moving the state-of-the-art to visualize molecules at the cellular level, which promises to be an area of exceptional contributions from the IRP in years to come.

***Computational and structural biology and tools:*** The IRP is home to the National Center for Biotechnology Information of the NLM, which provides foundational resources for biomedical science, including PubMed, PubMed Central, GenBank, PubChem, dbGaP, The Genetic Testing Registry, BLAST, and other indispensable research tools. These core capabilities are essential both for (a) the conduct of biomedical research in government laboratories, academic research centers, universities, and industry, and (b) the clinical care of patients. NCBI will continue to foster such collaborations and develop novel computational methods and tools for harvesting and organizing knowledge from a complex array of data sources. Its ssDNA-seq, a new experimental technology that first appeared in 2013, is one such futurist tool for mining data from which the entire research community can benefit. The IRP will work with its NIH partners on big data approaches and computational capacity that are essential for support of a robust program of structural biology, genomic analysis, and clinical and cellular imaging.

***Natural products:*** The IRP can contribute to a national program for natural products discovery for new molecules that target biological processes central to human disease, including a comprehensive Natural Products Library that includes pre-fractionated compounds for modern high-throughput targeted screening technologies and a public database and bioinformatics platform to integrate source organism, activity, structural, and genomic data.

***Animal modeling:*** The IRP can apply its distinctive program of animal models to facilitate translation of research findings into the clinical setting. Animal models include genetically engineered non-human primates, germ-free mice, zebrafish, and new models for integrating human biology and behavior. The IRP will also engage in a needs assessment and planning process to assess its animal research needs, including a proposed centralized vivarium adjacent to the NIH Clinical Center. The IRP's existing high containment facilities provide opportunities to assess new vaccines and therapeutics for many high-risk infectious agents using novel and known animal models. The IRP also will create a CRISPR core for making transgenic animals.

Many of the scientific visions elaborated by the ICs involve taking advantage of several of these cross-cutting opportunities. For example, the NCCAM pain initiative will draw heavily on animal modeling, studies on inflammation, clinical imaging, and neuroscience activities. Many of these initiatives involve clinical components which depend on a vital and stably supported Clinical Center.

## **IV. Issues and Challenges for the IRP as Part of the Overall Biomedical Research Enterprise**

**A. Sustaining the NIH Clinical Center:** There is agreement at the NIH that the Clinical Center is at the heart of the IRP and that it must be sustained as a critical component of the IRP. This view is shared by the NIH Director, IC Directors, SDs, the NIH Advisory Board for Clinical Research, and the Clinical Center Governing Board. However, there are significant issues associated with clinical research at the NIH, both at the CC and at other NIH IRP sites, which need attention.

The 2010 SMRB Working Group report ([Appendix 6](#)) recommended the establishment of the Clinical Center Governing Board (CCGB) to strengthen governance of clinical research. Subsequent steps have improved the overall climate for clinical research and intensified review of the CC budget. Nonetheless, budgetary management of the CC continues to be challenging, given the continuing inflation of health care costs. There is still need for ICs to strengthen the review and prioritization of clinical protocols conducted at the CC to assure the greatest impact and highest quality and appropriate attention to use of CC resources.

To assure that clinical research at the CC remains cutting edge, the ICs need to be able to recruit the most talented clinical investigators; this is being addressed by development of a career track, including the entry level independent position of Assistant Clinical Investigator and the still evolving tenure-track NIH-Lasker Clinical Research Scholars program.

Many of the areas of scientific opportunity described in Section III depend on a robust NIH CC ([Appendix 8](#)). Therefore, it is essential that the CC budget, as deemed appropriate by the CCGB and the NIH Director, be supported through fair contributions from the ICs, currently assessed by a “school tax” reflecting the size of each IC’s intramural program. Further steps should be taken to ensure consistently rigorous review of protocols that make extensive use of CC resources. Review should remain IC-based, but involvement of the IC Scientific Directors and CCGB in the development of consistent review standards is needed. Strengthened assessment, under guidance of the CCGB, is also needed to ensure alignment of services and space in the CC with the scientific priorities of the ICs.

NIH intramural scientists, including CC researchers, collaborate extensively with extramural colleagues through informal means and more formal cooperative agreements (U01s). The Bench-to-Bedside (B2B) Award Program in the CC established a model to encourage applications from bench and clinical scientists across NIH and from the extramural community to develop novel translational research opportunities. Now the Clinical Center's Opportunities for Collaborative Research (U01) Program represents the next generation of approaches to form teams of scientists (including extramural collaborators) who don't usually work together. The purpose of the U01 Program is to enhance utilization of the CC with outstanding collaborative clinical intramural-extramural science. It is not another B2B program.

Because of rules governing appointments at the NIH, it is difficult for an NIH scientist to interact freely with colleagues at academic medical centers. It is recommended that NIH develop a partnering network that would allow seamless movement of faculty, students, and patients among the various hospitals and academic centers in the Washington, D.C. area, and potentially, throughout the country. The core of this network could be faculty appointments both at the NIH and elsewhere. Careful attention to intellectual property issues, conflict-of-interest concerns, and continued high ethical standards expected of all government employees would be essential, so the terms and conditions of outside appointments of NIH scientists would need to be clearly delineated.

***B. Recruitment and retention of talented investigators and trainees in the IRP:*** One of the most important distinctive features of the IRP is the presence of more than 1,000 principal investigators, including tenure-track and tenured investigators, with a wide range of talents and interests (see [Appendix 9](#)). This makes possible immediate and productive collaborations when specific research problems arise at the NIH. The answer to most problems is across the hall, down the stairs, or across the street. The accelerating effect of this critical mass on productivity in science must not be underestimated. But because the IRP is losing 5 percent of its PIs per year as a result of less-than-excellent BSC reviews, funding limitations, retirements, and departures for career advancement — and losing an even greater percentage of our trainee population, a critical element of its success — it is conceivable that sometime in the next 10 years the number of scientists will fall below a level needed to support essential activities such as translational research in the CC, or specific scientific priorities. To compensate partially for the annual loss of PIs, the IRP hires new PIs, so that there is net loss of 2-3% of PIs annually. Nevertheless, the IRP needs a plan to stabilize the population of PIs at a level that reflects resource availability yet still maintains a needed mass of scientific talent, with an emphasis on trans-NIH recruitment of tenure-track investigators such as those represented by the highly successful Stadtman and fledgling Lasker Clinical Research Scholars programs. Efforts are underway to apply phased retirement and other retirement incentives to create opportunities for early- and mid-career scientists.

The IRP depends on a diverse, dynamic workforce of talented trainees and scientists at all career levels, from senior PIs, to Staff Scientists and Staff Clinicians, to postdoctoral fellows, and to trainees at various levels of their development. If the IRP fails to recruit and retain highly qualified, competitive candidates and fill vacant positions in a timely manner, then the otherwise talented NIH IRP workforce will not include entry-level recruits to meet its mission and vision, and the institution could face mediocrity and decline. New recruits may, however, be unwilling to entertain government positions for various reasons, including inefficiencies in hiring practices, real or perceived barriers to career development, restrictive government ethics and travel rules, and insufficient resources to support their research. The NIH currently competes successfully in providing comparable pay for fellows and early career investigators compared with outside positions, but it frequently cannot compete at senior scientist levels. These disincentives to careers at the NIH lead to the need to identify other advantages of being employed at the NIH to attract and retain top researchers for the future, such as little or no requirement to write grants, freedom to pursue innovative research of the investigator's choosing, and relatively stable

resources. All flexibilities in hiring should be pursued including partnerships with neighboring institutions and hiring select scientists by the Foundation for the NIH (FNIH) as recommended by the IOM in 1988.

Even in this time of tight budgets, promoting diversity and inclusion in the biomedical research workforce must continue to be a priority. A growing body of literature indicates that teams of diverse individuals tend to outperform teams of homogeneous individuals in solving difficult problems. Therefore, promoting diversity and inclusion is expected to contribute significantly to the ability of the NIH IRP to sustain its capacity to make distinctive contributions to biomedical research, even in the face of reduced buying power. NIH has a large but not particularly diverse staff, mirroring the situation in academic medical centers across the country (see [Appendix 10](#)). It is essential that the factors that lead to lack of diversity be identified and efforts made to correct this serious deficiency. NIH has invested extensively in training programs at all levels for both laboratory-based and clinical investigators that increase the pool of eligible women and under-represented minorities (see [Appendices 11, 12](#), a proposal to increase diversity in [Appendix 10](#), and individual reports of the ICs in [Appendix 13](#)), and has initiated trans-NIH recruitments such as the Stadtman tenure-track investigator search that are beginning to demonstrate progress in diversifying the NIH workforce.

The proposal in [Appendix 10](#) addresses some of the major factors that contribute to the lack of diversity in the biomedical workforce: (1) Inadequacy of mentoring; (2) Poor functional communication among NIH entities that are involved in training, recruitment, hiring, and retention of scientists, and between NIH leadership and members of under-represented groups; and (3) Poor evaluation of existing programs to allow determination of best practices. The recent creation of the position of Chief Officer for Scientific Workforce Diversity and the recruitment of a nationally recognized scientist and diversity expert offers some new hope that an infusion of new ideas and energy can make a significant difference. One important, additional approach will be partnering of the IRP with faculty, students, and institutions that are more diverse through participation in the NIH's Building Infrastructure Leading to Diversity (BUILD) and National Research Mentoring Network (NRMN) programs. BUILD provides research opportunities for students from non-research intensive institutions [<http://commonfund.nih.gov/diversity/>].

