

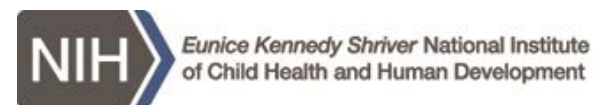
DIRECTOR'S REPORT



Alan E. Guttmacher, M.D.
Director

**National Advisory Child Health and Human
Development Council**

January 22, 2015



What's To Come

- News from NIH
- News from NICHD
- Budget and legislative updates
- Discussion and Q&A with you

News from NIH



National Library of Medicine Changes



- Don Lindberg, M.D., director of the National Library of Medicine, will retire at the end of March
- Dr. Collins formed an ACD working group to formulate a new vision for NLM over the next decade
- Co-chaired by Harlan Krumholz (Yale) and Eric Green (NHGRI)

NCCAM Is Now NCCIH

- Effective December 17, the National Center for Complementary and Alternative Medicine has a new, Congressionally-mandated name: the National Center for Complementary and Integrative Health, or NCCIH



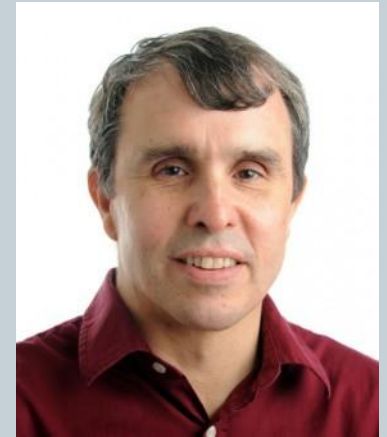
© Matthew Lester
Courtesy: National Center for
Complementary and Integrative Health



2014 Nobel Prize in Chemistry



- Went to Eric Betzig, Ph.D. - along with Stefan Hell and William Moerner - for the development of super-resolved fluorescence microscopy
- Betzig's key experiment was done at NICHD in Jennifer Lippincott-Schwartz's lab
- Wonderful example of high-risk/high-reward research and the importance of collaboration and the freedom to pursue ideas - and of NIH scientists with the vision to encourage and support this research



President Obama Visits NIH



- President Obama visited NIH in December to congratulate scientists for delivering a potential Ebola vaccine
- He also emphasized that scientific research will help fight global health threats

Precision Medicine

- And, in the State of the Union Message, noted:

“I want the country that eliminated polio and mapped the human genome to lead a new era of medicine -- one that delivers the right treatment at the right time. In some patients with cystic fibrosis, this approach has reversed a disease once thought unstoppable. Tonight, I'm launching a new Precision Medicine Initiative to bring us closer to curing diseases like cancer and diabetes -- and to give all of us access to the personalized information we need to keep ourselves and our families healthier.”

Use of a Single Institutional Review Board for Multi-Site Research

- NIH seeks public comment on a draft policy to promote use of a single IRB for domestic sites of NIH–funded multi-site studies
- Goal is to enhance and streamline the IRB review process and reduce inefficiencies so that research can proceed efficiently without compromising ethical principles and protections
- Submit comments electronically by January 29 to SingleIRBpolicy@mail.nih.gov

National Children's Study



- On December 12, 2014, the NCS Working Group of the ACD recommended the closure of the National Children's Study
- NIH adopted this recommendation
- Dr. David Murray, director of NIH's Office of Disease Prevention, will oversee the closing of the study
- More to come later in the morning, after the break

NIH Council of Councils



- Kimberly K. Leslie, MD, was approved by the Secretary of HHS to serve on the NIH Council of Councils
- The Council is made up of members selected from NIH Institute and Centers (IC) Advisory Councils
- Members bring knowledge about ICs but they are not official representatives; they provide advice beyond the research agenda of any individual IC

News from NICHD



Relevant Congressional Report Language

- Expects NIH Rehabilitation Coordinating Comm.:
 - to host a trans-NIH State of the Science Conference on Medical Rehabilitation Research, develop and update a trans-NIH plan for medical rehabilitation science, and better coordinate the grants to adhere to the definition of rehabilitation research recommended by the Blue Ribbon Panel on Medical Rehabilitation Research
 - to establish benchmarks to assess whether the coordination proposals being implemented are having a positive impact on rehabilitation science at NIH
- The NICHD and NIH Directors will hold a briefing to discuss progress in rehabilitation research across the NIH

And...

- Congress expects NIH “to promote the advancement of biomedical science in a manner that builds public trust and accountability and expects NIH to conduct rigorous oversight prior to the awarding of funds to ensure that all grants are connected to the core mission and priorities of NIH.”
- The report expresses Congress’ expectation that study sections that are reviewing pediatric research applications “have permanent or ad hoc members who are experts in the field.”

NICHD-Related Significant Items for Congress

- Angelman syndrome
- Autism
- BRAIN initiative
- Chromosome abnormalities
- Chronic pelvic pain
- Contraception research and development
- Duchene muscular dystrophy
- Fragile X
- Usher syndrome
- Health disparities in children and adolescents
- Human placenta project
- Maternal morbidity
- Medications in pregnancy
- Mitochondrial disease
- National Pediatric Network Act
- Preterm birth
- Sleep disorders
- Spina bifida
- Training and career development (K and T awards)
- Trans-NIH basic behavioral and social science opportunity network

Muscular Dystrophy

- Signed by the President on September 26, PL-113-166, the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008, of 2014, reauthorizes and amends the muscular dystrophy research program at the NIH
- Expands to cover all forms of muscular dystrophy
- Continues and expands the inter-agency Muscular Dystrophy Coordinating Committee, which I currently chair

TBI Reauthorization Act

- Signed by the President on November 26, PL-113-196 reauthorizes federal prevention, surveillance, and registry programs relating to traumatic brain injury through 2019
- Requires HHS Secretary to improve coordination of federal activities and to develop a traumatic brain injury coordination plan within one year
- Requires CDC Director, in consultation with NIH Director, to review the scientific evidence related to brain injury management in children, identifying ongoing and potential opportunities for research

Newborn Screening

- Signed on December 18, PL-113-240, the Newborn Screening Saves Lives Reauthorization Act of 2014 amends and reauthorizes current agency authorities relating to newborn screening, including NICHD's Hunter Kelly Newborn Screening program
- Federally funded research on newborn dried blood spots is considered research on human subjects requiring informed consent that cannot be waived by institutional review boards
- NICHD will convene a meeting in March to discuss optimal timing and methods for collecting consent

Now it's your turn...



Comments, questions?