National Advisory Neurological Disorders and Stroke

Director’s Report

2016 AUPN meeting

Walter J. Koroshetz, M.D.
Director, National Institute of Neurological Disorders and Stroke, NIH
Leadership Changes at NINDS

• Office of Clinical Research:
  – Elizabeth McNeil MD, left for a position at Biogen
  – Claudia Moy, MD, is Acting OCR Director
  – Search is ongoing

• Office of Translational Research:
  – Alan Willard, PhD continues as Acting OTR Director
  – Search is ongoing

• Executive Officer:
  – Caroline Lewis took an Assistant VP position at USUHS
  – Maryann Sofranko is Acting Executive Officer
  – Search is ongoing
Discussion Items

• **NINDS Budget** (Big thanks to Quynh Ly)
  – ’16 budget and spending plan
  – ’15 spending report (Thanks to Anna Taylor and Christine Torborg)

• **BRAIN initiative** (Thanks to BRAIN Team members especially Ned Talley and Alan Willard, Amy Adams, Sam White, Khara Ramos)

• **Alzheimers Disease Related Dementia program** (Thanks to Rod Corriveau and ADRD team)

• **Mind Your Risks Public Info Campaign** (Thanks to Marian Emr and OCPL and Katie Pahigiannis)

• **Programs in Chronic Fatigue** (Thanks to Vicky Whittemore)

• **Pain research programs** (Thanks to Linda Porter, Cherysse Sankar)

• **Trans-NIH policy discussions.**
  – Select Pay
  – Focus shift from grants to people
  – Others coming soon.
Consolidated Appropriations Act (P.L. 114-113)

Passed December 18, 2015

- $32.1 B for NIH
- $2 B increase (~6.5%) over FY2015 enacted
  - $1.696 B to NINDS
  - $150 M ($85 M boost) for BRAIN Initiative (pooled across ICs)
  - $350 M boost for Alzheimer’s disease research (to NIA)
  - $200 M for PMI ($130 to Common Fund and $70 M to NCI)
  - $100 M boost to combat antimicrobial resistance

Other Provisions of Interest:

- National Academies study on policies affecting the next generation of researchers in the U.S. (Partner with National Academy of Sciences)
- Increase stipends for NRSA grantees (consistent with the Federal employee pay raise)
- Strengthen privacy protections for human research participants
- Continued support for high-risk, high-reward research (through Common Fund)
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<tbody>
<tr>
<td><strong>NINDS</strong></td>
<td>$1,622,003</td>
<td>$1,624,830</td>
<td>$1,533,795</td>
<td>$1,588,904</td>
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<td><strong>NINDS %</strong></td>
<td>Base</td>
<td>0.2%</td>
<td>-5.6%</td>
<td>3.6%</td>
<td>1.0%</td>
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<td><strong>NIH %</strong></td>
<td>Base</td>
<td>0.6%</td>
<td>-5.5%</td>
<td>3.4%</td>
<td>0.5%</td>
<td>6.6%</td>
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</table>

- NINDS received specific increase of $27.93m for BRAIN Initiative
- Minus the BRAIN initiative increase, the NINDS general increase was 3.925%
- Noncompeting grants to be awarded at full committed levels (amount on most recent NGA)
- Funding up to 15th percentile, our projection prior to the increase in funding was a payline at the 12 percentile.
- Administrative cut 17.5% non-modular & 12.5% modular
FY 2016 Appropriation Budget Distribution

**FY 2016 Budget Authority:**
$1,695,180K

<table>
<thead>
<tr>
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<th>FY 15 Actuals</th>
<th>FY 16 % increase</th>
<th>FY 16</th>
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<tr>
<td>DIR</td>
<td>159,498</td>
<td>4.0%</td>
<td>165,878</td>
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<tr>
<td>RMS</td>
<td>63,894</td>
<td>4.9%</td>
<td>67,050</td>
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</table>

