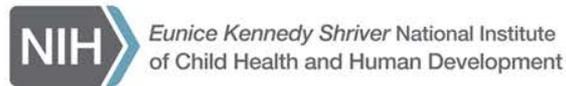


# Division of Extramural Research: Update

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





**Steven  
Hirschfeld**  
Associate  
Director  
for  
Clinical  
Research



**Sheri Ann Hild**  
Scientific  
Review  
Officer



**Alicia Christy**  
Medical  
Officer



**Carla Walls**  
Scientific  
Review  
Officer



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



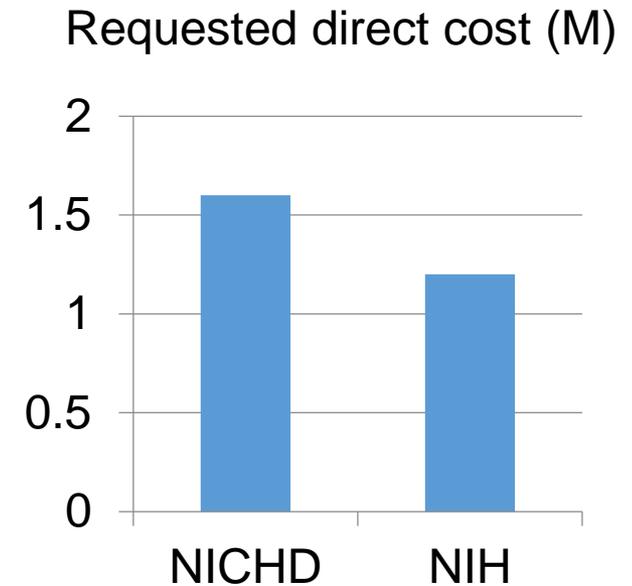
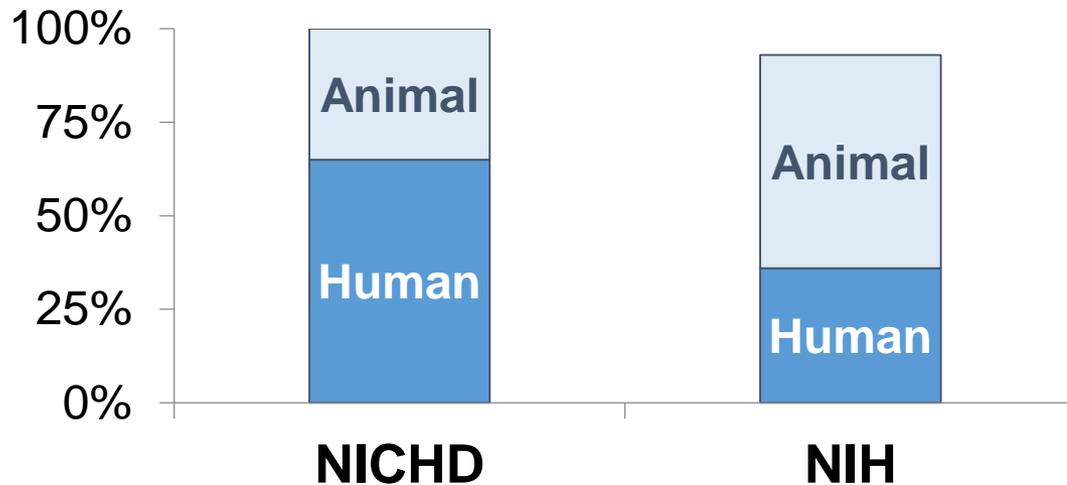
# Understanding NICHD Awards