Very important components of the NIH workforce are the Staff Scientists and Staff Clinicians who support much of the research in the labs and clinics at the NIH. Individuals in both of these categories are on time-limited appointments, subject to performance standards and programmatic need. A recent review of Staff Clinicians at the NIH recommended a variety of ways to enhance the recognition and review of these critically important personnel, and these recommendations have been implemented. A similar approach needs to be taken to provide recognition and review of our Staff Scientists.

Training the next generation of leaders is an important part of the IRP mission. The IRP is responsible for as many as 10-15% of Ruth Kirschstein NRSA-supported post-doctoral fellows. The IRP addresses the national need for a well-trained scientific workforce by

sponsoring internships and training opportunities for students at all educational levels, including high school and college students, recent college graduates, graduate students, professional students, and postdoctoral fellows in laboratory and clinical research. (see [Appendices 11, 12](#))

The largest, but decreasing, group of doctoral-level scientists at the NIH is post-doctoral fellows. As with other academic medical centers, these fellows are chosen after application to individual laboratories at the NIH without a vetting process at the IC leadership level. Consequently, there is no information about the diversity of the pool from which they are chosen and currently, no central information about the characteristics of these fellows other than their being U.S. citizens, permanent residents, or visiting fellows. A new tracking system, created in partnership with the system being developed for tracking all NIH-supported trainees, will be put in place to follow these fellows throughout their careers. In addition, each IC should make an effort to assure that the diversity of these fellows reflects the diversity of the pool of qualified candidates.

***C. Review of Intramural Science:*** A rigorous, multilevel intramural peer review process that is largely retrospective has evolved to ensure that the mission of the Intramural Research Program is fulfilled. This process has demonstrated repeatedly that research in the IRP is competitive and has assured the highest quality of research and training. This specially tailored review process depends on external peer review panels of scientific experts, or Boards of Scientific Counselors (BSCs), who review each intramural principal investigator every 4 years. The BSCs are chartered under the Federal Advisory Committee Act. They thus have the same status as the extramural review panels or study sections. Reviews are overseen by the Office of Intramural Research, Office of the Director, and the National Advisory Councils or Boards. Reviewers comment on methodology, budget, timeliness, and originality of the research, and Scientific Directors use these reviews to increase or decrease resources, or to close non-productive laboratories. Reviews are mainly retrospective, reflecting the past success of scientific staff, but also prospective, projecting new projects and ideas. A survey in 2013 indicated that 62% of senior investigators were fully outstanding, but 17% were less than fully excellent. In response to BSC reviews, 27 of more than 220 laboratories reviewed in 2013 were closed or recommended for closure and 14 additional laboratories were downsized by more than 30%.

A key feature of intramural research is the selection of the most talented researchers through an extensive national/international search process that is also overseen at the level of the Office of Intramural Research. Each of the 24 ICs with an intramural program has an SD, who is responsible for assignment of resources based on the search and review processes. The performance of SDs is reviewed by outside, expert committees every 4–6 years. Finally, an overall review of the quality, productivity, innovation, and impact of each IC's intramural program is conducted by a separate external Blue Ribbon Panel approximately every 10 years. The recommendations of these reviews are reported to the IC Director, the Deputy Director for Intramural Research, and the NIH Director to guide changes needed for the future.

As stated, one core IRP principle is the belief in visionary science and the funding of people, not projects. This should begin with the IC Directors, the SDs, and their deputies and Laboratory and Branch Chiefs. The SDs are chosen by IC Directors for their commitment to visionary science and their ability to select/recruit individuals and projects to pursue that vision, as well as their ability to manage complex research programs. IC Directors and SDs must encourage their scientific staff to conduct innovative research, and a history of success in this domain should be acknowledged by the BSCs. The NIH as a community must provide an environment that mitigates risk so that the best ideas can succeed. Taking intellectual risks must be accompanied by a greater tolerance for failure, particularly for those early-career scientists on the tenure track. The BSCs must be convinced to help the IRP demand a greater amount of innovative, high-impact research in its research portfolio, balanced with high-quality, scholarly, systematic studies. Some of the processes needed to encourage more innovative science include:

- incentives that encourage investigators and scientific teams to undertake projects with a risk of failure but potentially high-impact, including funds in each IC for high-risk, high-priority projects;
- encouragement to undertake visionary, long-term projects that take advantage of the relatively stable support in the IRP;
- procedures that link innovative projects to resources and promotions;
- tools to monitor the progress of this action and clearly determine success and failure; and
- leadership that strongly affirms the scientific value of failing to confirm an hypothesis, as long as: (a) the underlining hypothesis was sound, (b) the technical implementation of the project had no major flaws, and (c) every effort was made in the design stage to detect failure early in the process.

***D. New models for funding research:*** The IRP Scientific Directors and Institute and Center (IC) Directors have concluded that an essential element assuring both creative and high-quality science in the IRP is a healthy balance between investigator-driven and collaborative team science in a collegial culture. Investigator-initiated science and team science are not necessarily mutually exclusive; oftentimes, individual investigators work together in teams of two or more to pursue ideas that are the result of a shared scientific vision. Some of the teams at NIH are generated by programmatic need, for example in the areas of population-based studies, vaccine development, the National Toxicology Program, or in the development of specific diagnostics or therapeutics such as what occurs at NCATS and other ICs. For some investigator-initiated projects, a mechanism is often needed to amplify the impact of the research by expanding the resources of an individual program or by engaging collaborators within the NIH IRP, in the extramural community, or both. It is difficult, if not impossible in some instances, for very successful individual investigators in the IRP to assemble the resources to do this.

New ways to incentivize collaboration and team science are needed to facilitate the formation of future research teams that transcend Institute boundaries. One approach

would be the formation of a central, NIH-wide pool of funds or shared funds within groups of ICs, for which investigators wishing to form collaborative groups could apply to incentivize selected research projects or aid in recruitment. These funds could be derived from the OD, individual ICs, or the IRP, preferably if and when these budgets begin to increase. A current modest fund of \$1.5M in the Office of Intramural Research has been very effectively used to encourage trans-NIH science and augment and supplement budgets within individual institutes. The creation of the Intramural AIDS Targeted Antivirals Program years ago through specific Congressional action had the effect of stimulating intramural investigators to apply their expertise in structural biology and cell biology to the area of AIDS research. Such a funding mechanism would also facilitate recruitment of diverse scientists to support the areas of scientific emphasis detailed in [Appendix 7](#). The NIH has a well-established system of Scientific Interest Groups, NIH faculty who join together across Institute boundaries who share common scientific interests or technology. These groups supporting areas of research emphasis could be encouraged to develop trans-NIH research projects, help recruit new talent, and provide advice to the SDs about future research directions.

Under special circumstances, ICs may set aside funds to enable expansion of particularly important research. For some laboratory investigations, and for most clinical investigations, research may be best conducted in teams. While this is easily established within the NIH IC-based lab/branch structure, it is not so easy to accomplish across ICs. Teams must be able to form and disperse in response to scientific opportunities (as seen historically in the great genetic code race of the 1960s and more recently in the set of high-resolution optical imaging breakthroughs realized by several research laboratories). NCATS, a new intramural program, has organized entirely into cross-functional collaborative teams, without independent investigators, to achieve its goal of catalyzing innovative methods and technologies that will enhance development of innovative diagnostics and therapeutics. Note that for scientists whose work is predominately associated with teams, appropriate recognition of accomplishments is critical, including team awards and promotions as appropriate, including tenure. Many of these issues are discussed in detail in a publication from the NIH entitled “Collaboration and Team Science: A Field Guide” (<http://teamscience.nih.gov>).

***E. Increase sharing of resources and inter-institute interactions at the NIH:*** A variety of trans-NIH shared resources and common infrastructure ([Appendix 14](#)) and the availability of collaborative opportunities have significantly ameliorated a tendency for each NIH IC to retreat into silos. One of the IRP’s strengths is its critical mass of expertise in close proximity, where science benefits by the melding of multiple IC missions and expertise. The new John Edward Porter Neuroscience Research Center on the NIH Bethesda campus, with more than 80 scientific groups from 10 ICs in an expansive and open lab space, reflects this commitment to integrated inter-institute interactions in areas such as neurogenetics, neuroimmunology, and neurovirology. Joint appointments across ICs also increase such synergy. A survey of current facilities with some extra capacity as well as agreements among ICs to facilitate sharing of facilities — such as a new optogenetics facility, germ-free mouse facilities, and human genomic sequencing facilities — has led to many new research opportunities, especially for the smaller IC-based

intramural programs. This is the right direction. In addition to sharing research resources, ICs should increasingly form service centers that optimize administrative support and avoid duplication of administrative support services among ICs.

There is a notion shared by some, even within the NIH, that the IRP is cut off from many productive interactions with extramural colleagues and industry. In fact, IRP collaborations with academia and industry are extremely common nationally and internationally. Cooperative Research and Development Agreements (CRADAs) and the Transfer Agreement Dashboard (TAD) are two collaborative mechanisms that IRP scientists exploit. There are, however, few well-advertised mechanisms that specifically support and encourage research teams that include both intramural and extramural investigators. As new research opportunities arise, consideration should be given to the development of more cooperative agreements (U01s) that include intramural scientists.