1,462,252
86.3%

165,878
9.8%

67,050
4.0%

Dollars in Thousands
NINDS Funding Trends

Competing Dollars

Competing Awards
## Competing RPG Trends

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<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tr>
<td><strong>Competing Awards</strong></td>
<td>699</td>
<td>749</td>
<td>701</td>
<td>702</td>
<td>750</td>
<td>819</td>
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<td><strong>Number of Applications</strong></td>
<td>3,097</td>
<td>3,549</td>
<td>3,588</td>
<td>3,551</td>
<td>4,002</td>
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<tr>
<td><strong>Success Rate</strong></td>
<td>22.6%</td>
<td>21.1%</td>
<td>19.5%</td>
<td>19.8%</td>
<td>18.7%</td>
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<td><strong>Average Cost</strong></td>
<td>$405K</td>
<td>$392K</td>
<td>$378K</td>
<td>$378K</td>
<td>$396K</td>
<td>$379K</td>
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<td><strong>Payline (Percentile)</strong></td>
<td>14</td>
<td>14</td>
<td>15</td>
<td>14</td>
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</table>

Data includes complete RPG portfolio of Unsolicited Announcements, RFAs, PAs, PASs
NINDS Success Rate

Other IC FY15 Success Rates:
- NEI: 23.5%
- NIA: 20.9%
- NIDA: 22.3%
- NIGMS: 29.0%
- NIMH: 22.2%
Senate L-HHS-Ed Appropriations Subcommittee Hearing:
“NIH: Investing in a Healthier Future”

- October 7, 2015
- Witnesses: NIH Director; directors from NINDS, NIGMS, NCI, NIDDK, NIDA
- Chairman Blunt asked witnesses to talk about their research programs and how to increase opportunities and training for young investigators
- Several broad themes emerged
  - What would you do if you had $2-3 billion more money?
  - Ramifications of a Continuing Resolution (e.g. on PMI, BRAIN)
  - Importance of increasing opportunities for young scientists to ensure future discoveries and sustain economic benefits of biomedical research
  - Balance of funding across various diseases at NIH (e.g. HIV)
NINDS Funding Opportunity Announcements on AD-Related Dementias Planned for FY 2016

• NINDS leads Alzheimer’s Disease Related Dementia Research
  • Lewy body disease and Parkinson’s related Dementia
  • Frontotemporal Dementia
  • Vascular contribution to dementia; AD and Vascular Dementia

• Funding from NIA

• NINDS FOA’s in FY16 for ~ $17.8million
  • Biomarkers for small vessel vascular contributions to cognitive impairment and dementia (VCID)
  • Basic research on diffuse white matter disease in VCID
  • Biomarkers for Lewy body dementia
  • Tau biology and contribution to neurodegeneration
  • Health Disparities in Dementia
• Will take place at NIH March 29-30, 2016
• Update research recommendations:
  • Frontotemporal degeneration
  • Lewy body dementia
  • Multiple etiology dementias
  • Vascular contributions to cognitive impairment and dementia
  • Health disparities
  • New in 2016: NGO Session
• Registration is free and open to the public: https://meetings.ninds.nih.gov/meetings/ADRelatedDementias2016/
• Hosted by NINDS in collaboration with NIA
Mind Your Risks
A New NINDS Public Education Campaign

- Raise awareness among middle-aged people with hypertension that controlling blood pressure may decrease risk for dementia, as well as stroke, in later life
- Provide scientific evidence for doctors who wish to discuss this topic with their patients
- Campaign launched with PSA placement in Stroke Belt States
- NINDS-led campaign in partnership with Million Hearts®, NHLBI and NIA
Mind Your Risks Website Offers information for the public and healthcare

## FY 2016 BRAIN Appropriation (approx.)

<table>
<thead>
<tr>
<th>IC</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016 Δ</th>
<th>FY 2016 Total</th>
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<td></td>
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<td>1,000,000</td>
<td>3,643,000</td>
<td>$4,643,000</td>
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<tr>
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<td>2,732,000</td>
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<td>Blueprint</td>
<td>10,000,000</td>
<td>19,107,785</td>
<td></td>
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<tr>
<td>ICO* Add’l $</td>
<td>5,431,142</td>
<td>10,492,257</td>
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<td><strong>Total</strong></td>
<td><strong>$46,131,142</strong></td>
<td><strong>$84,981,042</strong></td>
<td></td>
<td><strong>~$150,000,000</strong></td>
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*ICO – Institutes, Centers, and OD Offices that provided additional $ beyond BRAIN appropriations

