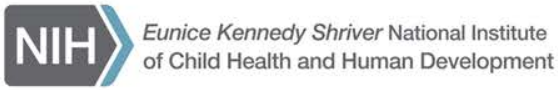
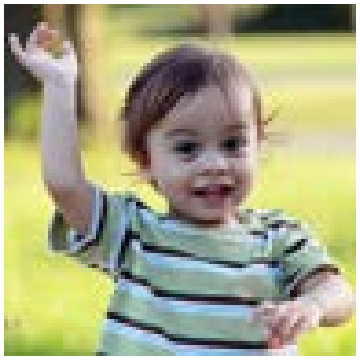
Division of Extramural Research: Update

September 21, 2016

Della M. Hann, Ph.D.



Overview



- Staff Updates & Awards
- Understanding NICHD Awards
- Funding the Best Science
- Upcoming Changes: Clinical Trials

New to NICHD Extramural

Nasreen Jones
OHE/OGH

Sanah Zia
OCM

Madjid (MJ) Karimi
OCM

Robert Borie
OCM

Shilpi Agrawala
GHDB

Staff Transitions: Departures from NICHD Extramural

Steven Hirschfeld

Associate Director for Clinical Research

Sheri Ann Hild

Scientific Review Officer

Alicia Christy

Medical Officer

Carla Walls

Scientific Review Officer

Staff Transitions: Retirements in Extramural

Mary Ellen Michel

NCMRR

Program Officer

NIH Director's Awards

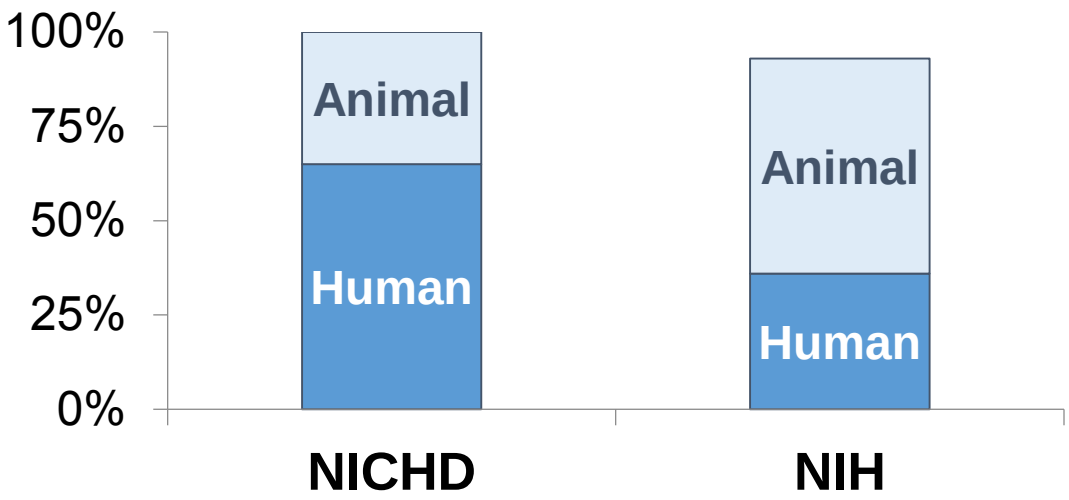
- Valerie Cotton and Lorette Javois for the Gabriella Miller Kids First Pediatric Research Program Coordination Team
- Marita Hopmann for a the RPC Reviewer Guidance Working Group
- Eugene Hayunga for his dedication, commitment and leadership to the NICHD and NIH community

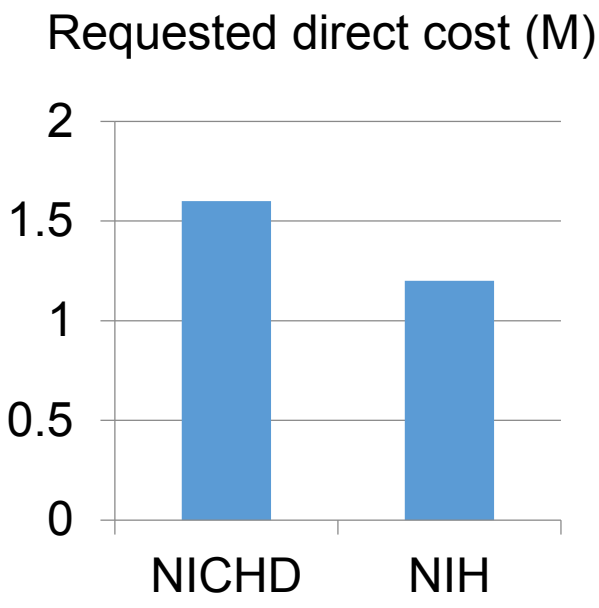
Understanding NICHD Awards

Data on R01 Awards by Research Type

Characteristics of scored applications

Human Study	65% (2836)	36% (26855)
Animal Study	35% (1517)	57% (42671)
Requested Direct Costs ($M)	1.2 1.6 2.4	1.2 1.2 1.8