*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





# OER Analysis: Results for Cumulative Costs: Requested Direct

Requested Direct  
Cost of NICHD R01  
grants

≥

Requested Direct  
Costs of non-NICHD  
NIH R01 grants

*NICHD higher, and  
statistically  
significant for human*

## Animal



## Human





# OER Analysis: Results for Cumulative Costs: Committed Direct

Committed Direct  
Cost of NICHD R01  
grants

≈

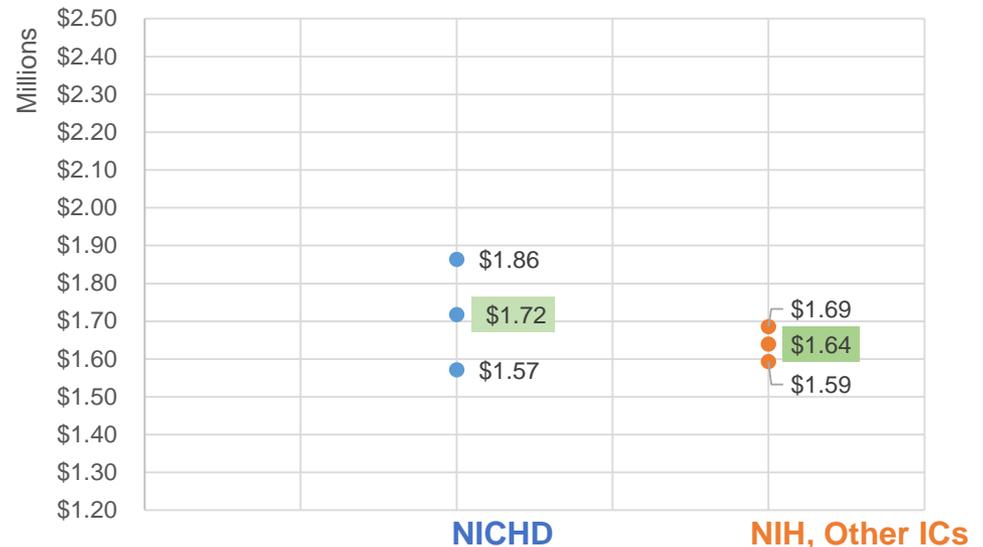
Committed Direct  
Costs of non-NICHD  
NIH R01 grants