**FY16 President’s Budget request: $70M new**

**FY16 BRAIN appropriation: $85M new**
BRAIN Neuroethics

BRAIN Neuroethics Workgroup

• A consultative ethics group to work with BRAIN leadership and BRAIN investigators
• Co-chaired by Dr. Christine Grady and Hank Greely

• Services:
  • Advise NIH on neuroethics questions important for BRAIN that could be answered through focused empirical research
  • Draft relevant guidance documents to address critical ethical issues associated with BRAIN research
  • Consider proposed funding areas for BRAIN projects for questions of ethical risk

• Workgroup meeting February 9th with BRAIN PIs conducting invasive human studies
• New joint BRAIN/Blueprint neuroethics project team (Team N)

http://braininitiative.nih.gov/about/newg.htm
Mission Statement: The aim of the BRAIN Initiative Alliance is to coordinate and facilitate communications from its members related to the White House BRAIN Initiative.

Short Term Focus: Website that serves as a single point of communication for all BRAIN Initiative-related announcements of funding opportunities and accomplishments.
International Partnerships

Goals:

• Develop a coordinated program to foster collaborative research in areas of mutual interest within the BRAIN Initiative
  • Jointly support research projects involving Danish and U.S. scientists; exchange of scientific information.
  • Funding for projects in Denmark funded by Foundation.

• Similar to partnerships between NIH and research organizations in Canada and Australia
Launch of New BRAIN Website

WHAT IS THE BRAIN INITIATIVE?

The Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is part of a new Presidential focus aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space. Long desired by researchers seeking new ways to treat, cure, and even prevent brain disorders, this picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve vast quantities of information, all at the speed of thought.

Explore New Features: www.braininitiative.nih.gov
Technical Note
Human brain diffusion tensor imaging at submillimeter isotropic resolution on a 3 Tesla clinical MRI scanner
Hing-Chiu Chang, Mark Sundman, Laurent Petit, Shayan Guhaniyogi, Mei-Lan Chu, Christopher Petty, Allen W. Song, Nan-kuei Chen

Neuron
A Comprehensive Optogenetic Pharmacology Toolkit for In Vivo Control of GABA_A Receptors and Synaptic Inhibition

Highlights
- Tools for optogenetic pharmacology are introduced for all GABA_A receptors
- Photo-control is rapid, reversible, and isoform specific in

Authors
Wan-Chen Lin, Ming-Chi Tsai, Christopher M. Davenport, ..., Neil M. Wilson, Hillel Adesnik, Richard H. Kramer

Optical focusing inside scattering media with time-reversed ultrasound microbubble encoded light
Haowen Ruan, Mooseok Jang & Changhuei Yang

Multiscale photoacoustic tomography using reversibly switchable bacterial phytochrome as a near-infrared photochromic probe
Junjie Yao, Andrii A Kaberniuk, Lei Li, Daria M Shcherbakova, Ruiying Zhang, Lidai Wang, Guo Li, Vladislav V Verkhusha & Lihong V Wang
High-speed recording of neural spikes in awake mice and flies with a fluorescent voltage sensor

Yiyang Gong,1,2,3* Cheng Huang,1 Jin Zhong Li,1,2 Benjamin F. Grewe,1,2 Yanping Zhang,1,2,4 Stephan Eismann,1,2 Mark J. Schnitzer1,2,4*

Molecular Identity of Human Outer Radial Gila during Cortical Development

Alex A. Pollen,1,3,4* Tomasz J. Nowakowski,1,3,4 Xiadong Chen,1,2 Hanna Retallack,1,2 Carmen Sandoval-Espinosa,1,2 Cory R. Nicholas,1,2 Joe Shuga,1 Siyuan John Liu,1,2 Michael C. Oldham,1 Aaron Diaz,1,4 Daniel A. Lim,1,4 Anne A. Leyrat,1 Jay A. West,1 and Arnold R. Kriegstein1,2

