

ACD Long-Term Intramural Research Program (LT-IRP) Planning Working Group

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Cato T. Laurencin, MD, PhD

ACD Member and Co-chair, LT-IRP WG



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- Office of Intramural Research
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- Other NIH Staff

Working Group Roster

- Gilda Barabino, PhD
- Jeffery Bluestone, PhD
- Arturo Casadevall, MD, PhD
- Barry Coller, MD
- Diane Griffin, MD
- David Hunter, MB, MPH, ScD
- Carl June, MD
- Cato Laurencin, MD, PhD
- Philippa Marrack, PhD
- Robert Nussbaum, MD
- Nicholas Peppas, ScD
- Amita Sehgal, PhD
- Harinder Singh, PhD
- Allen Spiegel, MD
- Lawrence Tabak, DDS, PhD

Background

IRP Reports:

- 1988 – Institute of Medicine (IOM) Report
- 1994 – Marks-Cassell Report
- 2014 – ACD LT-IRP working group report

Additional Reports:

- 2003 – IOM review of NIH organizational structure
- 2004 – Benz-Goldstein Report on Clinical Research
- 2010 – Scientific Management Review Board (SMRB) Review of Clinical Research Center (CRC)

Charge to the Working Group

- Recommend how the Intramural Research Program (IRP) should **ensure its distinctive role**, and how it should **differ from extramural** research institutions
 - Define the essential components of the IRP and the components that need modification
 - Articulate potential barriers to achieving this vision (e.g., budget constraints, organizational limitations)
 - Define what, if any, changes are needed or should be avoided to achieve this vision
- Identify **areas of opportunity** to focus on in the next 10 years to take advantage of the IRP's distinctive features
- Identify **steps to ensure sustainability** of the IRP's distinctive features, including the Clinical Research Center
- Assure alignment of recommendations with the work of other ACD and internal NIH Working Groups (WGs)

Process and Materials Reviewed

- 5 Meetings
 - 3 teleconferences
 - 2 face-to-face meetings
- 2 Campus “Site Visits”
- Background Materials:
 - Prior reports of the IRP
 - Individual Institute and Center (IC) and Synthesis Reports
 - Relevant ACD working group reports
 - Background and general IRP information and data (from Office of Intramural Research [OIR])
 - Trans-IC IRP program information
 - Information on IRP-Extramural interactions

Intramural Research Program: Distinctive Features

- Rigorous (mainly) retrospective peer review
- Established and stable infrastructure
- PI focus on research and mentoring
- Large population of trainees at all levels
- Clinical Research Center

Issues and Challenges: Research

- Standing of the IRP
- Impression of IRP isolation within the scientific community (siloed)
 - Across ICs
 - With the extramural community
- Not fully capitalizing on the IRP's unique capabilities, including those of the CRC

Recommendations: Research

- **Identify “Great Scientific Challenges”**
 - Standing committee of IRP and outside experts to biennially advise the NIH Director on important future research areas or challenges
- **Bolster Support for Highly Innovative Research**
 - *Establish a trans-NIH innovation fund*
 - Reserve ~1% of the IRP budget for a fund to address one or more of the “great scientific challenges,” among others
 - Competitive application process overseen by Deputy Director of Intramural Research (DDIR), with proposals from individual Principal Investigators (PIs) or collaborative teams
 - *Encourage the formation of an optional IC innovation fund*
 - Reserve no less than 5% of their non-personnel intramural budget
 - Competitive application process overseen by the ICs

Recommendations: Research

- **Encourage Interdisciplinary and Team Science; Promote More Synergistic Intramural and Intramural-Extramural Collaborations**
 - *Evaluate the “Porter” approach to integrated science*
 - Analyze the benefits and disadvantages of this integrated approach to determine if it should be expanded to other fields
 - Consider lessons learned from the extramural community (e.g., the Women’s Health Initiative) and within the IRP (e.g., Framingham Heart Study)
 - *Develop a mechanism to respond to health crises*
 - Using the recent NIH response to the Ebola crisis as a model, develop a trans-IRP mechanism to prepare the IRP to be the Nation’s “first line of research” for emergent health threats
 - *Expand IRP-Extramural Interactions*
 - Review mechanisms for IRP-extramural partnerships (e.g., U01s, Cooperative Research And Development Agreements [CRADAs])
 - Better utilize the Visiting Scientist program
 - Create mechanisms to combine IRP and extramural funds to support collaborations

Recommendations: Research

- **Encourage Team Science and Collaborations (cont'd)**
 - *Host 4-6 annual scientific meetings at NIH*
 - Partner with associations and societies to address the “great scientific challenges” and to further encourage collaboration
- **Refocus the Mission and Function of the CRC**
 - Retain focus on rare and undiagnosed disease, but also place a larger emphasis on more common public health challenges
 - Emphasize genotype-phenotype correlation
 - Continue to focus on vaccine development and drug resistance of pathogens and to cancer therapies

Issues and Challenges: Workforce

- PI numbers have been reducing gradually – net 2-3% loss annually
- Increasing numbers of staff scientists
- Lack of diversity – national imperative to address
- Large internal recruitment
- Need for altered review process with increased external involvement
- Flat or declining budgets with increasing research costs