The NIH has an extensive technology transfer community in its ICs that is engaged in reviewing patents and licensing inventions, developing various cooperative agreements with industry, and spearheading new approaches that leverage NIH investments with those of the private sector. Sales of NIH licensed products by the private sector were \$7B in FY 2013. The licenses, patents, and royalties received by the NIH as a result of technology transfer activities over the past few years are shown in [Appendix 15](#). A recent extensive review of the NIH Office of Technology Transfer has catalyzed a major reorganization of the distribution of responsibilities to align the full range of technology transfer activities, including patenting and licensing, with a limited number of IC-based technology transfer offices in order to encourage more creative approaches to public-private partnerships at the NIH.

The IRP's distinctive features can be harnessed to pilot important programs of national importance. The NIH IRP already has provided essential services of value to the entire biomedical community through the NCBI and Clinical Center activities. Another domain in which the IRP can provide value is by piloting programs as potential models for recruiting a diverse workforce, training the next generation of scientists, and creating teams to explore disease pathogenesis and solve next-generation problems in developing drugs and therapeutics. For example, following the success of the NIH's Undiagnosed Disease Program (UDP), this program was propagated to extramural sites using Common Funds. Continued effort should assure availability of IRP-developed reagents, animal models, and special resources.

Finally, over the past 10 years, the NIH SDs have developed a model for developing and managing shared resources known as the Shared Resources Subcommittee (SRS). This approach generally involves extensive discussion and concurrence of the need for a shared resource, the development of a funding model that usually involves an agreement for all ICs to share 25% of the total cost of the facility with the remaining 75% funded on a fee-for-service basis, and the annual review of the performance and budget of the shared resource (see [Appendix 14](#) for a list of current shared services). This approach has proved very effective and should be expanded as needed. Individual ICs that have developed core resources with excess capacity are willing to make these available to scientists across the

NIH, and a better system for reimbursement of expenses needs to be developed. Groups of ICs that share a common research interest, such as the neuroscience institutes, also should pool resources to allow shared recruitment, equipment purchases, and administrative support.

***F. Efficiency of Operations:*** Because of the increasing relative cost of administrative and central services at the NIH compared to expenditures related directly to science, there needs to be full transparency in the management budget process, with expenses broken out as line items to the extent possible, especially for all central services, including the NIH Office of Research Services (ORS) and Office of Research Facilities (ORF). Currently, effective management is addressed by having an internal, customer-focused review of NIH central administrative services. More client representation on advisory and budget committees dealing with management and central services would be useful, as would inclusion of representatives of the scientific community on a planning process with the Deputy Director for Management and the NIH Executive Officers.

There is an urgent need to find more effective ways to deal with the current travel rules, specifically those related to efficient spending, and to document the added administrative burden required in order to comply with the rules. The current travel policies are already becoming a recruitment and retention issue for the IRP.

Given that finding new efficiencies requires some effort, one recommendation is to create incentives to find efficiencies (e.g., for every dollar in savings, a portion would go back to the ICs for re-purposing).

The NIH physical plant is valued at \$5-\$10 billion and funding available to maintain and renovate research facilities is barely adequate. Efforts should be made to free up additional facilities funds by consolidating intramural staff spread in the Bethesda area in off-campus leased facilities back to the main campus as leases expire.

Another important tool for efficient management of intramural funds would be legislative authority to allow carry-over of funds from year to year to support long-term research projects and provide flexibility to allow alignment of expenditures with priorities.

Many of the same issues identified in this report were also identified in a report prepared by the NIH Assembly of Scientists, who represent the full spectrum of researchers in the NIH IRP ([Appendix 16](#)). Their thoughtful recommendations encompass most of the same themes identified above, and emphasize the need for more creative approaches in recruiting researchers, especially entry-level junior researchers; in addressing travel restrictions and reporting; in promoting multidisciplinary team research; and in assuring that independent resources are allocated to individual principal investigators.

### **Summary of Possible Approaches to Issues and Challenges**

- Stable funding for the Clinical Center aligning CC resources with IC research priorities;

- Continued support for cooperative agreements (U01s) to allow extramural-intramural collaboration in the CC;
- Development of partnerships with local academic centers to encourage joint recruitments of clinical investigators to enhance both short- and long-term scientific endeavors;
- Use of flexible hiring tools to recruit talented scientists to the NIH, including the possibility of FNIH-supported appointments;
- Multidimensional approaches to improving recruitment, retention, and inclusion of a more diverse scientific workforce;
- Sustain a research environment that encourages highly innovative, high-impact research by appropriate recruitment, review processes that align with this goal, and rewarding meritorious high-risk science despite outcome;
- Incentivize trans-NIH recruitments and collaborative and team science with resources, both central and IC-specific;
- Expand current shared resources and accessibility of cores across the NIH;
- Seek legislation to carry over research funds from one fiscal year to the next;
- Improve efficiency of administrative services such as hiring and travel procedures; improve transparency of administrative processes; as leases expire and space becomes available, bring scientists back to main campus.

## Appendix 2

### Intramural Research Program Personnel Designations

#### Full-Time Equivalent (FTE) NIH employees:

**Scientific Director** – each Institute and Center (IC) with an intramural research program has a Scientific Director (SD) who oversees research within that program. The SD is a highly accomplished scientist chosen by a national/international search conducted by the IC Director to whom the SD reports. Authority to manage intramural resources and administration is delegated by the IC Director to the SD, who also is a member of the Board of Scientific Directors convened by the NIH Deputy Director for Intramural Research (DDIR).

#### 5 Levels of Principal Investigators (PIs):

Have independent research resources and are reviewed by Boards of Scientific Counselors (BSC), if appointments are for 4 years or more

**Senior Investigator** – PIs who have achieved tenure at NIH. Since 1994, when the NIH Central Tenure Committee (CTC) was established, candidates for tenure are reviewed by the CTC whether they are more established (recruited through the required DDIR-approved national/international search and committee) or from the NIH tenure track and approved by the DDIR. Since 1994, the CTC has reviewed 645 cases of which 73% were from the tenure track and 27% directly from national/international searches. 90% of the cases from the tenure track that are reviewed by the CTC achieve tenure (although the overall tenure rate from the tenure track is 67%, failure is mostly at the BSC review level). 93% of the cases directly from national/international searches reviewed by the CTC achieve tenure. Tenure in the NIH IRP includes assurance of continuing salary even if scientific resources are cut back. The amount of research support, however, must depend on the quality of science as determined by the BSC and other reviews.

**Investigator (tenure-track)** – all Investigator positions require a DDIR-approved national/international search and committee and DDIR approval of the selected individual. Investigators doing research not involving human populations have a maximum of 7 years to achieve tenure. Investigators doing clinical or other human population research have a maximum of 9 years to achieve tenure. Investigators are generally reviewed twice by the BSC during their tenure track.

**Senior Clinician** – is manager of a large clinical IC program/department with responsibility for substantial resources. Although Senior Clinicians do not have tenure in the IRP, all Senior Clinician positions require a DDIR-approved national/international search and committee, review and recommendation of the selected individual by a DDIR-chaired committee of Scientific Directors and IC Directors, and DDIR approval.

**Senior Scientist** – is manager of a large IC program/department with responsibility for substantial resources. Although Senior Scientists do not have tenure in the IRP, all Senior Scientist positions require a DDIR-approved national/international search and committee, review and recommendation of the selected individual by a DDIR-chaired committee of Scientific Directors and IC Directors, and DDIR approval.

**Assistant Clinical Investigator** – is a temporary PI position designed for clinicians to build an independent research portfolio to be highly competitive for tenure-track positions at NIH or outside. The position may last for a maximum of 5 years. A national/international search and approval of the selected candidate by the DDIR is required.

**Non-PI Positions:**

Have no independent resources

**Staff Clinician** – is a physician or dentist who spends a majority of her/his time providing critical patient care services and training of Clinical Fellows, but who may also be the principal investigator on clinical protocols, under the supervision of a PI (above). Staff Clinicians may manage research resources but these are under the purview of a responsible PI.

**Staff Scientist** – is a doctoral level scientist selected by the IC to support the long-term research of a PI or as a member or head of a core facility. Staff Scientists do not receive independent research resources, although they often work independently and have sophisticated skills and knowledge essential to the work of the laboratory. Staff Scientists are capable of independently designing experiments, but do not have responsibilities for initiating new research programs.

**Clinical Fellow** – is a doctoral-level health professional with interest in biomedical research relevant to NIH program needs, who is employed on a time-limited appointment. Clinical Fellows participate in protocol-based clinical research as well as laboratory research. Scientists with considerable experience beyond postdoctoral training (PGY-9 equivalent or beyond) may be designated Senior Clinical Fellow provided they fulfill the competitive selection requirements.

**Research Fellow** – is an NIH scientist with a doctoral degree employed on a time-limited appointment. Research Fellows provide service relevant to the IC's program needs. Scientists with more than 10 years of postdoctoral training mostly outside NIH may be designated Senior Research Fellow.