Data from M Lauer, OER, NIH

OER Analysis: Results for Cumulative Costs: Requested Direct

Requested Direct Cost of NICHD R01 grants

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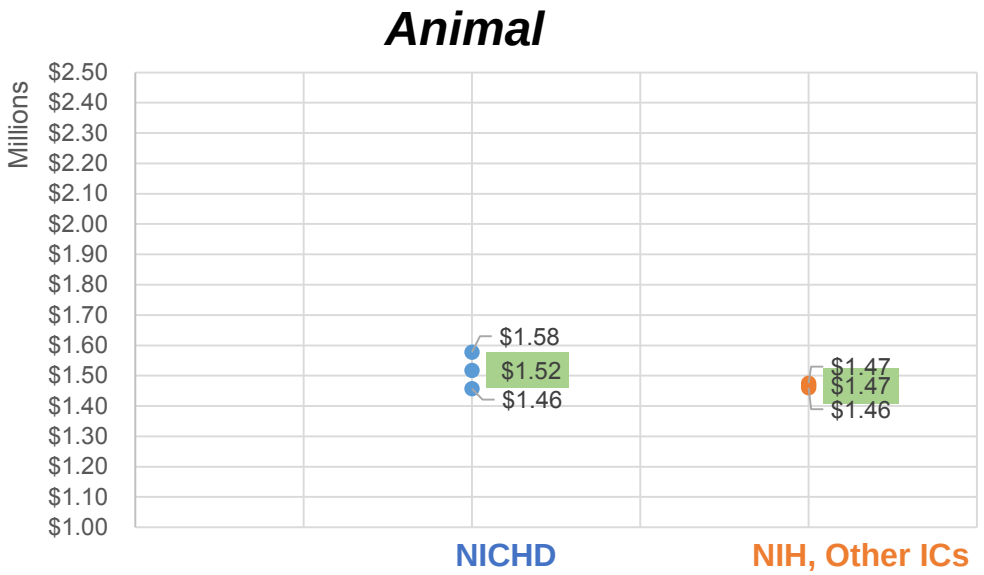
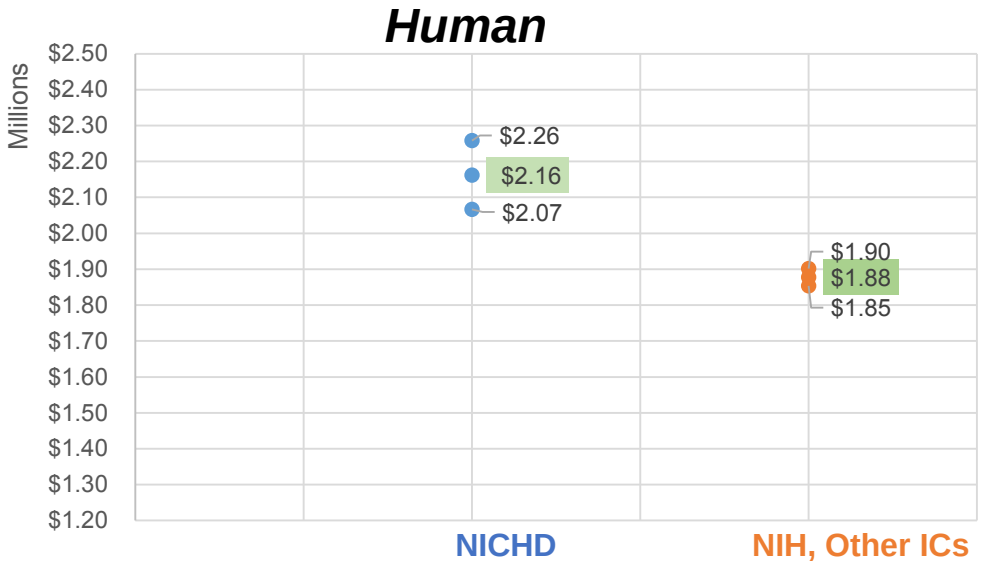
Requested Direct Costs of non-NICHD NIH R01 grants