Recommendations: Workforce

■ Increase Diversity

- *Develop new, innovative models to diversify the workforce*
 - IRP should be a test-bed to pilot new approaches to address recruitment, retention, and support of those from underrepresented groups (URGs)
 - Chief Officer for Scientific Workforce Diversity (COSWD) should create competitive program to increase Early-Stage Investigator (ESI) recruitment, mentorship, and sponsorship for those from URGs

■ Restructure the BSC Review Process

- *Trans-NIH review based on scientific area*
 - Review PIs every 5-7 years by major scientific field
 - Trans-NIH extramural review panel overseen by Office of Intramural Research (OIR) and ICs
 - Recognize team science, where appropriate
- *Institute a rigorous review of staff scientists*
 - Standardized trans-NIH review every 4 years by scientific area¹³

Recommendations: Workforce

■ Strengthen Recruitment

- *Expand and publicize current recruitment efforts*
 - Increase recruitment from extramural and consider inclusion of Board of Scientific Counselors (BSC) members and PIs from other ICs on search committees
 - Highlight unique recruitment incentives (e.g., Loan Repayment Plan)
 - Focus on ESIs and evaluate the success of the Stadtman award
- *Recruit Staff Scientists and Clinicians through a national/international process*
 - Institute a trans-NIH national/international search process for all staff scientist and staff clinician positions
- *Enhance the Assistant Clinical Investigator (ACI) program*
 - Increase program visibility
 - Consider trans-NIH recruitment, similar to Lasker award
 - Analyze the Lasker program to determine how to improve it

Recommendations: Workforce

- **Identify the Most Sustainable Workforce Size**
 - Evaluation to determine optimal critical mass by OIR and external advisors
 - Considerations:
 - Analyze the current investigator cohort by years of service to model workforce dynamics and size
 - Determine optimal distribution of IC support of scientific areas in the extramural research vs. IRP portfolios
 - Identify scientific strengths and weaknesses
 - Determine desired ratio of basic, translational, clinical, and population-based research
 - Support reinstated programs allowing partial retirement from federal service

Issues and Challenges: Training

- Lack of diversity – national imperative to address
- Need for additional support and mentoring
- Decline of MD investigators

Recommendations: Training

■ Enhance Diversity of IRP Trainees

- Expand current diversity-related efforts
- Continue to build partnerships with under resourced institutions
- Continue to provide mentoring and broad career resources
- Enhance collection of outcomes data on trainees

■ Support for Clinical Research Trainees

- *Broaden the MSTP size, support, and opportunities*
 - Provide Medical Scientist Training Program (MSTP) students the opportunity to participate in clinical research at the CRC
 - Explore broadening support beyond NIGMS and increase size
- *Create a mechanism for MD research training at CRC*
 - For ESIs and similar to the K08 and K23 mechanisms
 - Increase awareness of NIH-Duke U. Master's program and LRP₁₇

Issues and Challenges: Infrastructure/Facilities

- Impression of IRP isolation within the scientific community (siloed)
 - Across ICs
 - With the extramural community
- Instability of funding for the CRC
- Pending data and computing issues, including access to data

Recommendations: Infrastructure/Facilities

- **Develop Joint Clinical Initiatives with Extramural**
 - *Evaluate the feasibility of a phase 1 clinical trials unit in the CRC*
 - Clinical Center Governing Board (CCGB) should evaluate the of feasibility and success of establishing a phase 1 clinical trials unit to raise revenue
 - *Develop joint initiatives with local partners*
 - Consider additional partnerships with local pediatric hospitals in the DC area to target neonatal pediatric research
 - Explore partnerships with the Dept of Defense (DoD) and Veterans Affairs (VA) to potentially increase utilization of CRC
- **Open Access to and Review of All Core Resources**
 - Open access to all shared resources, including other unique equipment/facilities to the entire IRP
 - Develop guidelines for evaluating, opening, closing, managing, and reimbursing for shared resources

Recommendations: Infrastructure/Facilities

- **Accelerate Efforts on Data and Computing Needs**
 - *Develop a comprehensive data storage and computing plan*
 - Scientific Data Council should develop a plan to address future computing needs
 - *Partner with PCORI to provide IRP investigators with special access to PCORnet databases*
 - Expand access to the PCORnet databases and publicize availability of Common Fund Collaboratory databases
 - *Expand pilot programs for electronic lab notebooks*
 - Continue and expand existing programs to pilot the use of electronic lab notebooks within the IRP
 - Broadly share the results

Recommendations: Infrastructure/Facilities

- **Explore the Feasibility of a Centralized Biobank**
 - Convene a panel to determine the feasibility of a centralized biobank housed within the CRC
 - Open access to those in the intramural and extramural communities

Administrative

Issues and Challenges:

- Concerns about transparency of implementation

Recommendations:

- **Develop an Implementation and Reporting Plan**
 - Include metrics to evaluate progress and efficacy
 - Periodic reporting on the implementation status

Areas of Concern: Administrative

- WG recognizes NIH has no control over the following issues
- Included in the report to raise awareness and emphasize the burden on the IRP
- **Budget**
 - Currently, process introduces additional budgetary uncertainty
 - WG supports a 2 year budget for NIH for added flexibility
 - Considers current IRP budget percentage (11%) appropriate
- **Travel Restrictions**
 - Burdensome, increased costs, and hinders collaboration
 - Amend federal conference and travel legislation to exclude NIH
 - Attendance approval should be performed at the NIH level
- **Conflict of Interest**
 - Inhibits recruitment and hiring of senior investigators
 - Change Dept of Health and Human Services (DHHS) policies