**Non-NIH Employees:**

**Training Authorities:**

The NIH IRP has two training authorities that do not require FTE positions: the Intramural Research Training Award (IRTA, denominated CRTA at NCI) and the Visiting Fellowship (VF) program. The IRTA is for US citizens and US permanent residents. The VF program is for foreign nationals on visas.

**Postdoctoral IRTA/CRTA/VF** – must start at NIH within less than 5 years of receipt of their last doctoral degree and may remain in a non-FTE capacity at NIH for no more than 5 years.

**Predoctoral IRTA/CRTA/VF** – are graduate students enrolled as doctoral candidates at a university who conduct at least part of their doctoral dissertation research in the IRP in partnership with the university.

**Post-Baccalaureate IRTA/CRTA** – must start at NIH within 2 years of receipt of their Bachelor’s degree and conduct research full time in an IRP laboratory for a maximum of two years, during which they are required to apply to graduate or professional school for their next career step.

**Technical IRTA** – individuals who either have a Master’s degree or whose Bachelor’s degree was received longer than two years before arrival at NIH who pursue training and education for 3 years to become a laboratory technician.

#### **Volunteer Authorities:**

**Special Volunteer** – are individuals who provide research services, direct patient care, clerical support, technical assistance, or any other necessary services for NIH. Special Volunteers are not financially compensated by the NIH for their activities or services.

**Guest Researcher** – are scientists, engineers, and students who are permitted to engage in scientific studies and investigations using NIH facilities. Guest Researchers further their own research by using equipment and resources that are otherwise unavailable to them. They provide no direct services to NIH. They may not have any patient contact. Guest Researchers are not financially compensated by the NIH for their activities.

**On-site Research Collaborator (RC)** – include but are not limited to scientists, engineers, physicians and other scientific or health care providers who are engaged in research collaborations with the NIH intramural research program (IRP) staff and are authorized by NIH to engage in scientific studies and investigations with IRP staff using NIH facilities. RCs further collaborative research projects with NIH by interacting with IRP investigators and utilizing equipment and other resources located within NIH IRP facilities that are otherwise unavailable to or not easily accessible by them. RCs cannot be financially compensated by the IRP for their collaborative efforts, but they may be recipients of extramural NIH grants and fellowships, and they may receive funds from commercial collaborators (for instance, as part of a Cooperative Research and Development Agreement) or other sources outside of NIH.

#### **Other Personnel Mechanisms:**

**Contract Workers** – ICs may hire staff on contract following Federal procurement regulations and HHS policies.

# Appendix 3

## Intramural Research Program Personnel Demographics

### IRP Principal Investigators

#### IRP Principal Investigators by Gender

Intramural Professional Designation (IPD)	Total	Females	Males
Senior Investigator <sup>1</sup>	843	169 (20%)	674 (80%)
Investigator (tenure-track) <sup>1</sup>	222	83 (37%)	139 (63%)
Senior Clinician <sup>1</sup>	19	7 (37%)	12 (63%)
Senior Scientist <sup>1</sup>	45	14 (31%)	31 (69%)
Lab/Branch Chief (not a separate IPD, included in SrI, SrC or SrS above) <sup>2</sup>	270	46 (17%)	224 (83%)
Scientific Director (may be included in an IPD above) <sup>3</sup>	26	4 (15%)	22 (85%)
Assistant Clinical Investigator <sup>1</sup>	37	19 (51%)	18 (49%)
Staff Clinician <sup>4</sup>	221	109 (49%)	112 (51%)
Staff Scientist <sup>4</sup>	1332	497 (37%)	835 (63%)
Clinical Fellow/Senior CF <sup>4</sup>	294	158 (54%)	136 (46%)
Research Fellow/Senior RF <sup>4</sup>	614	257 (42%)	357 (58%)

#### IRP Principal Investigators by Race/Ethnicity

IPD	White/Not Hispanic	Am. Indian/ Alaska Native	Black/Not Hispanic	Hispanic	Asian/Pacific Islander	Foreign Nationals	Total
Senior Inv. <sup>1</sup>	678 (80%)	1 (0.1%)	13 (1.4%)	29 (3.4%)	119 (14%)	3 (0.3%)	843
Investigator <sup>1</sup>	128 (58%)	1 (0.4%)	3 (1.4%)	8 (3.6%)	67 (30%)	15 (6.7%)	222
Sr. Clinician <sup>1</sup>	15 (79%)	0	0	2 (10.5%)	2 (10.5%)	0	19
Sr. Scientist <sup>1</sup>	36 (80%)	0	3 (6.7%)	0	5 (11%)	1 (2.2%)	45
Asst. Clin. Invest. <sup>1</sup>	24 (65%)	0	3 (8%)	2 (5%)	4 (11%)	4 (11%)	37
Lab/Br. Ch. (not a separate IPD) <sup>2</sup>	231 (85%)	0	7 (2.6%)	11 (4.1%)	21 (7.7%)	0	270
Scientific Director <sup>3</sup>	25 (96%)	0	1 (4%)	0	0	0	26

Data source: <sup>1,3</sup>Office of Intramural Research (OIR), 4/1/2014; <sup>2</sup>From ICs, collected by OIR/OEDI, 9/30/2013; <sup>4</sup>Office of Equity, Diversity and Inclusion (OEDI) from nVision, 9/21/2013

#### IRP Principal Investigators by Disability Status

Data Source: Office of Equity, Diversity and Inclusion (OEDI), 10/1/2013; Targeted is a subset of Reportable Disability

Title		Total	Not Identified	No Disability	Reportable Disability	Targeted Disability	Unknown
SENIOR INVESTIGATORS	#	850	59	746	44	4	1
	% of Total	100.0%	6.9%	87.8%	5.2%	0.5%	0.1%

Title		Total	Not Identified	No Disability	Reportable Disability	Targeted Disability	Unknown
INVESTIGATORS	#	227	4	213	8	0	2
	% of Total	100.0%	1.8%	93.8%	3.5%	0.0%	0.9%

Title		Total	Not Identified	No Disability	Reportable Disability	Targeted Disability	Unknown
SENIOR CLINICIANS	#	19	0	18	1	0	0
	% of Total	100.0%	0.0%	94.7%	5.3%	0.0%	0.0%

Title		Total	Not Identified	No Disability	Reportable Disability	Targeted Disability	Unknown
SENIOR SCIENTISTS	#	44	0	40	4	1	0
	% of Total	100.0%	0.0%	90.9%	9.1%	2.3%	0.0%

Title		Total	Not Identified	No Disability	Reportable Disability	Targeted Disability	Unknown
ASSISTANT CLINICAL INVESTIGATORS	#	36	0	35	1	0	0
	% of Total	100.0%	0.0%	97.2%	2.8%	0.0%	0.0%

## Staff Clinician Workforce

### NIH-Wide Staff Clinicians by Sex

Sex	#	% of Grand Total
FEMALE	109	49.3%
MALE	112	50.7%
<b>Grand Total</b>	<b>221</b>	<b>100.0%</b>

### NIH-wide Staff Clinicians by Race/Ethnicity and Sex

Sex	WHITE/NOT HISP		BLACK/NOT HISP		HISPANIC		ASIAN/PACIF IS		AM-IND/ALASKA NATIVE		Total	
	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Grand Total
FEMALE	70	31.7%	6	2.7%	4	1.8%	28	12.7%	1	0.5%	109	49.3%
MALE	84	38.0%	2	0.9%	2	0.9%	24	10.9%	0	0.0%	112	50.7%
<b>Grand Total</b>	<b>154</b>	<b>69.7%</b>	<b>8</b>	<b>3.6%</b>	<b>6</b>	<b>2.7%</b>	<b>52</b>	<b>23.5%</b>	<b>1</b>	<b>0.5%</b>	<b>221</b>	<b>100.0%</b>

### NIH-Wide Staff Clinicians by Disability Status

Targeted is a Subset of Reportable Disability					
Disability Status	Not Identified	No Disability	Reportable Disability	Targeted Disability	Total
<b>Grand Total</b>	<b>3</b>	<b>207</b>	<b>11</b>	<b>3</b>	<b>221</b>
<b>% Grand Total</b>	<b>1.4%</b>	<b>93.7%</b>	<b>5.0%</b>	<b>1.4%</b>	<b>100%</b>

Source: nVision as of 9/21/2013

## Staff Scientist Workforce

### NIH-Wide Staff Scientists by Sex

Sex	#	% of Total
FEMALE	497	37.3%
MALE	835	62.7%
<b>Grand Total</b>	<b>1332</b>	<b>100.0%</b>

### NIH-Wide Staff Scientists by Race/Ethnicity and Sex

Sex	WHITE/NOT HISP		BLACK/NOT HISP		HISPANIC		ASIAN/PACIF IS		AM-IND/ALASKA NATIVE		Grand Total	
	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total	#	% of Total
FEMALE	311	23.3%	5	0.4%	10	0.8%	170	12.8%	1	0.1%	497	37.3%
MALE	480	36.0%	7	0.5%	16	1.2%	331	24.8%	1	0.1%	835	62.7%
<b>Grand Total</b>	<b>791</b>	<b>59.4%</b>	<b>12</b>	<b>0.9%</b>	<b>26</b>	<b>2.0%</b>	<b>501</b>	<b>37.6%</b>	<b>2</b>	<b>0.2%</b>	<b>1332</b>	<b>100.0%</b>