NICHD higher, and statistically significant for human





Data from NICHD OSPRA

OER Analysis: Results for Cumulative Costs: Committed Direct

Committed Direct Cost of NICHD R01 grants

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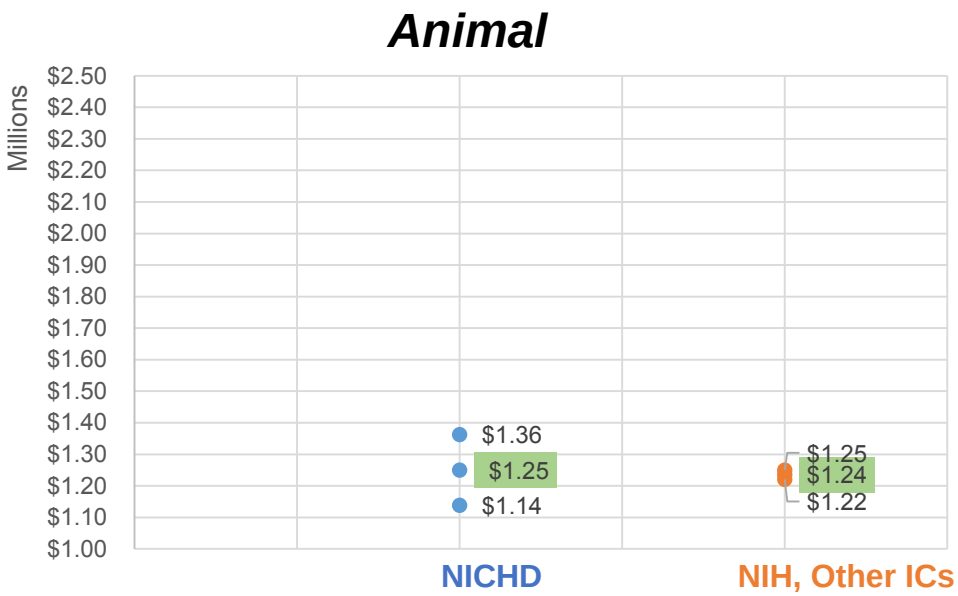
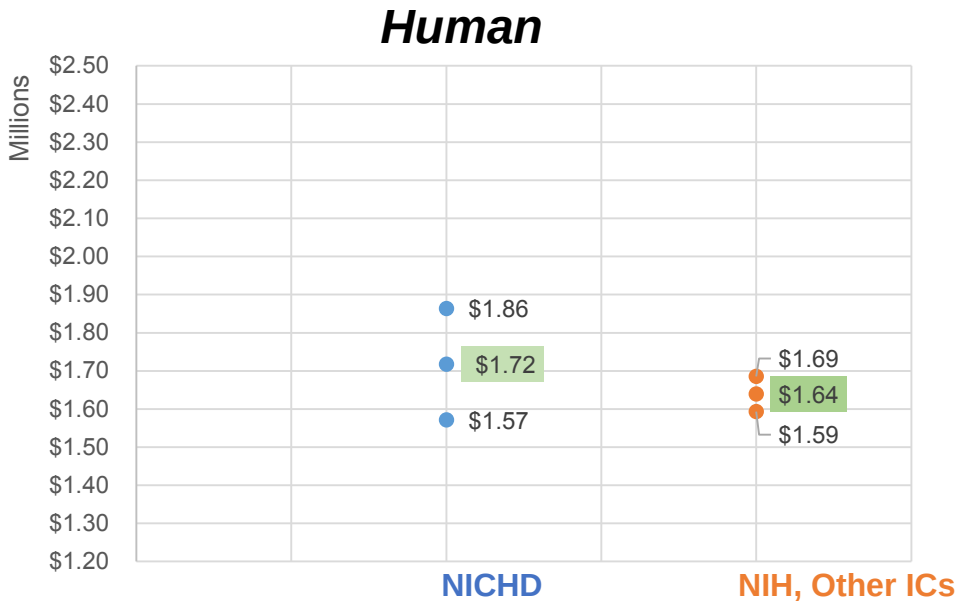
Committed Direct Costs of non-NICHD NIH R01 grants

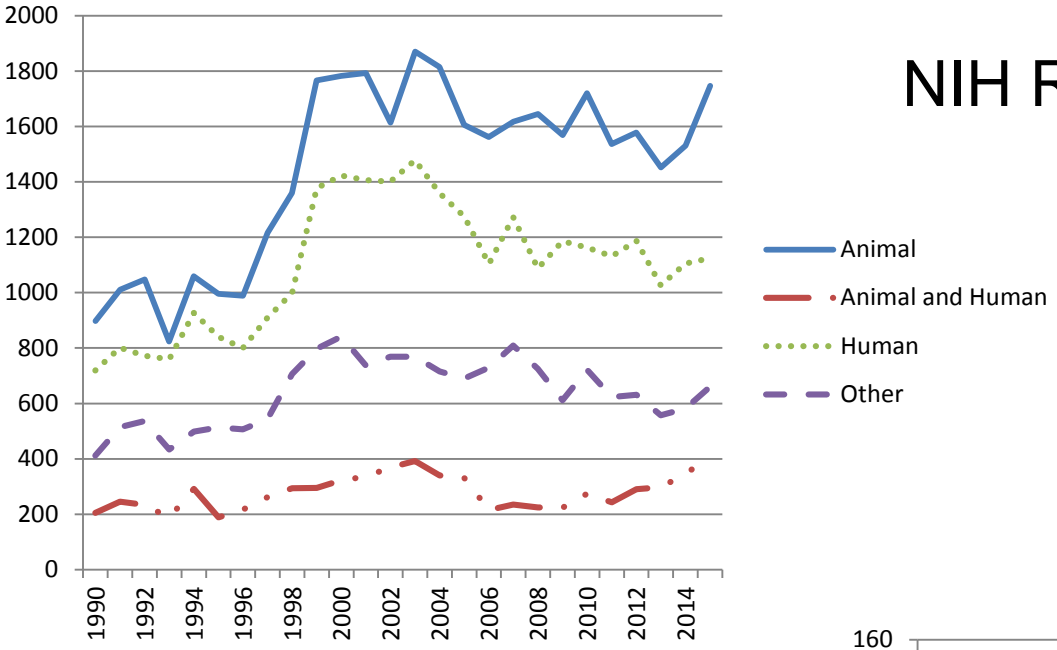
NICHD higher, but not statistically significant

