

How the National Institutes of Health and NIH Peer Review Advances Biomedical Research and Development

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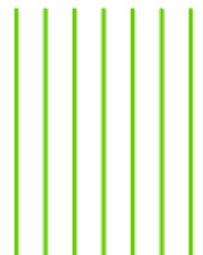
center for
scientific review

**Fostering Partnerships to Enhance Medical Research
and Development: Creating a Pipeline for the Future**

October 5, 2012

National Institutes of Health

U.S. Department of Health and Human Services






Journey Ahead

- **Overview of NIH**
- **How NIH Catalyzes Research and Economic Development**
- **Key Components of NIH**
- **Peer Review: the Foundation for NIH Success**

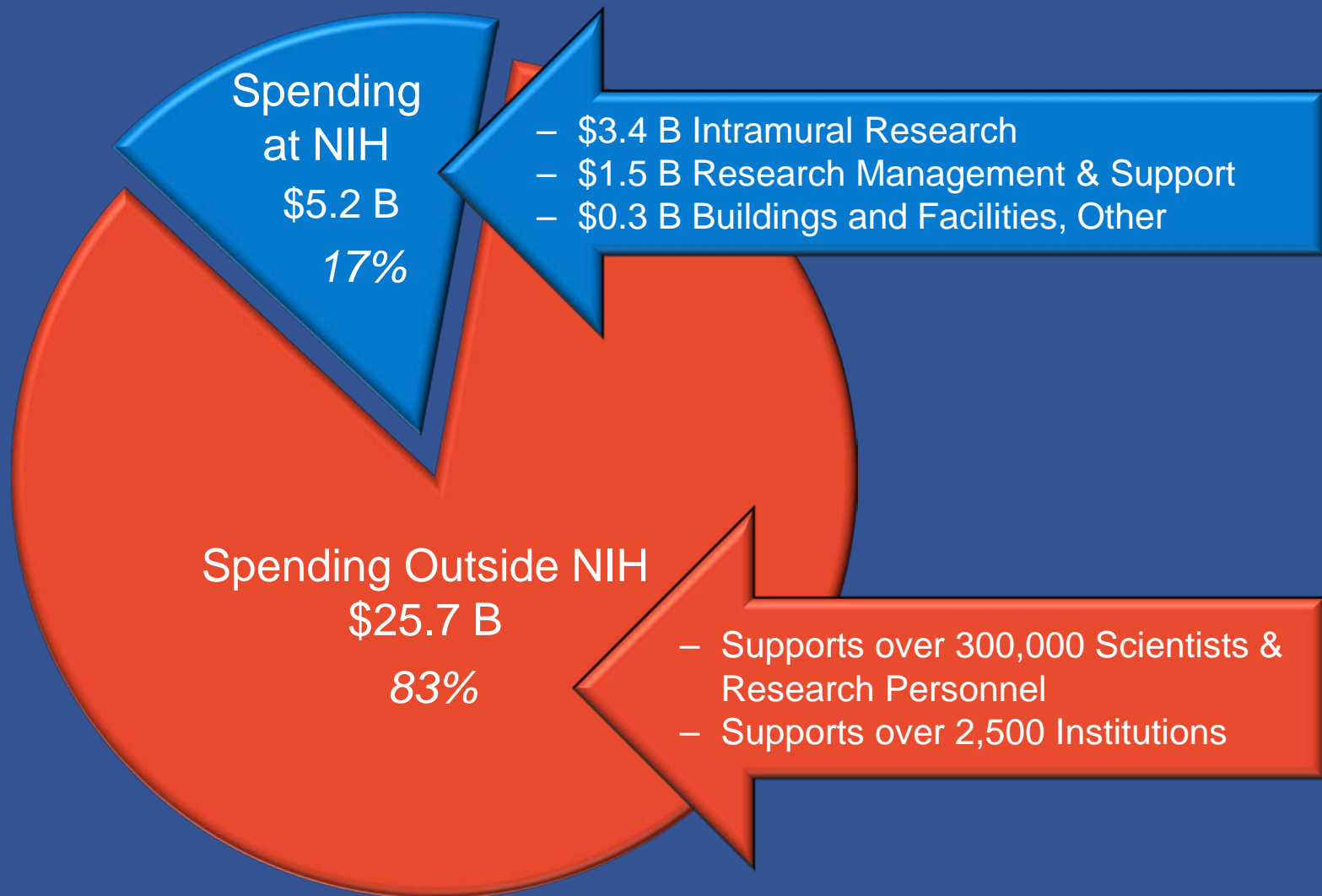


National Institutes of Health Mission

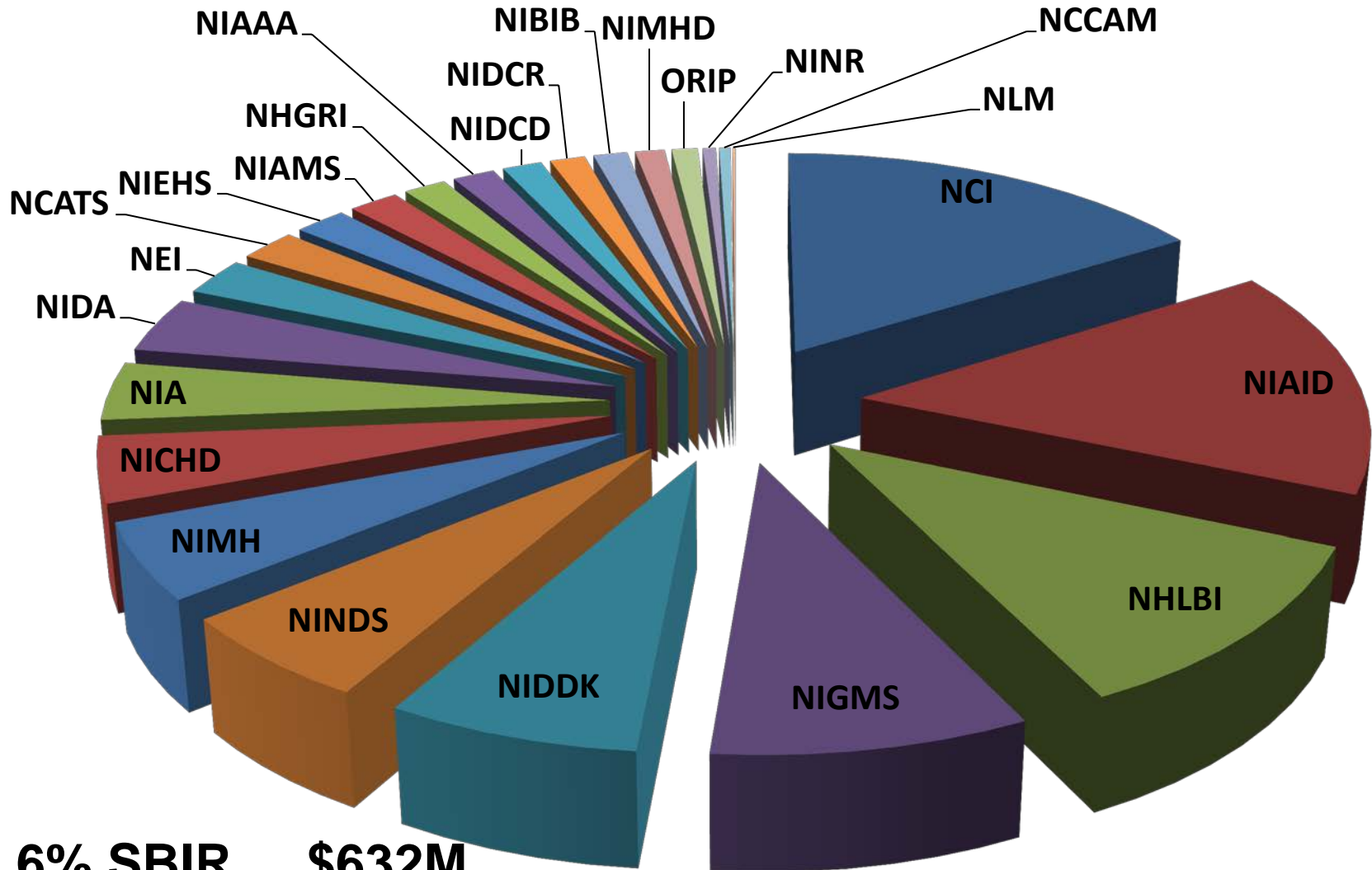
An aerial photograph of the National Institutes of Health campus in Bethesda, Maryland. The image shows a large, multi-story brick building complex with a central courtyard and surrounding greenery. The building is surrounded by a road and a parking lot. The background shows a hazy cityscape and distant hills.