### NIH-Wide Staff Scientists by Disability Status

Targeted is a Subset of Reportable Disability					
Disability Status	Not Identified	No Disability	Reportable Disability	Targeted Disability	Total
<b>Grand Total</b>	<b>14</b>	<b>1286</b>	<b>32</b>	<b>3</b>	<b>1332</b>
<b>% Grand Total</b>	<b>1.1%</b>	<b>96.5%</b>	<b>2.4%</b>	<b>0.2%</b>	<b>100%</b>

Source: nVision as of 9/21/2013

## NIH-Wide Research and Clinical Fellows Demographics

### IRP Trainees (Non-FTE)<sup>1</sup>

<b>Trainee Type</b>	<b>Total</b>
Postdoctoral IRTA/CRTA	956
Postdoctoral VF	1383
Predocctoral IRTA/CRTA (graduate students)	276
Predocctoral VF (graduate students)	76
Postbaccalaureate IRTA/CRTA (includes Bach.CRTA)	796
Technical IRTA (includes Master's CRTA)	95
Student, short term (summer, medical/dental, pre-Bac CRTA, etc.)	650

IRTA/CRTA are US Citizens or US Permanent Residents

VF are Foreign Nationals (on visas, non-US citizens and non-US permanent residents)

For IRTA/CRTA programs, the gender proportion is approximately 57% female, 43% male.<sup>1</sup>

For VF programs, the gender proportion is approximately 41% female, 59% male.<sup>2</sup>

<sup>2</sup>Of 75 countries represented in the VF programs, the following 12 make up ~80% of the total: China (24%), India (15%), Japan (9%), South Korea (8%), Canada (4%), France (4%), Italy (4%), Germany (3%), Brazil (2%), Spain (2%), Taiwan (2%), United Kingdom (2%)

Data Source: <sup>1</sup>NIH nVision - Fellowship Payment System, June 2014; <sup>2</sup>NIH Division of International Services, ORS, Oct 2013 – March 2014

### NIH-Wide Research Fellows by Race/Ethnicity and Sex

Research Fellow Type	WHITE/NOT HISP		BLACK/NOT HISP		HISPANIC		ASIAN/PACIF IS		AM-IND/ALASKA NATIVE		Total	
	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title
<b>RESEARCH FELLOWS</b>	<b>142</b>	<b>45.7%</b>	<b>11</b>	<b>3.5%</b>	<b>8</b>	<b>2.6%</b>	<b>149</b>	<b>47.9%</b>	<b>1</b>	<b>0.3%</b>	<b>311</b>	<b>100.0%</b>
FEMALE	57	40.7%	5	3.6%	4	2.9%	74	52.9%	0	0.0%	140	100.0%
MALE	85	49.7%	6	3.5%	4	2.3%	75	43.9%	1	0.6%	171	100.0%
<b>RESEARCH FELLOWS (VP)</b>	<b>98</b>	<b>36.4%</b>	<b>1</b>	<b>0.4%</b>	<b>10</b>	<b>3.7%</b>	<b>160</b>	<b>59.5%</b>	<b>0</b>	<b>0.0%</b>	<b>269</b>	<b>100.0%</b>
FEMALE	43	41.3%	0	0.0%	5	4.8%	56	53.8%	0	0.0%	104	100.0%
MALE	55	33.3%	1	0.6%	5	3.0%	104	63.0%	0	0.0%	165	100.0%
<b>SENIOR RESEARCH FELLOWS</b>	<b>9</b>	<b>30.0%</b>	<b>3</b>	<b>10.0%</b>	<b>1</b>	<b>3.3%</b>	<b>17</b>	<b>56.7%</b>	<b>0</b>	<b>0.0%</b>	<b>30</b>	<b>100.0%</b>
FEMALE	4	30.8%	3	23.1%	0	0.0%	6	46.2%	0	0.0%	13	100.0%
MALE	5	29.4%	0	0.0%	1	5.9%	11	64.7%	0	0.0%	17	100.0%
<b>SENIOR RESEARCH FELLOWS (VP)</b>	<b>1</b>	<b>25.0%</b>	<b>0</b>	<b>0.0%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>75.0%</b>	<b>0</b>	<b>0.0%</b>	<b>4</b>	<b>100.0%</b>
FEMALE	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
MALE	1	25.0%	0	0.0%	0	0.0%	3	75.0%	0	0.0%	4	100.0%
<b>Grand Total</b>	<b>250</b>	<b>40.7%</b>	<b>15</b>	<b>2.4%</b>	<b>19</b>	<b>3.1%</b>	<b>329</b>	<b>53.6%</b>	<b>1</b>	<b>0.2%</b>	<b>614</b>	<b>100.0%</b>

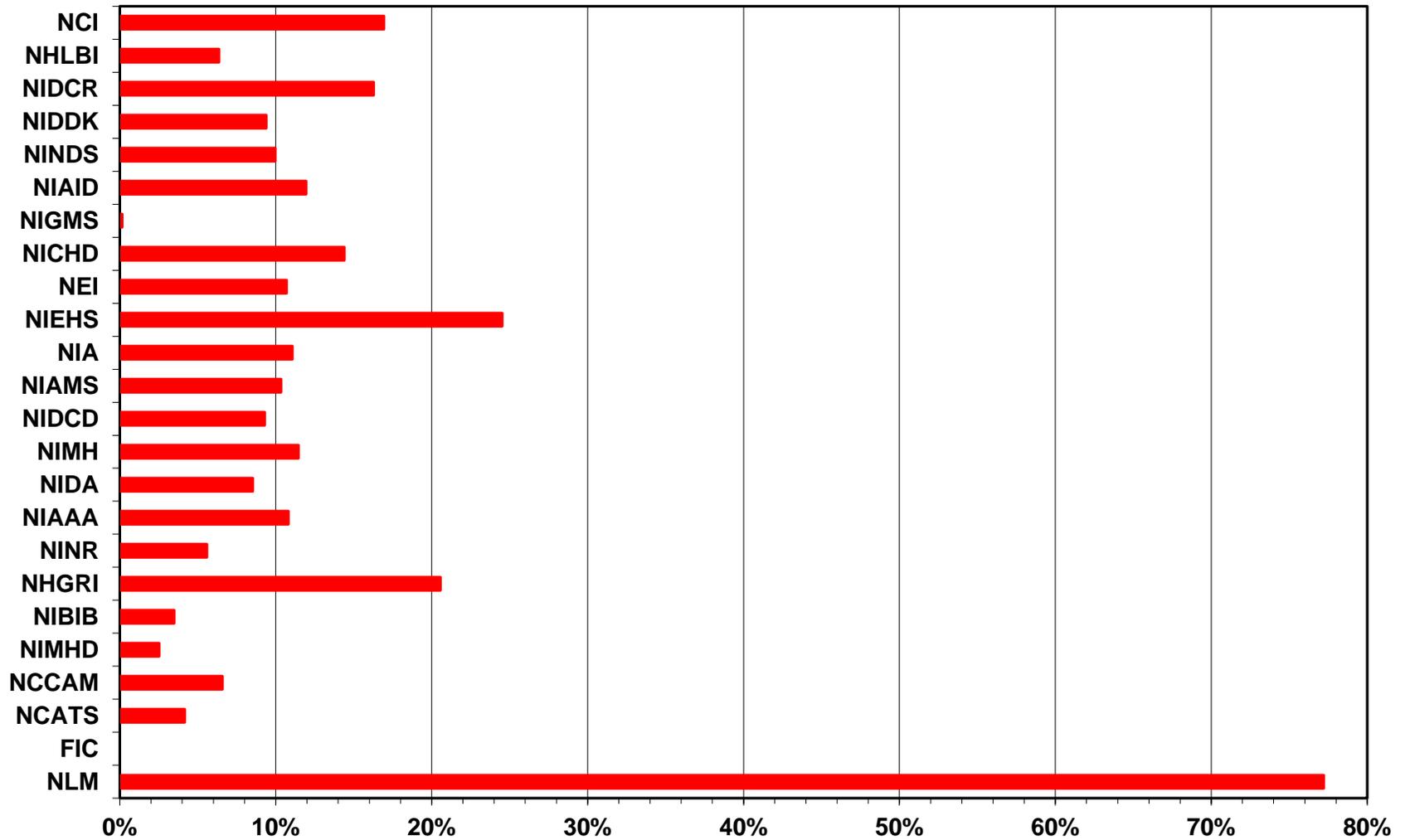
### NIH-Wide Clinical Fellows by Race/Ethnicity and Sex