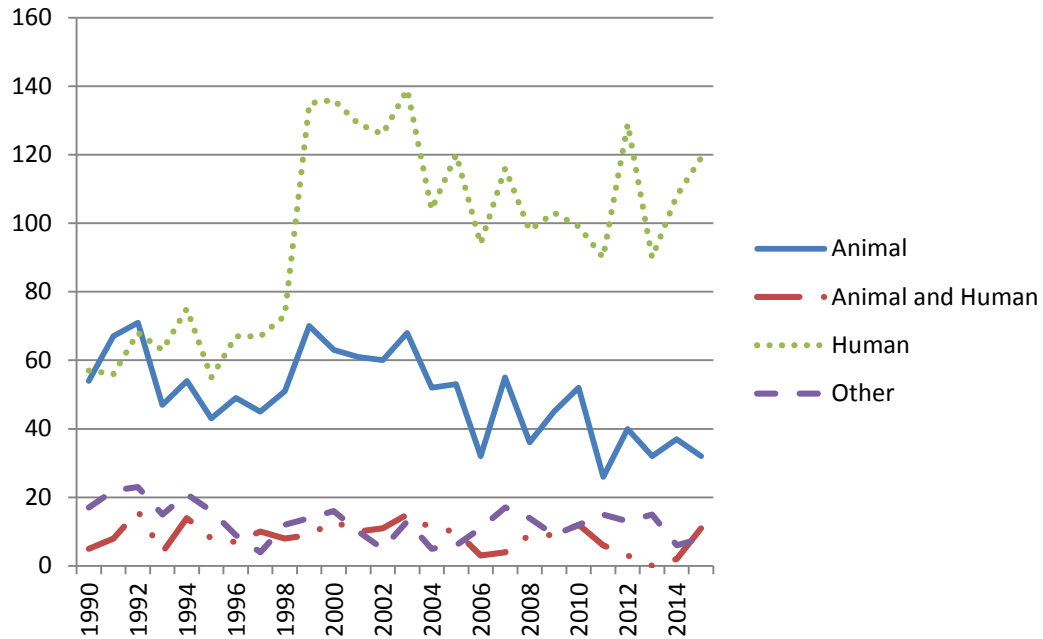




Data from NICHD OSPRA

Number of R01 Awards - Types of Research

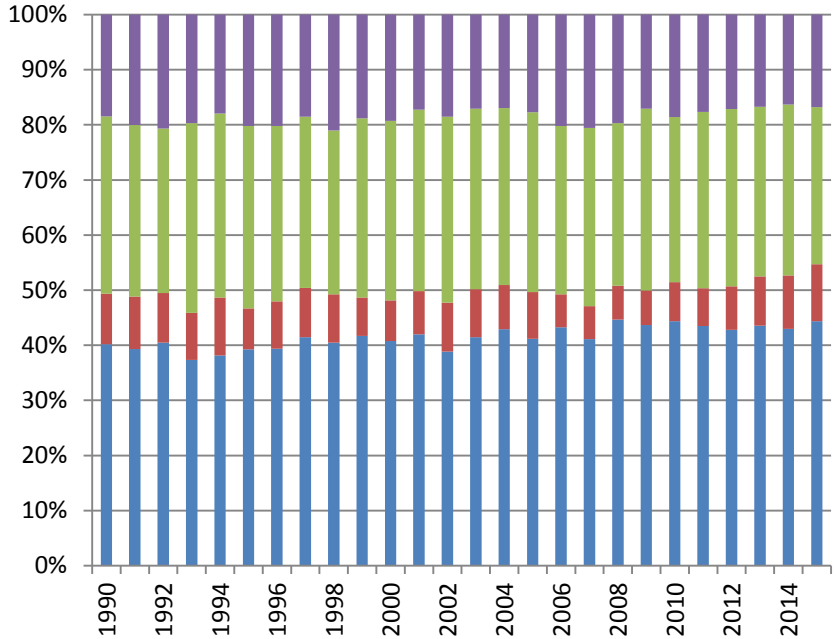




NICHD R01 Awards

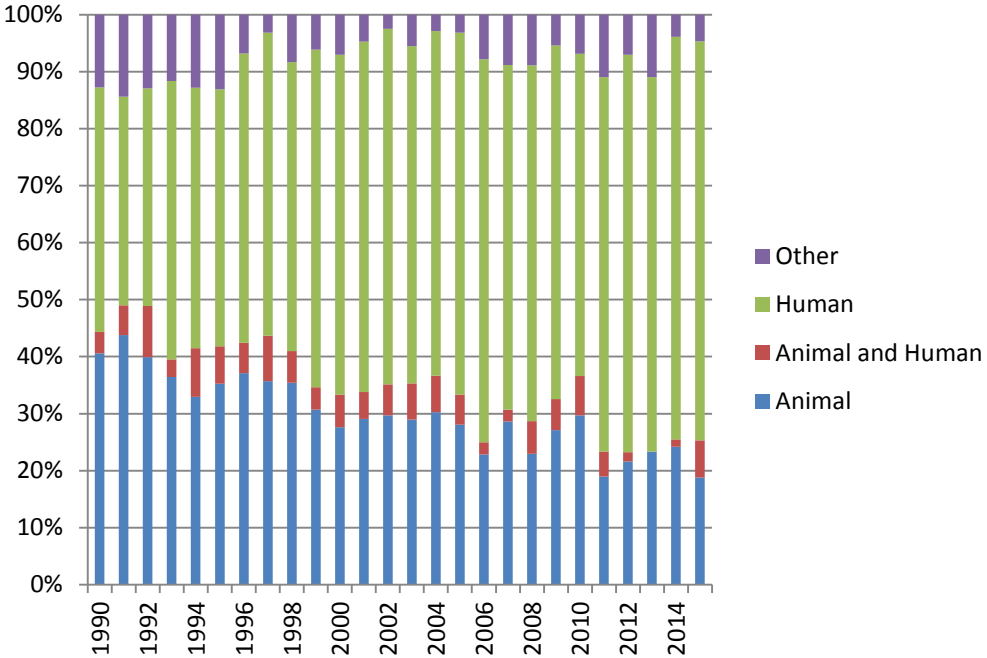
Data from OER SARB

Proportion of R01 Awards- Types of Research



NIH R01 Awards

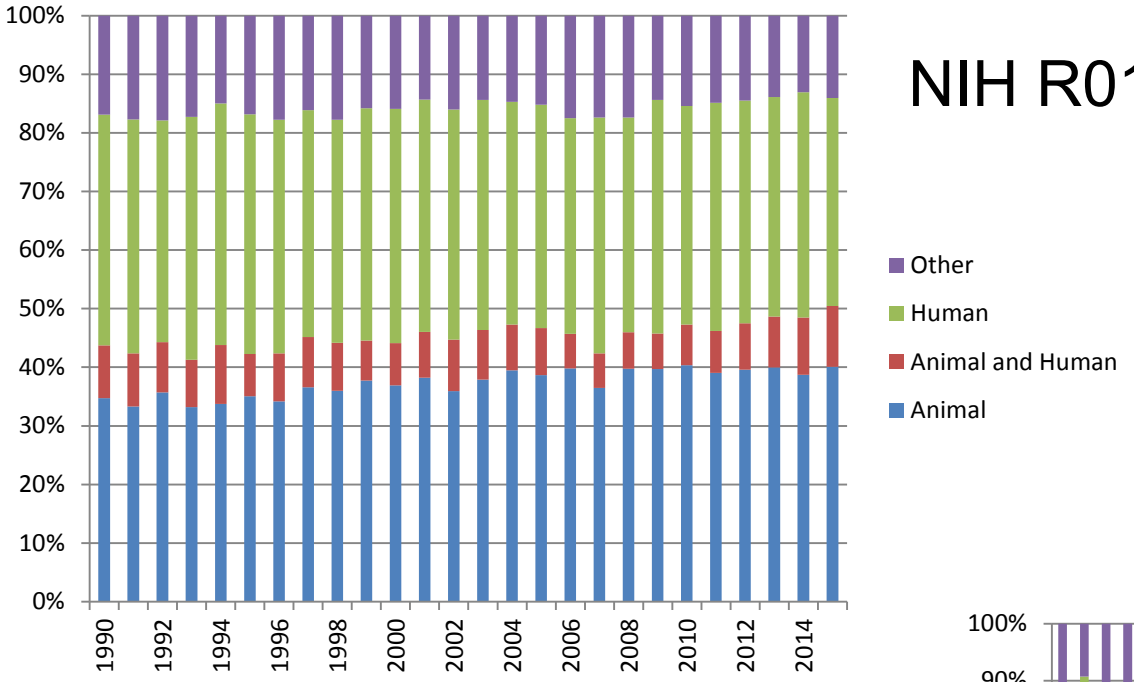
Other
Human
Animal and Human
Animal



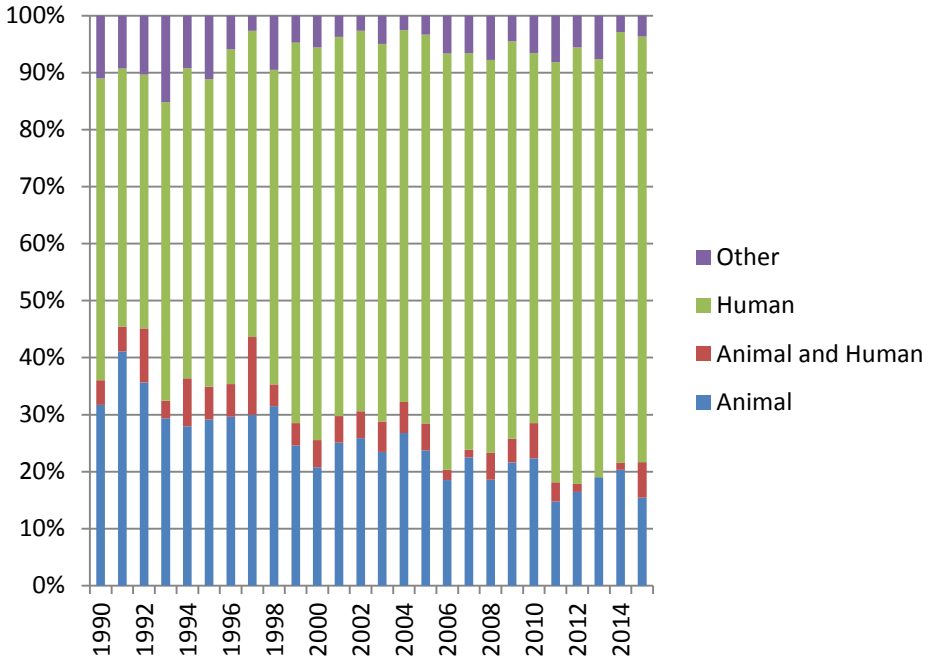
NICHD R01 Awards

Data from OER SARB

R01 Awards – Proportion of Year 1 Costs by Types of Res



NIH R01 Awards



NICHD R01 Awards

Data from OER SARB

Summary: R01 Awards at NICHD

- Requested Costs are higher than other NIH ICs
  - For Research involving Humans, but not Animal
- Awarded Costs are more comparable to other NIH ICs – both Human and Animal
- NICHD R01 Awards higher percentage of research involving humans compared to other NIH ICs
  - Major increase in human research during doubling
- NICHD invests higher proportion of R01 funding in research involving humans
  - Notable growth during the doubling

Funding the Best Science

Options for Improving the Payline

Clarify the Message

- ✓Tighten referral guidelines
- ✓Tighten transfer acceptance
- ✓Clinical trials by FOA
- ✓Stricter methods for large grant acceptance
- ✓Limit PA, PAR, and secondary assignments
- ✓Communicate priorities

Communicate Priorities

- Each branch developed up to 7 priority topics
  - Vision Document
  - Strategic Plans
  - Portfolio Assessment
- Identifying gaps and science needed to address
- Post on branch websites

Supporting the Best Science

- Using Priorities to Drive Funding Decisions
- Posting Priorities on each Branch Web Page
- We will continue to welcome, encourage, and support investigator-initiated applications that help advance our mission goals.

Director's Corner

Share this:

Supporting the Best Science

Using Priorities to Drive Funding Decisions