Scanning color optical tomography (SCOT)

Poorya Hosseini,1,2 Yongjin Sung,1,3,4 Youngwoon Choi,4 Niyom Lue1 Zahid Yaqoob1 and Peter So1,2

An acetylcholine-activated microcircuit drives temporal dynamics of cortical activity

Naiyan Chen1,3, Hiroki Sugihara1,3 & Mriganka Sur1

Distinct relationships of parietal and prefrontal cortices to evidence accumulation

Timothy D. Hanks, Charles D. Kopec, Bingni W. Brunton, Chunyu A. Duan, Jeffrey C. Erlich & Carlos D. Brody
Update on Concussion Research

Two neuropath studies ongoing

- Published guidelines for pathologic diagnosis of CTE
- Screen of May neuro brain bank for CTE
  - Found in 30% of those with some history of playing contact sports. 0% in matched non-sports cohort and 0% in female cohort.
- Screen of Queen’s Square neuro bio bank
  - CTE in 12% and history of TBI in 94%, but TBI not sports related, question raised whether TBI related to falls from neuro conditions.
  - NINDS funded longitudinal study to characterize clinical syndrome of CTE from its appropriated budget.

NINDS-funded longitudinal study to characterize clinical syndrome of CTE from its appropriated budget

NINDS will form a working group of Council to discuss next highest priority opportunities in concussion research

- In concert with NICHD
- Jonathan Mink to lead

- Will hold a workshop and create research plan
- Concept clearance for Council
- Discuss research plan with FNIH
Chronic Fatigue Syndrome

- Affects between 800,000 - 2.5 million in the US
- 75% affected are women
- Cause unknown but many have distinct onset with flu-like symptoms
- Plans for CFS/Myalgic Encephalitis Research
  - NIH-wide intramural protocol through IRB to begin phenotyping, neuro and immunologic studies
    - Led by Dr. Avi Nath
  - Trans-NIH working group developing an extramural research program
    - Led by Dr. Vicky Whittemore
NINDS’s Role in CFS

• NINDS leads Trans-NIH ME/CFS Working Group

  – Goals
    • Advance research on the cause, prevention, diagnosis, pathophysiology and treatment of ME/CFS
    • Communicate ME/CFS research information with ICs, OD

  – Activities
    • Organize Federal Partners meeting (follow-up to 2014 Pathways To Prevention (P2P) Workshop)
      – Develop disease parameter
      – Create new knowledge
        » Diagnostics, Epi studies, Prognostics
        » Causation- immunologic, neurologic, genomic
      – Develop outcome measures
      – Develop and test treatment
      – Training and education
Fatigue Prominent in Many Disorders

Central Nervous System
- Multiple Sclerosis
- Post Stroke
- Post TBI
- Post Polio Syndrome
- Post posterior fossa surgery/path

Neuroendocrine
- Hypothyroidism
- Hypothalamic Pituitary Adrenal Axis

Metabolic
- Renal failure
- Heart Failure
- Anemia

Malignant
- Renal failure
- Heart Failure
- Anemia

Infectious and Post Infectious
- Mononucleosis
- Lyme
- Influenza

Inflammatory/Rheumatic Diseases

Environmental
- Heat
- Altitude sickness

Drug AEs

Central Nervous System
- Overtraining Syndrome
- Myasthenia Gravis
- Mitochondrial disorders
- Chronic Guillain Barre

Infectious and Post Infectious
- Mononucleosis
- Lyme
- Influenza

Psychological
- Depression
- Post traumatic stress disorder
- Anxiety Disorder

Cancer
- Cancer and Post cancer
- Radiation and Chemotherapy

Aging

Drug AEs

Central Nervous System
- Overtraining Syndrome
- Myasthenia Gravis
- Mitochondrial disorders
- Chronic Guillain Barre

Infectious and Post Infectious
- Mononucleosis
- Lyme
- Influenza

Psychological
- Depression
- Post traumatic stress disorder
- Anxiety Disorder

Cancer
- Cancer and Post cancer
- Radiation and Chemotherapy

Aging
What’s known: Two Major Categories of Fatigue

Physical fatigue is an exercise-induced reduction in maximal voluntary muscle force.