*NICHD higher, but not  
statistically significant*

## Animal



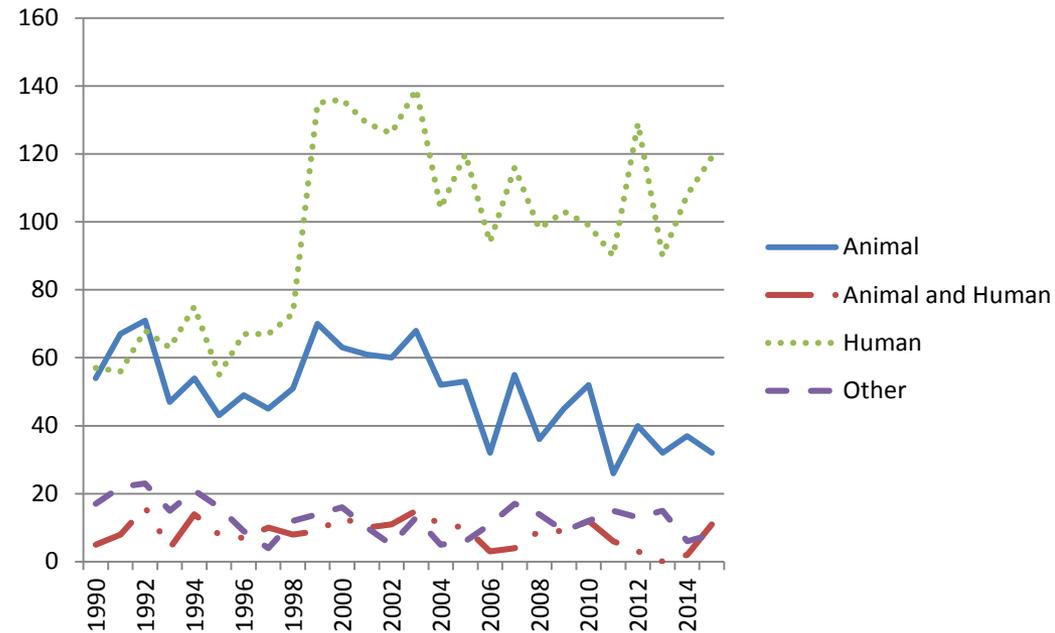
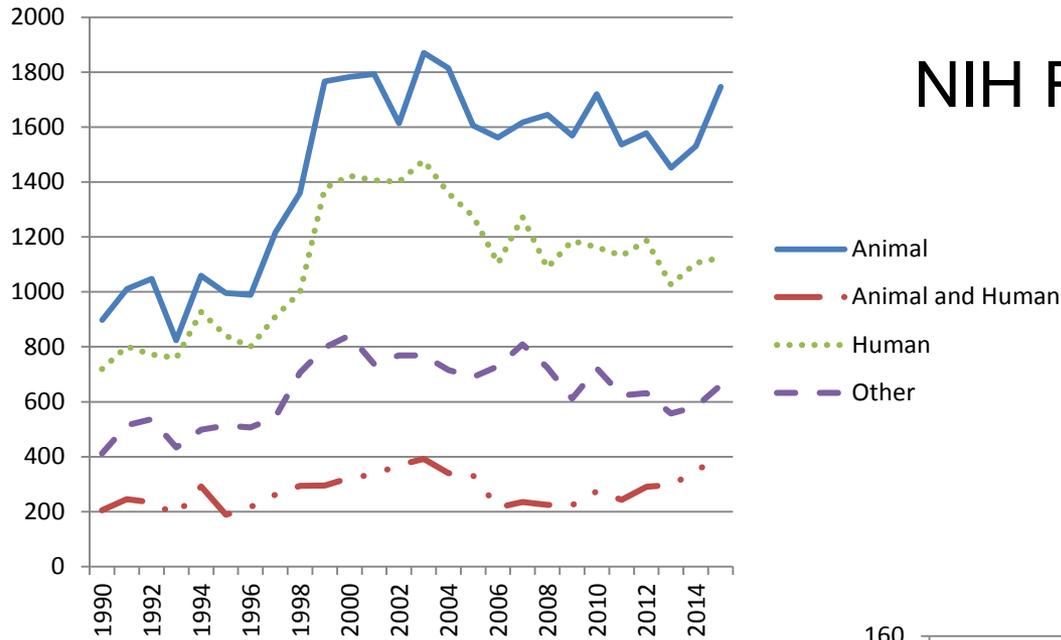
## Human