Public health needs and scientific discovery continually evolve, and it is critical for research-funding agencies to remain ahead of the curve. As opportunities arise, agencies must be agile enough to re-prioritize funding and channel resources toward newly defined goals. A good example of this is NIH's response to the Zika virus outbreak. In February 2016, as Zika began attracting international attention, several NIH institutes, including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), issued a funding opportunity designed to accelerate research on the virus and its complications. This rapid funding mechanism enables continuous receipt and review of grant applications and expedites funding for Zika-related projects that do not yet have preliminary data.

About NICHD
Institute Overview
Organization
- Organization Charts
- Office of the Director (OD)
- Division of Extramural Research (DER)
  - Extramural Scientific Branches
    - Child Development and Behavior Branch (CDBB)
    - Contraception Research Branch (CRB)
    - Developmental Biology and Structural Variation Branch (DBSVB)
    - Fertility and Infertility (FI) Branch
    - Gynecologic Health and Disease Branch (GHDB)
    - Intellectual and Developmental Disabilities Branch (IDDB)
    - Maternal and Pediatric Infectious Disease Branch (MPIDB)
    - Obstetric and Pediatric

Contraception Research Branch (CRB)

Share this:

- NEW: Overview and Research Priorities
- Staff Directory
- Programs & Program Areas
- Supported Research Networks, Programs, and Initiatives
- Training and Career Development
- Scientific Resources
- Funded Projects
- Highlights

Overview