Clinical Fellow Type	WHITE/NOT HISP		BLACK/NOT HISP		HISPANIC		ASIAN/PACIF IS		AM-IND/ALASKA NATIVE		Total	
	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title	#	% of Position Title
<b>CLINICAL FELLOWS</b>	<b>136</b>	<b>61.5%</b>	<b>9</b>	<b>4.1%</b>	<b>5</b>	<b>2.3%</b>	<b>71</b>	<b>32.1%</b>	<b>0</b>	<b>0.0%</b>	<b>221</b>	<b>100.0%</b>
FEMALE	65	57.0%	5	4.4%	4	3.5%	40	35.1%	0	0.0%	114	100.0%
MALE	71	66.4%	4	3.7%	1	0.9%	31	29.0%	0	0.0%	107	100.0%
<b>CLINICAL FELLOWS (VP)</b>	<b>33</b>	<b>47.1%</b>	<b>4</b>	<b>5.7%</b>	<b>3</b>	<b>4.3%</b>	<b>30</b>	<b>42.9%</b>	<b>0</b>	<b>0.0%</b>	<b>70</b>	<b>100.0%</b>
FEMALE	16	37.2%	4	9.3%	2	4.7%	21	48.8%	0	0.0%	43	100.0%
MALE	17	63.0%	0	0.0%	1	3.7%	9	33.3%	0	0.0%	27	100.0%
<b>SENIOR CLINICAL FELLOWS</b>	<b>1</b>	<b>33.3%</b>	<b>1</b>	<b>33.3%</b>	<b>0</b>	<b>0.0%</b>	<b>1</b>	<b>33.3%</b>	<b>0</b>	<b>0.0%</b>	<b>3</b>	<b>100.0%</b>
FEMALE	1	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	100.0%
MALE	0	0.0%	1	50.0%	0	0.0%	1	50.0%	0	0.0%	2	100.0%
<b>Grand Total</b>	<b>170</b>	<b>57.8%</b>	<b>14</b>	<b>4.8%</b>	<b>8</b>	<b>2.7%</b>	<b>102</b>	<b>34.7%</b>	<b>0</b>	<b>0.0%</b>	<b>294</b>	<b>100.0%</b>

Source: nVision Human Resources database as of 9/21/2013

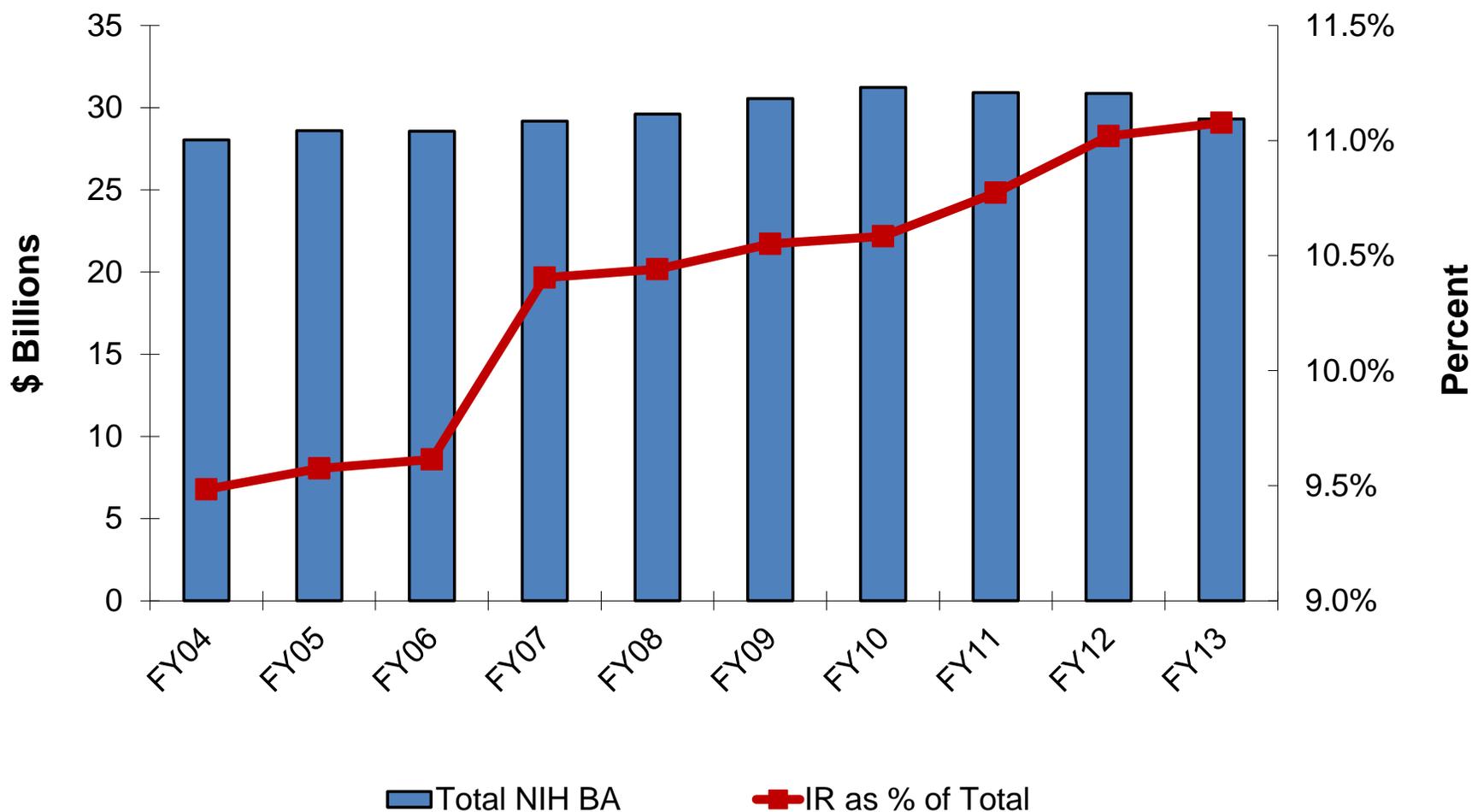
Intramural Research Program Budget

Institute and Center Contributions for Fiscal Year (FY) 2013 (by % of IC Budget)