# Number of R01 Awards - Types of Research



## NIH R01 Awards



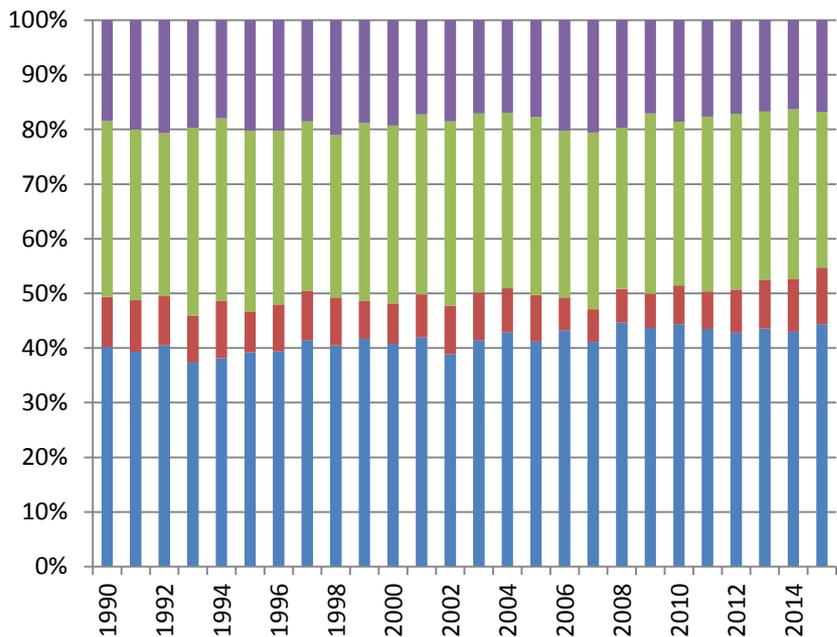
## NICHD R01 Awards

# Proportion of R01 Awards- Types of Research

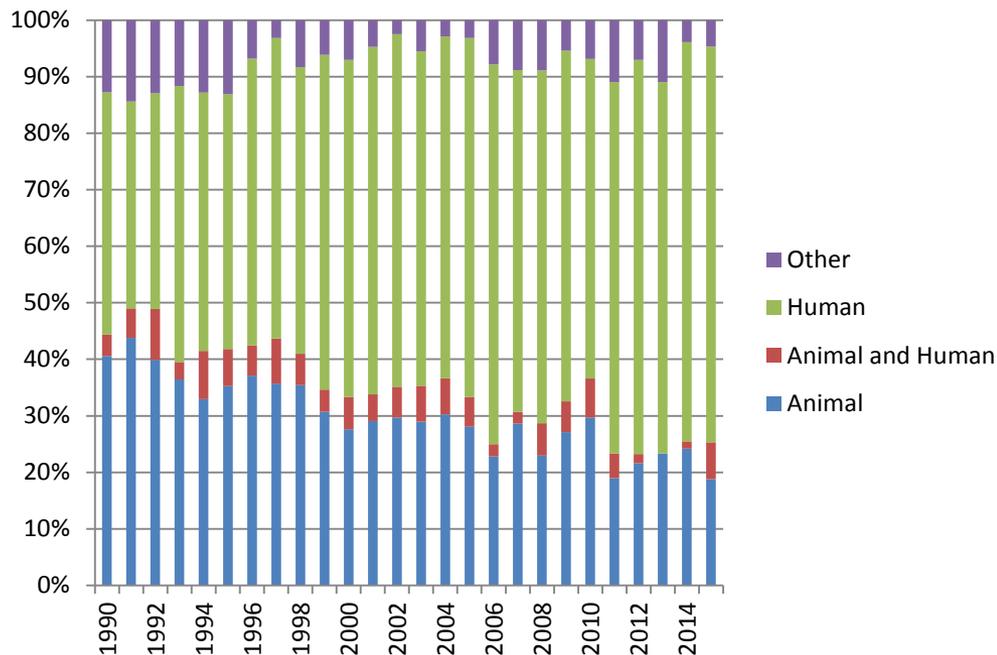


## NIH R01 Awards

- Other
- Human
- Animal and Human
- Animal

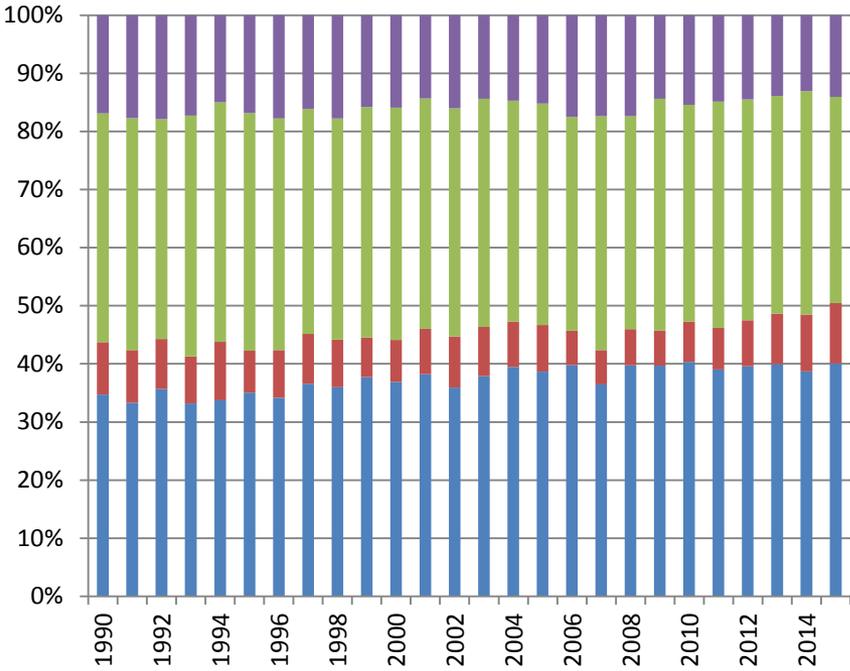


## NICHD R01 Awards



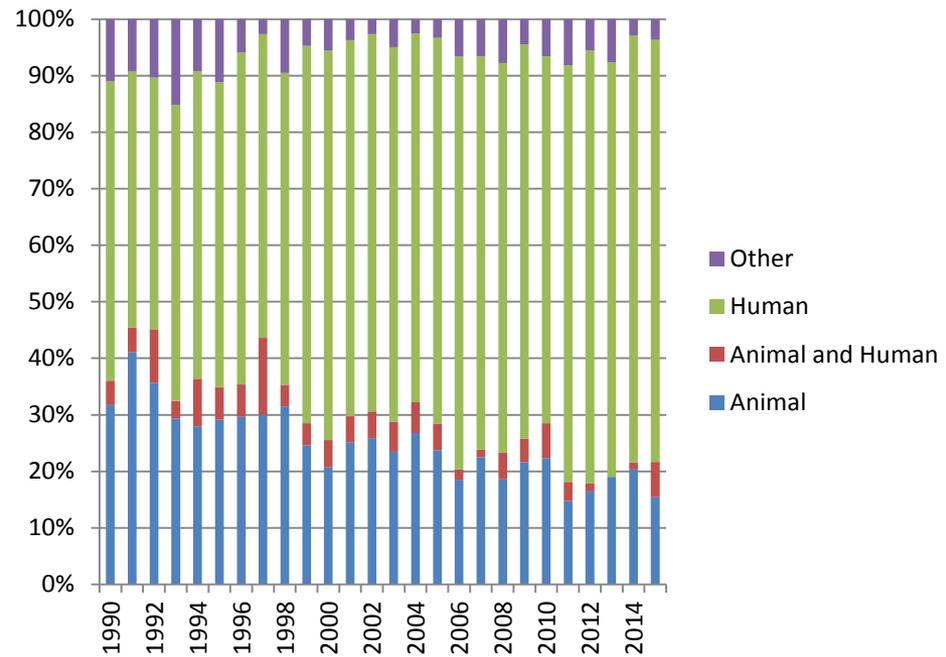


## NIH R01 Awards



- Other
- Human
- Animal and Human
- Animal

## NICHD R01 Awards



- Other
- Human
- Animal and Human
- Animal

# 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



## 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





- 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](mailto: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](#)