The CRB, formerly the Contraception Discovery and Development Branch, develops and supports research and research training programs in contraceptive discovery and development. Major research areas include studies of: new contraceptive methods; mechanisms of action and effects of contraceptive and reproductive hormones, drugs, devices, and procedures as well as optimal formulations and dosages of contraceptive agents and spermicidal microbicides.

For more information on the Branch, read the Assessment of the Contraceptive Research Activities of the NICHD: Executive Summary (PDF 138 KB).

New: Research Priorities

Innovative Devices and Delivery Mechanisms

Gap: A key problem in contraceptive development is the delivery of pharmacologic agents to the sites of gamete production, maturation, and function.

Priority: Support research and development of novel and innovative device and delivery mechanisms for existing or novel contraceptive agents to improve ease of use, delivery schedule, and/or efficacy over current contraceptive methods. This work also should support post-marketing of the device and related behavioral research.

Contact Information

Name: Dr. Daniel Johnston
Branch Chief
Contraception Research Branch
Phone: 301-496-8535
Email:
daniel.johnston@nih.gov

Staff Directory

Related A-Z Topics

Bacterial Vaginosis
Contraception and Birth Control
HIV/AIDS
All related topics

NICHD News and Spotlights

NICHD appoints new chief for contraception research
Q&A with NICHD Acting Director Catherine Spong, M.D.
NICHD Launches New Data Sharing Resource to Accelerate Scientific Findings, Improve Health
All related news

Related Conferences

Past Events

Funding the Best Science: Use Priorities

- Increase flexibility for discretionary funding
  - No fixed pay line for investigator-initiated R01, R21, R03, R13 and R15
- Be more strategic about our investments:
  - Mechanisms
    - Example: Strategic use of P01 for areas in need of synergy announced https://grants.nih.gov/grants/guide/notice-files/NOT-HD-16-019.html
  - Acceptance of large grants
  - Participation in FOAs