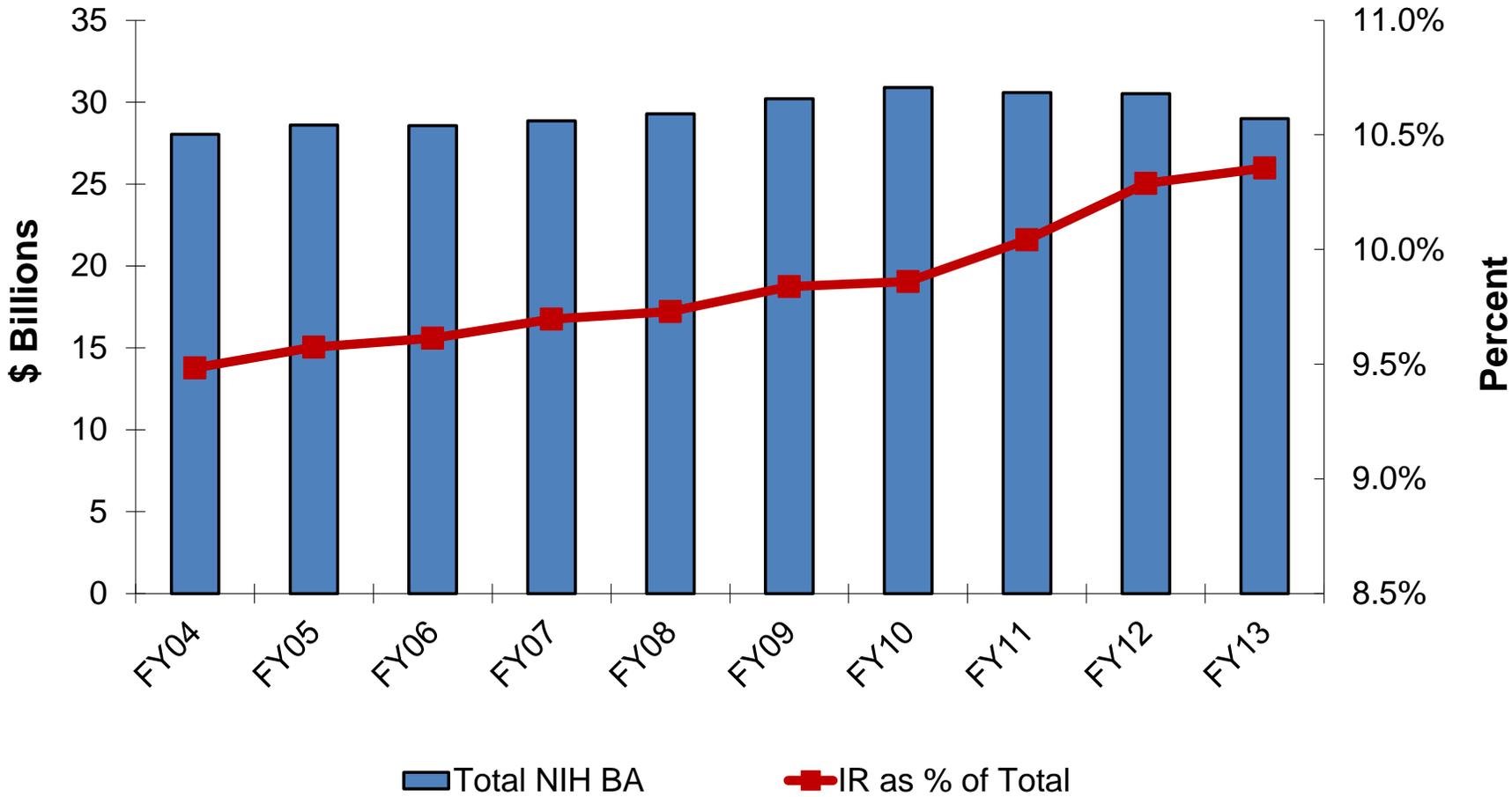
Note: Includes Superfund, as applicable

### NIH Total Budget Authority (BA) and IR Obligations as % of Total



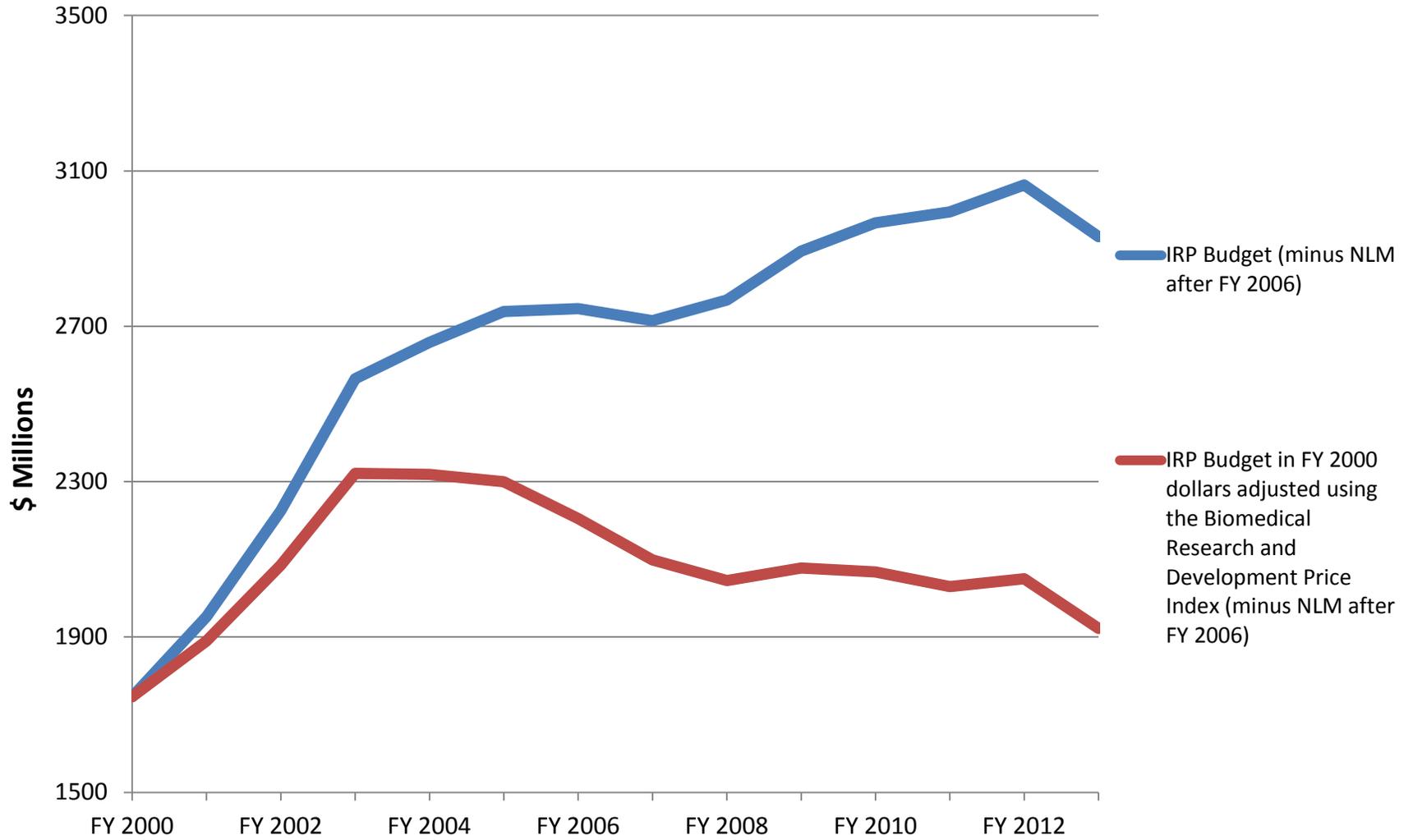
Note: Includes Superfund; the increase in FY 2007 is from the addition of NLM to the IRP budget line

**NIH Total Budget Authority (BA) and IR Obligations as % of Total**



Note: Includes Superfund and excludes NLM

# NIH Intramural Research Program Budget



# Appendix 5

## Intramural Research Program Workforce Trends

<b>Intramural Professional Designation (IPD)</b>	<b>1990-1994</b>	<b>2000-2002</b>	<b>2006-2007</b>	<b>2014</b>
Senior Investigator	1145	968	943	843
Investigator	156	295	251	222
Staff Clinician <sup>#</sup>	*	129	267	221
Staff Scientist	*	594	1215	1332

<sup>#</sup>Does not include GS employees or medical officers in the Commissioned Corps who function as Staff Clinicians

\*IPD did not exist

# Inside the IRP

## Our Review Process: A Step-by-Step Guide

The Intramural Research Program (IRP) is the nation's biomedical research enterprise, with 1,200 Principal Investigators and more than 4,000 postdoctoral fellows conducting basic, translational, and clinical research. To ensure that only the most outstanding research is funded, IRP researchers are evaluated both on accomplishments since their last review and on proposed plans for future research.

IRP researchers are reviewed using a rigorous set of evaluation criteria:



Significance



Approach



Innovation



Environment



Support



Training



Productivity



Mentoring

IRP researchers are usually reviewed every



IRP researchers are reviewed on the entirety of their research program

IRP reviews are largely retrospective



IRP researchers are reviewed by **Boards of Scientific Counselors (BSCs)**, external individuals with outstanding scientific credentials who are committed to providing rigorous, objective reviews



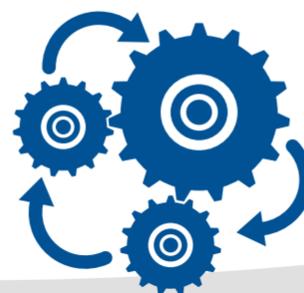
Scientific experts conduct **in-person site visits** to evaluate the quality of work of the individual Principal Investigator



The Principal Investigator may also be evaluated **in the context of the overall portfolio** of the Institute or Center



Final BSC recommendations are approved by the Institute Council, which then influences subsequent **funding levels, staffing, and promotions**



Rigorous reviews are critical for planning and to ensure that only the **most outstanding research** is funded. If a program fails to meet expectations, funds are redeployed

## **Intramural Research Program Principal Investigator Pathways**

All tenure-track investigators are identified through a vigorous national search process. During the past five years:

- 53% of tenure-track investigators were recruited from outside institutions (extramural)
- 82% of senior investigators were recruited directly into their tenured positions through national/international searches (34 scientists total)
- 60% of all recruited investigators (senior or tenure-track; from national/international searches) are from outside institutions (extramural)
- 75% of tenure appointments are made from the NIH tenure-track pool (tenure-track investigators mentioned above)
  - The success rate of those tenure-track scientists achieving tenure at NIH is understandably high due to the rigorous search process

	National/International Searches for Tenure Track Investigators	National/International Searches for Senior Investigators (Tenured)	Total Recruited PIs (Tenured and Tenure Track)
Extramural	53% (62)	82% (28)	60% (90)
Intramural	47% (54)	18% (6)	40% (60)

## Major Shared and Multi-Institute Research Resources

The NIH Intramural Research Program has a long history of interactions and shared resources among its investigators. These include core facilities that support crucial research activities, such as a sequencing center, a magnetic resonance imaging facility, a mass spectroscopy service, and a protein expression service. The most prominent example is the NIH Clinical Center, the nation's largest hospital devoted entirely to clinical research, providing comprehensive services and facilities in support of clinical research

sponsored by the institutes and centers. In addition, the NIH Office of Intramural Training and Education organizes and sponsors a variety of training and career-development activities for the entire intramural community. Various mechanisms are used to support these resources, including contributions from participating NIH institutes and centers such as the management funds, user fees, and program support from the Office of Intramural Research.

