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

Advisory Committee to the Director Meeting
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- Office of Intramural Research
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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 area
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 LRP
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 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