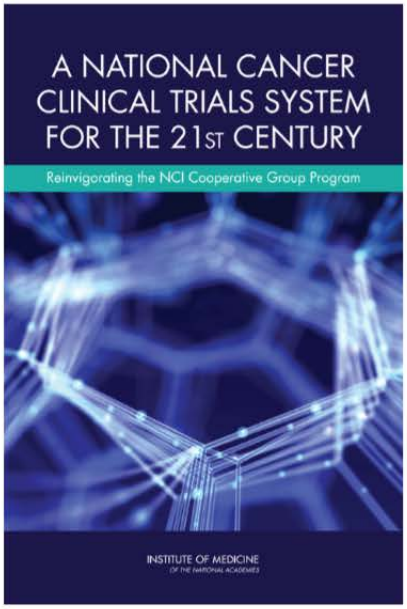
Clinical Trials

Newly Announced Changes in Policy

Problems Noted in 2010

A National Cancer Clinical Trials System for the 21st Century

Reinvigorating the NCI Cooperative Group Program



"Many stakeholders have expressed concern that the program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care."
Published in 2010

United States Government Accountability Office

Report to Congressional Committees

March 2016

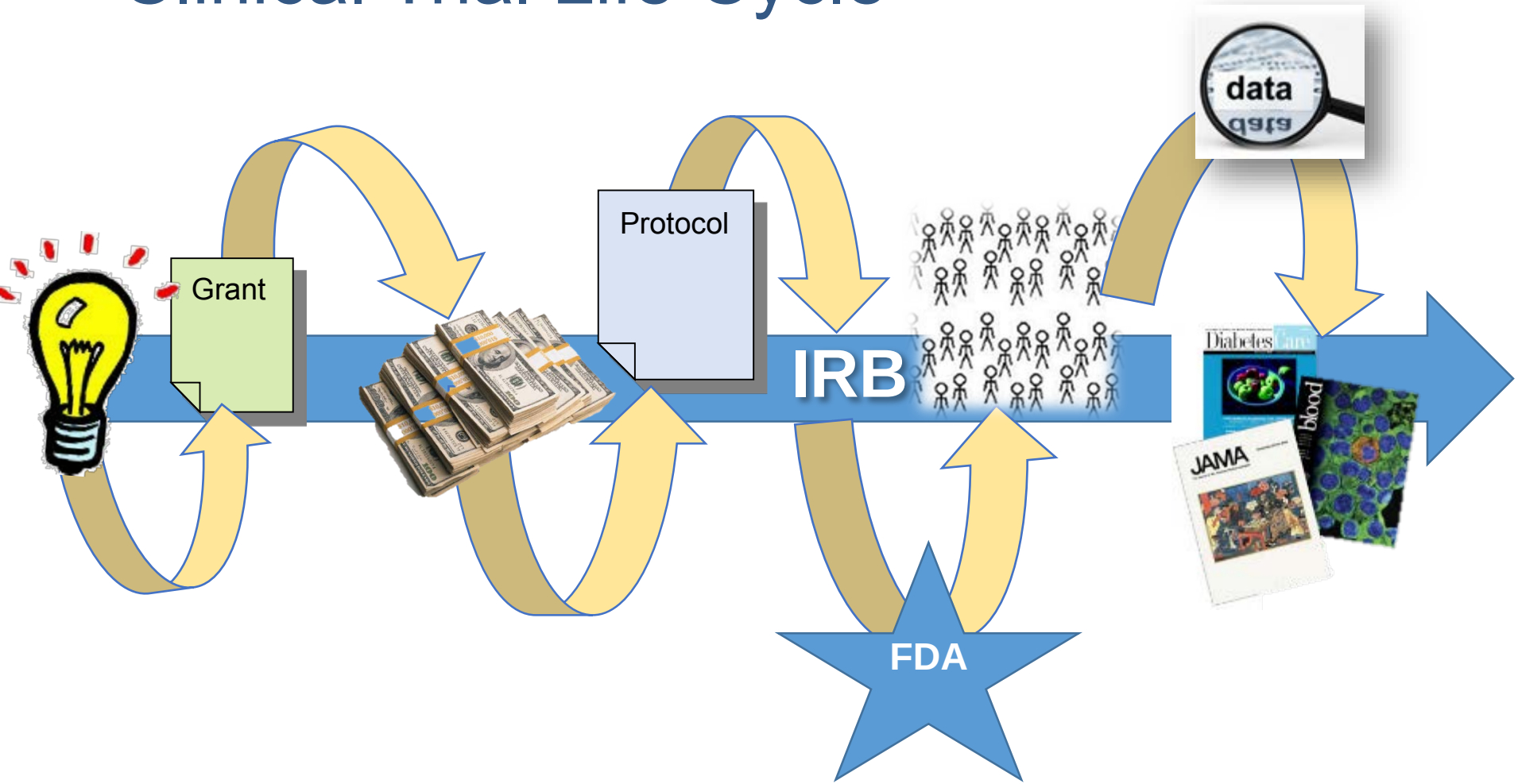
NATIONAL INSTITUTES OF HEALTH

Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency

Main Concerns

- Poorly designed trials
- Inconsistent oversight and monitoring
- Inability to assess across IC’s