- 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





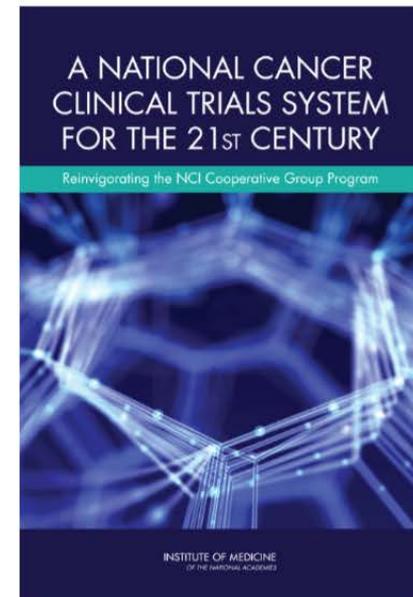
# Clinical Trials

*Newly Announced Changes in Policy*



## **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

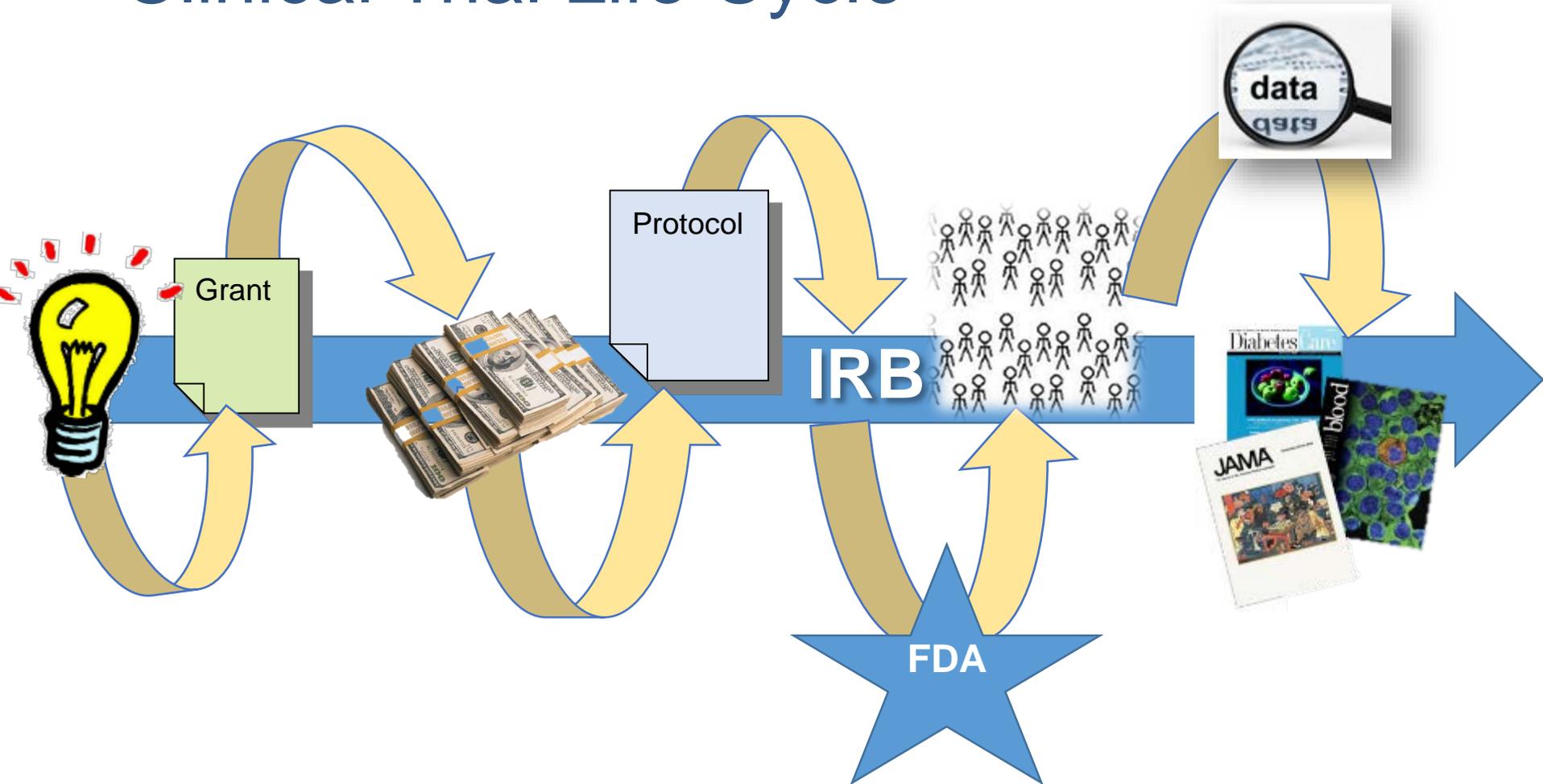


# Main Concerns

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



# Clinical Trial Life Cycle

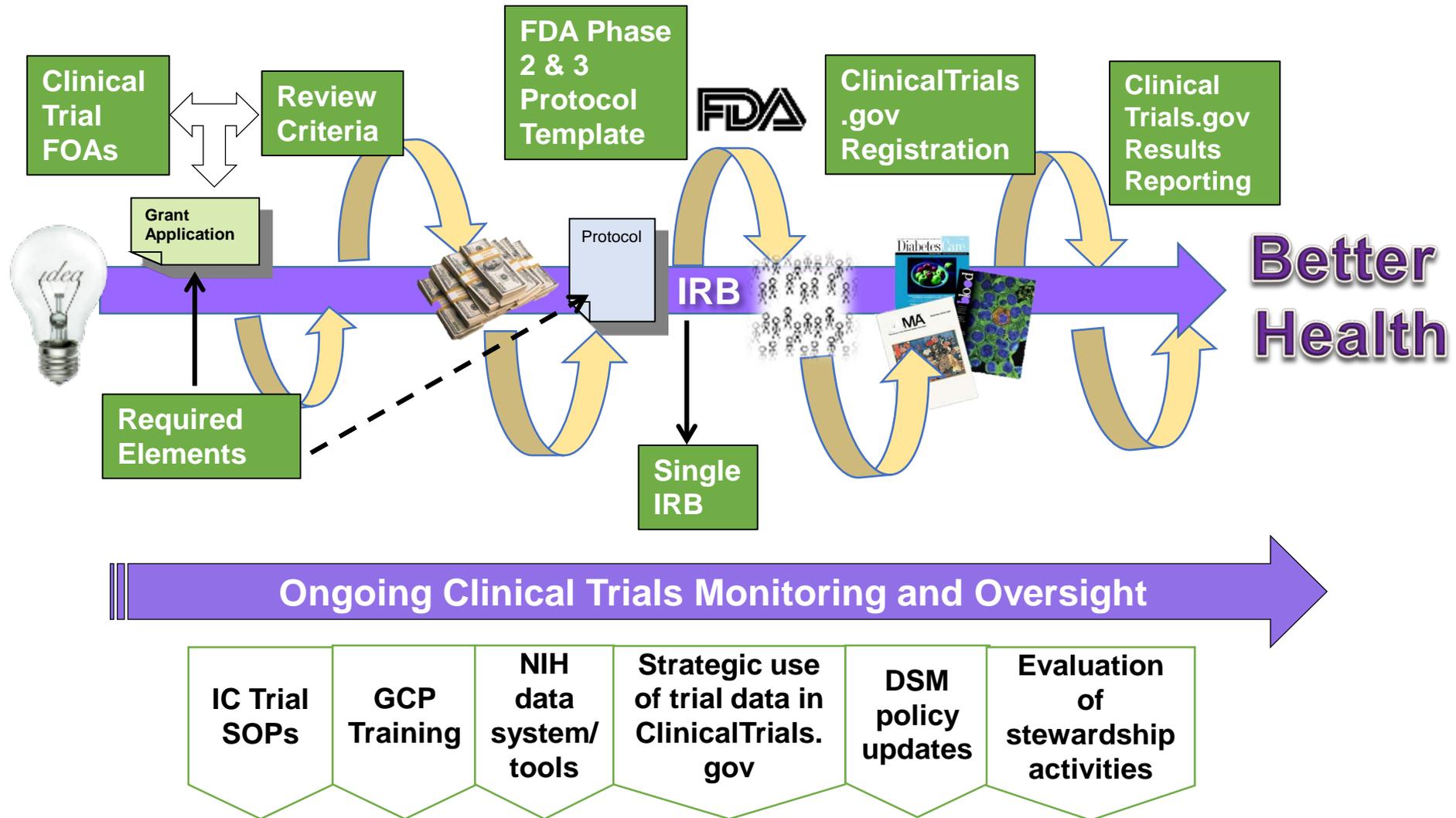




- Revised Definition of Clinical Trials
  - Notice [NOT-OD-15-015](#); Effective October 2014
- Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  - Notice [NOT-OD-16-094](#); Effective May 25, 2017
- Policy on Funding Opportunity Announcements (FOA) for Clinical 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

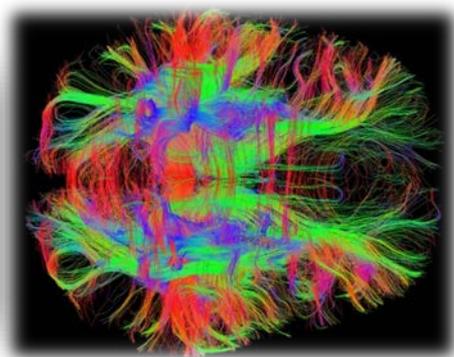


# Interventions at All Points...





# Funding the Best Science at NICHD...



# to Advance Science & Health for All