- The central nervous system fails to drive the motoneurons maximally.
- How the brain interprets signals from muscle to produce sense of fatigue is not clear.

Mental fatigue is associated with affective, behavioral, and cognitive impairments especially in attention, planning, increased distractability.

- N.B. It is not related to ↓ ATP.
FY 2018 Common Fund Proposals

• **Mechanisms of Fatigue**
  – The concept for this program is to determine whether universal molecular, chemical, or imaging signatures of fatigue can be established; if so, a program in this area would explore mechanisms through which fatigue occurs and how it is resolved by rest/sleep in healthy individuals.

• **Transformative Cryo-Electron Microscopy**
  – The concept for this program is to increase capacity for high resolution Cryo-EM analyses in the US through infrastructure support, training, and further enhancements to the technology.

• **Human Cell Atlas**
  – The concept for this program is to define human tissues at a single cell level over time and in different conditions, such as different phases of life or in health versus disease.
2011: Relieving Pain in America

2012 Assistant Secretary for Health, HHS tasked IPRCC and NIH to address IOM Recommendation: “develop a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames, and resources.”

Agency clearance February 2016
Focus on the Continuum of Pain: pain as a temporal process, beginning with an acute phase that may progress to a chronic maladaptive state.

PREVENTION OF ACUTE & CHRONIC PAIN
ACUTE PAIN & ACUTE PAIN MANAGEMENT
TRANSITION FROM ACUTE TO CHRONIC PAIN
CHRONIC PAIN & CHRONIC PAIN MANAGEMENT

WHAT HAPPENS AND TO WHOM?
WHY AND HOW DOES IT HAPPEN?
HOW TO MANAGE?

BASIC SCIENCE
CLINICAL SCIENCE
UNDERSTAND MECHANISMS
TRANSLATE/TREAT

Completion January 2017
Clinical Questions

• Determining when to initiate or continue opioids for chronic pain
• Opioid selection, dosage, duration, follow-up, and discontinuation
• Assessing risk and addressing harms of opioid use

12 Recommendations

• Non-opioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care.

• When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose.

• Providers should always exercise caution when prescribing opioids and monitor all patients closely.
FY16 NIH PMI Appropriation - Enacted

<table>
<thead>
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<th>NIH PMI Research Program</th>
<th>Appropriation</th>
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<tr>
<td>• <em>PMI Cohort Program</em></td>
<td>$130 million</td>
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<tr>
<td>• <em>PMI for Oncology</em></td>
<td>$70 million</td>
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<td><strong>TOTAL</strong></td>
<td><strong>$200 million</strong></td>
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The President’s PMI has many components:

- FDA
- ONC
- OCR
- etc.
Approach to Assembling the PMI Cohort

• **One million or more** U.S. volunteers
  – Broadly reflect the diversity of America (including family members of all ages, health statuses, geographic areas, etc.)
  – Strong focus on underrepresented groups

• **Longitudinal cohort**, with continuing interactions, recontact for secondary studies
  – Collect EHR data, provide biospecimen(s) and survey, and complete a baseline exam

• Two methods of **enrollment**
  – Direct volunteers: anyone can sign up
  – Healthcare provider organizations (incl. FQHCs): diverse participants, robust EHRs, participant follow-up

• Substantial **participant engagement** in development, implementation, governance
NIH-Wide Strategic Plan

NIH unveils FY2016 – 2020 Strategic Plan.