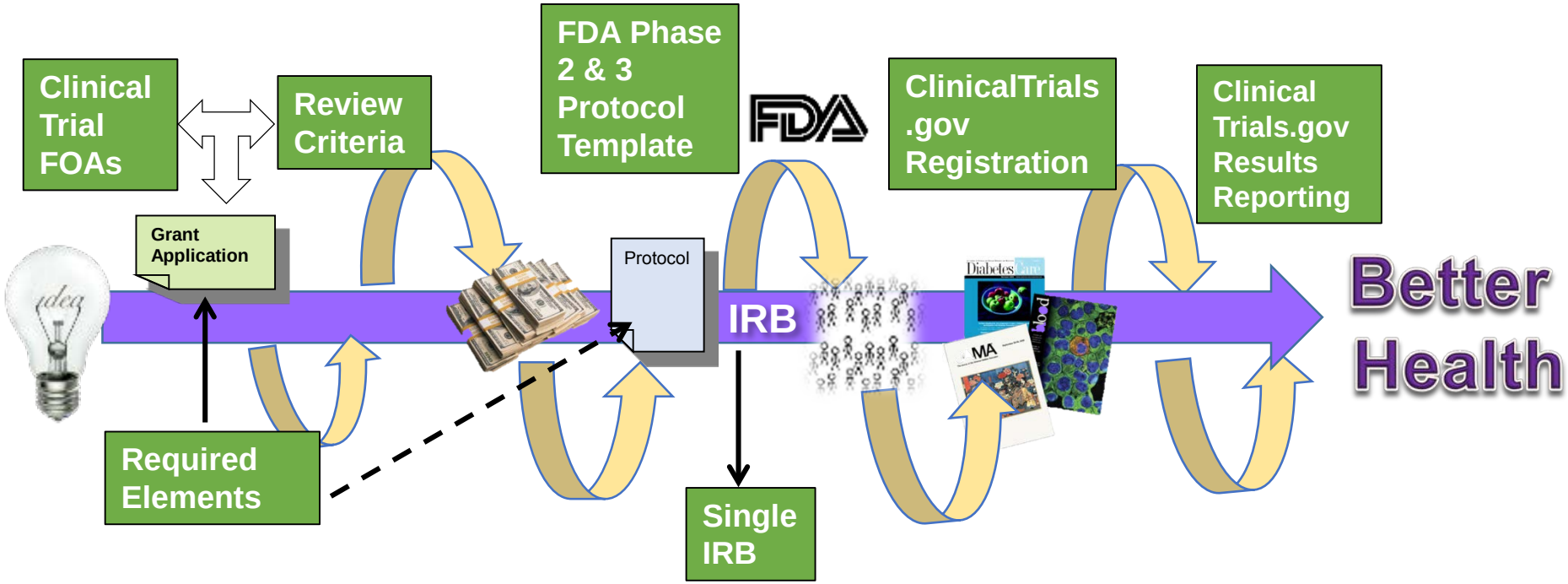
Clinical Trial Life Cycle



Series of Policy Changes: Implementation Timeline

- Revised Definition of Clinical Trials
  - Notice NOT-OD-15-015; Effective October 2014
- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  - Notice NOT-OD-16-094; Effective May 25, 2017
- Policy on Funding Opportunity Announcements (FOA) for Clinical Trials
  - Notice NOT-OD-16-147; Effective September 27, 2017
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
  - Notice NOT-OD-16-149; Effective January 18, 2017
- Policy on Good Practice Training for NIH Staff Involved in the Conduct, Management, and Oversight of Clinical Trials
  - Internal NIH Policy; Effective January 1, 2017

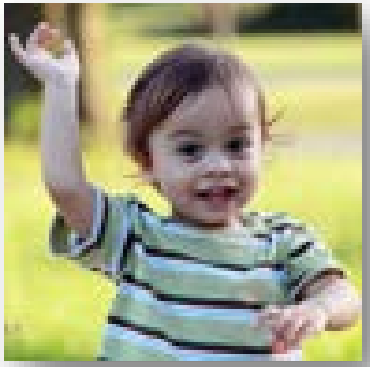
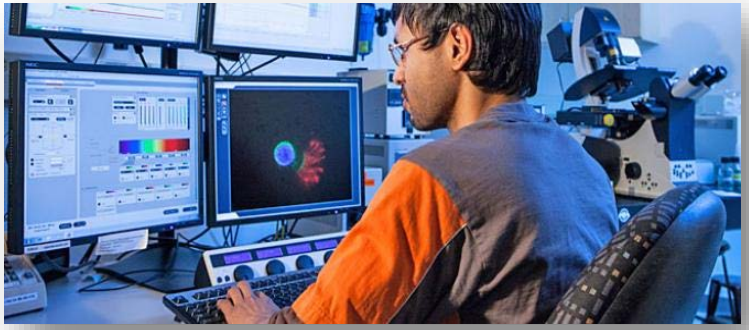
Interventions at All Points…



Ongoing Clinical Trials Monitoring and Oversight

- IC Trial SOPs
- GCP Training
- NIH data system/ tools
- Strategic use of trial data in ClinicalTrials. gov
- DSM policy updates
- Evaluation of stewardship activities

Funding the Best Science at NICHD…



to Advance Science & Health for All