RESOURCES AVAILABLE TO ALL INSTITUTES AND CENTERS (ICS)						
Research Resource	Location	Participants	Governance	Contact	Research Services	Review
Center for Information Technology (CIT)	Building 12 complex	All ICs	CIT	Benes Trus, acting scientific director	Image processing, bioinformatics, computational methods and algorithms, computer engineering, bioscience, molecular modeling, mathematical and statistical computing, supercomputing, software development; <a href="http://www.cit.nih.gov/science.html">http://www.cit.nih.gov/science.html</a>	Shared Resources Subcommittee, ICs
Division of Medical Arts	Building 10, B2 level	All ICs	Office of Research Services	Lem Canady, chief	Medical illustration, photomicroscopy, photomacroscopy, scientific posters; <a href="http://medarts.nih.gov">http://medarts.nih.gov</a>	
Division of Library Services	Building 10	All ICs	Office of Research Services	Terrie Wheeler, acting director	Full-service library, including electronic journals, electronic document desktop delivery and translations; <a href="http://nihlibrary.nih.gov">http://nihlibrary.nih.gov</a>	Users Committee, ICs
Division of Scientific Equipment and Instrumentation Services	Building 13	All ICs	Office of Research Services	Johnny Robbins, chief	Maintain scientific equipment and computers; design and fabricate custom instruments; lease and sell scientific and medical equipment; <a href="http://dseis.od.nih.gov">http://dseis.od.nih.gov</a> (NIH Intranet only)	Shared Resources Subcommittee, ICs
Division of Veterinary Resources	Building 14-28 complex; Bethesda; Poolesville	All ICs	Office of Research Services	Charmaine Foltz, director	Veterinary services (surgery, radiology, pharmacy, nutrition, animal behavior and enrichment); animal husbandry, procurement, quarantine, and health surveillance; diagnostics (pathology, bacteriology, parasitology, serology, mouse phenotyping)	Shared Resources Subcommittee, ICs
MULTI-INSTITUTE SHARED SERVICES						
Research Resource	Location	Participants	Governance	Contact	Research Services	Review
Biomedical Engineering and Physical Science	Building 13	Available to all ICs	Steering Committee	Henry Eden, Acting Chief	Micro analytical immunochemistry; microfabrication and microfluidics; transmission and scanning electron microscopy; scanning probe microscopy; quantitative methods for molecular interactions; clinical/basic infrared imaging; <a href="http://www.nibib.nih.gov/Research/Intramural/SharedResource">http://www.nibib.nih.gov/Research/Intramural/SharedResource</a>	Shared Resources Subcommittee, ICs, Steering Committee
Biotechnology Core Laboratory	Building 6, Room B1-33	Lead IC: NIDDK; major client: NICHD		Joseph Shiloach, director	Production and purification of biological material, especially scale-up protein production and purification; <a href="http://www2.niddk.nih.gov/NIDDKLabs/AllLabs/CoreFacilities/BiotechnologyCoreLaboratory.htm">http://www2.niddk.nih.gov/NIDDKLabs/AllLabs/CoreFacilities/BiotechnologyCoreLaboratory.htm</a>	Board of Scientific Counselors, ICs
Bone Marrow Stromal Cell Transplantation Center	Building 10	Steering Committee: CC, NIDCR, NIAID, NIAMS, NIBIB, NCI, NINDS	Oversight Committee: NINDS, NIAID, NCI, NIDCR	Harvey Klein (CC), Pamela Robey (NIDCR)	Production facility for bone marrow stromal (mesenchymal) stem cells for clinical research	
Center for Human Immunology (CHI)	CC	Available to all ICs	Steering Committee	Neal Young, director	Translational research in immunology, autoimmunity, and inflammation; <a href="http://www1.od.nih.gov/oir/sourcebook/ir-communicatns/chi.htm">http://www1.od.nih.gov/oir/sourcebook/ir-communicatns/chi.htm</a>	IC Director Steering Committee
Center for Inherited Disease Research	Bayview Research Campus, Baltimore	Lead contracting IC: NHGR; all ICs may participate	Review: CIDR Board of Governors	David Valle, Johns Hopkins University	Genotyping, DNA banking, statistical genetics consultation, mouse genotyping; <a href="http://www.cidr.jhmi.edu">http://www.cidr.jhmi.edu</a>	CIDR Access Committee (Camilia Day, NHGRI)
NIH Clinical Center	Building 10 complex	Available to all ICs	Clinical Center Governing Board	John Gallin, director	Research hospital that accommodates 234 inpatients, 80 day-hospital stations, and outpatients and provides comprehensive services and facilities in support of clinical research sponsored by the ICs; <a href="http://www.cc.nih.gov">http://www.cc.nih.gov</a>	Joint Comm.; Board of Scientific Counselors; NIH Advisory Board for Clinical Research

**MULTI-INSTITUTE SHARED SERVICES (continued)**

Research Resource	Location	Participants	Governance	Contact	Research Services	Review
Imaging Probe Development Center (IPDC)	9800 Medical Center Dr., Building B, Room 3042, Rockville, Md.	Lead IC: NHLBI	Roadmap Initiative	Gary Griffiths, director	Production of new imaging probes for the intramural NIH research community; <a href="http://nihroadmap.nih.gov/molecularlibraries/ipdc/contact.asp">http://nihroadmap.nih.gov/molecularlibraries/ipdc/contact.asp</a>	
Mouse Imaging Facility	Building 10, In Vivo NMR Center	Lead ICs: NINDS, NHLBI; Participants, all ICs but NIEHS are paid charter members	Steering Committee	Alan Koretsky, director	Mouse radiologic imaging; 7T rodent MRI, microCT, high-frequency ultrasound, laser Doppler; <a href="http://intranet.nmr.nih.gov/">http://intranet.nmr.nih.gov/</a> (NIH Intranet only)	Shared Resources Subcommittee, ICs, Steering Committee
NIH Chemical Genomics Center (NCGC)	9500 Medical Center Drive, Rockville, Md.	Lead IC: NHGRI		Chris Austin, director	Ultra-high-throughput screening center of the Molecular Libraries Screening Center Network that generates chemical probes for understanding molecular and cellular functions and serve as starting points for drug development, particularly for rare and orphan diseases; <a href="http://www.ncgc.nih.gov/">http://www.ncgc.nih.gov/</a>	
NIH Intramural Sequencing Center (NISC)	5625 Fishers Lane, 5th Floor, Rockville, Md.	Participants: NHGRI, NCBI, NIDCD, NIAAA, NIDA, NHLBI, NIDDK, NICHD, NEI, NIAMS, NINDS, NIDCR, NIEHS, NIMH	Users Committee	Eric Green, director	Production-scale DNA sequencing, assimilation and analysis of sequence data, instrumentation, sequence analysis software; <a href="http://www.nisc.nih.gov">http://www.nisc.nih.gov</a>	
NIH Magnetic Resonance Imaging Facility	Building 10, In Vivo NMR Center	Lead IC: NINDS; all ICs except NIEHS	Steering Committee	Alan Koretsky, director	Human and animal MRI; other IC MRI instruments available; <a href="http://intranet.nmr.nih.gov/">http://intranet.nmr.nih.gov/</a> (NIH Intranet only)	Shared Resources Subcommittee, ICs, Steering Committee
PET Imaging	Building 10, Room 1C401	Lead IC: CC	Steering Committee	Peter Herscovitch, director	State-of-the-art facility with three medical cyclotrons and ten hot cells to produce positron-labeled radiopharmaceuticals, as well as four PET scanners; Good Manufacturing Practice facility with additional hot cells under construction; <a href="http://www.cc.nih.gov/pet/index.html">http://www.cc.nih.gov/pet/index.html</a>	
Protein Expression Lab	Building 6B, Room 1B130	Lead IC: NIAMS; Participants: NHGRI, NCBI, NIDCD, NIAAA, NIDA, NHLBI, NIDDK, NICHD, NEI, NIAMS, NINDS, NIDCR, NIEHS, NIMH; any IC may request service		Paul Wingfield, chief	Expression, purification, and structural characterization of HIV and HIV-related proteins via a variety of techniques; protein EXE software; supply HIV-1 protease; <a href="http://www.niams.nih.gov/Research/Ongoing_Research/Branch_Lab/Protein_Expression/default.asp">http://www.niams.nih.gov/Research/Ongoing_Research/Branch_Lab/Protein_Expression/default.asp</a>	Intramural AIDS Targeted Antiviral Program, ICs
Stem Cell Unit	Building 35, Room 3A201	Lead IC: NINDS	Steering Committee	Pam Robey, acting director	Facility uses a standardized paradigm to conduct side-by-side comparisons of the available cell lines on the NIH Human Embryonic Stem Cell Registry and shares the results with the scientific community; <a href="http://stemcells.nih.gov/research/nihresearch/scunit">http://stemcells.nih.gov/research/nihresearch/scunit</a>	
Synchrotrons:						
1. Advanced photon source	Argonne National Lab	DOE		<a href="http://www.aps.anl.gov">http://www.aps.anl.gov</a>	High-brilliance X-ray beams	

**CORE FACILITIES ON A SPACE-AVAILABLE BASIS**

Research Resource	Location	Participants	Governance	Contact	Research Services	Review
Facility for Biotechnology Resources (FBR): CBER Biotechnology Core Facility	Building 29, Rooms 200-208	Participants: NHGRI, NIDCD, NHLBI, NIDDK, NICHD, NEI, NIAMS, NIDCR, CC, NCI - fee-for-service	FDA's Center for Biologics Evaluation and Research (CBER)	Nga Y. Nguyen, CBER FDA	Services include: amino acid sequence analysis; DNA sequencing; oligonucleotide synthesis; peptide synthesis; mass spectrometry services; analytical and preparative HPLC services; capillary electrophoresis; <a href="http://128.231.52.66/default.htm">http://128.231.52.66/default.htm</a> (NIH Intranet only)	CBER
Mass Spectroscopy	Building 8A, Room B2A19-21; Building 10	Lead ICs: NIDDK, NHLBI, NIMH, NIAID, NINDS	Advisory Group		QTOF-LCMS; high-resolution magnetic sector; MALDI, LC-Ion trap	Board of Scientific Counselors, ICs
Structural Biology NMR	Buildings 5, 6A, and 50	All ICs	Steering Committee	Lead ICs: Ad Bax (NIDDK), Nico Tjandra (NHLBI)	Study of macromolecular structure and interaction; 500-, 600- and 800-MHz cryoprobe NMR spectrometers; 900-MHz spectrometer	ICs