Learn more »

http://www.nih.gov/about/strategic-plan
NIH-Wide Strategic Plan Framework

Overview
- Mission of NIH
- Unique moment of opportunity in biomedical research
- Current NIH-supported research landscape
- Constraints confronting the community in the face of lost purchasing power

Objective 1: Advance Opportunities in Biomedical Research

Fundamental Science
- Foundation for progress
- Consequences often unpredictable
- Technology leaps catalyze advances
- Data science increases impact/efficiency

Health Promotion/Disease Prevention
- Importance of studying healthy individuals
- Advances in early diagnosis/detection
- Evidence-based reduction of health disparities

Treatments/Cures
- Opportunities based on molecular knowledge
- Breakdown of traditional disease boundaries
- Breakthroughs need partnerships, often come from unexpected directions
- Advances in clinical methods stimulate progress

Objective 2: Set Priorities
- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity; need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic risk

Objective 3: Enhance Stewardship
- Recruit/retain outstanding research workforce
- Enhance workforce diversity
- Encourage innovation
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden

Objective 4: Excel as a Federal Science Agency by Managing for Results
1) Should NIH focus more on supporting a broad and diverse portfolio of investigators?

2) Should NIH require a minimum percent effort by principal investigators?

3) Should NIH establish shared regional research resources and facilities to improve access to cutting-edge technologies and reduce costs by economies of scale?
Spectrum of R01 Grants Awarded; FY 2015
Unsolicited R01/R37 grants (includes PAs but not RFAs)
Kernel Density Distributions for All NIH R01/R37 Grants

N=16,565
Overlap Coefficient=0.23

Award.Fate
Awarded
Not Awarded

Kernel Density Distributions for All NIH R01/R37 Grants
NINDS Funding Outcomes

All Investigators

New Investigators
Trends in R01/R37 Overlap Coefficients for NS, HD, MH, AG, and DA

Administering IC

- NS
- HD
- MH
- AG
- DA

Overlap Coefficient

Fiscal Year

2011 2012 2013 2014 2015

0.10 0.15 0.20 0.25
Thoughts

• IC’s more similar than different
• Not going strictly by payline
  – NIH overlap coefficient: 0.23; IC range: 0.11 to 0.26
  – Important to understand NINDS data more completely
    • Trend indicates our consistent approach to funding almost all applications below the payline
• How to communicate?
  – Funding strategies
  – Actual funding outcomes
  – Select pay is better seen in funding of initiatives, P’s,
Neuroscience Training: What’s Changed?

- Neuroscience is expanding in multiple directions
- Numbers of graduate students increased dramatically
- Time to independence increased dramatically
- Tools have become more sophisticated, and an increased degree of sophistication is needed for data analysis
- New emphasis on attracting scientists from outside biology
- New emphasis on rigor in experimental design and statistical analysis
- Funding climate became much more competitive during the 12 flat budget years and concern that associated pressures led to decline in career mentoring
- Early movement within BRAIN initiative to adapt a more “physics-like” model to engage team science to attack problems
  - Data platforms and data sharing
- Concern that attempts to increase diversity in trainees not translating as well as hoped into diversity in the academic science workforce
Trends in Fields of Study of Trainees and Fellows Receiving Ph.D.s

- Biochemistry
- Engineering
- Health Sciences
- Immunology
- Molecular Biology
- Neuroscience
- Physical Sciences
- Psychology
• **Transdisciplinary training.**
  
  • Training for neuroscientists needs more:
    – mentoring
    – experimental and analytical skills
    – communication and writing skills
    – lab and office management
    – ethics in science
    – fundamental neuroscience knowledge and its history,
    – teaching and mentoring
  
  • Training “in neuroscience” needs:
    – tracks for those coming from physical and computational backgrounds
    – team science
    – tracks for translational science
• Experimental and analytical skill development
  – Statistical reasoning and facility in statistical methods
  – Reducing bias by training for rigorous experimental design
  – Demystify neurotechnologies
  – Data analytic skills
    • programming, data management platforms, multidimensional cloud computing, data visualization and feature extraction, algorithm development, machine learning and computer modeling
NINDS
Seeking Knowledge about the Brain . . .
Reducing the Burden of Disease