To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

NIH Extramural & Intramural Funding FY 2012 Enacted: \$30.9 Billion



NIH SBIR/STTR Budget Allocations FY2012



2.6% SBIR \$632M

0.35% STTR \$85M

Total FY2012 \$717M



30 Years of Medical Innovation

- MRI and CT Imaging
- ACE inhibitors
- Angioplasty
- Statins
- Mammography
- Coronary Interventions
- H inhibitors and H2 Blockers
- Antidepressant
- Ultrasound Imaging
- Asthma Treatment
- Cardiac Enzymes
- Fluoroquinolones
- Hypoglycemic Agents
- HIV Testing and Intervention
- Tamoxifen
- PSA
- Cephalosporins
- Calcium Blockers

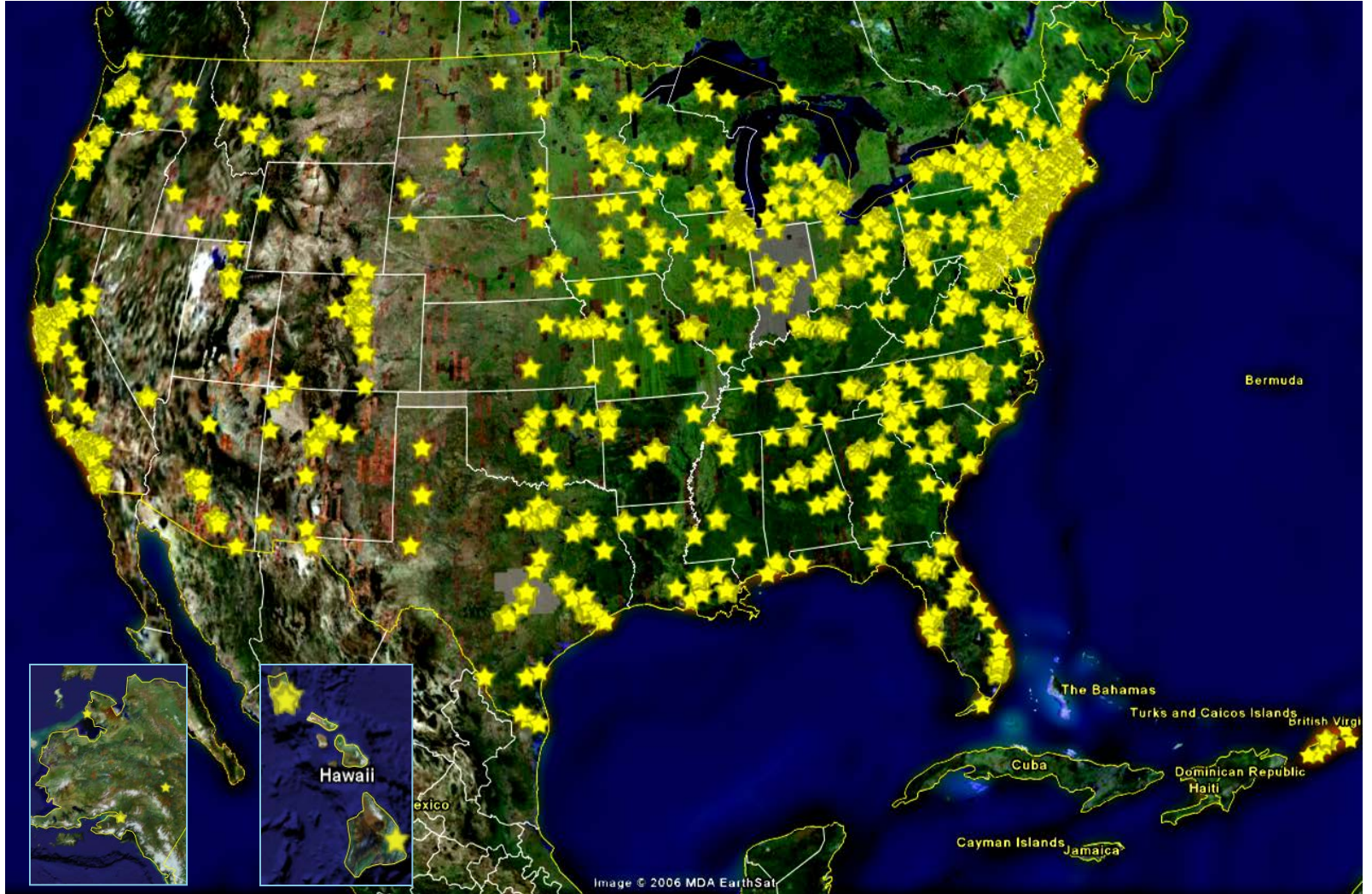


**80% of Nobel Prize Winners in
Physiology/Medicine Received NIH Support**

Since 1964: The NIH Almanac



Extramural Grants By Research Institutions





Economic Impact of NIH Research

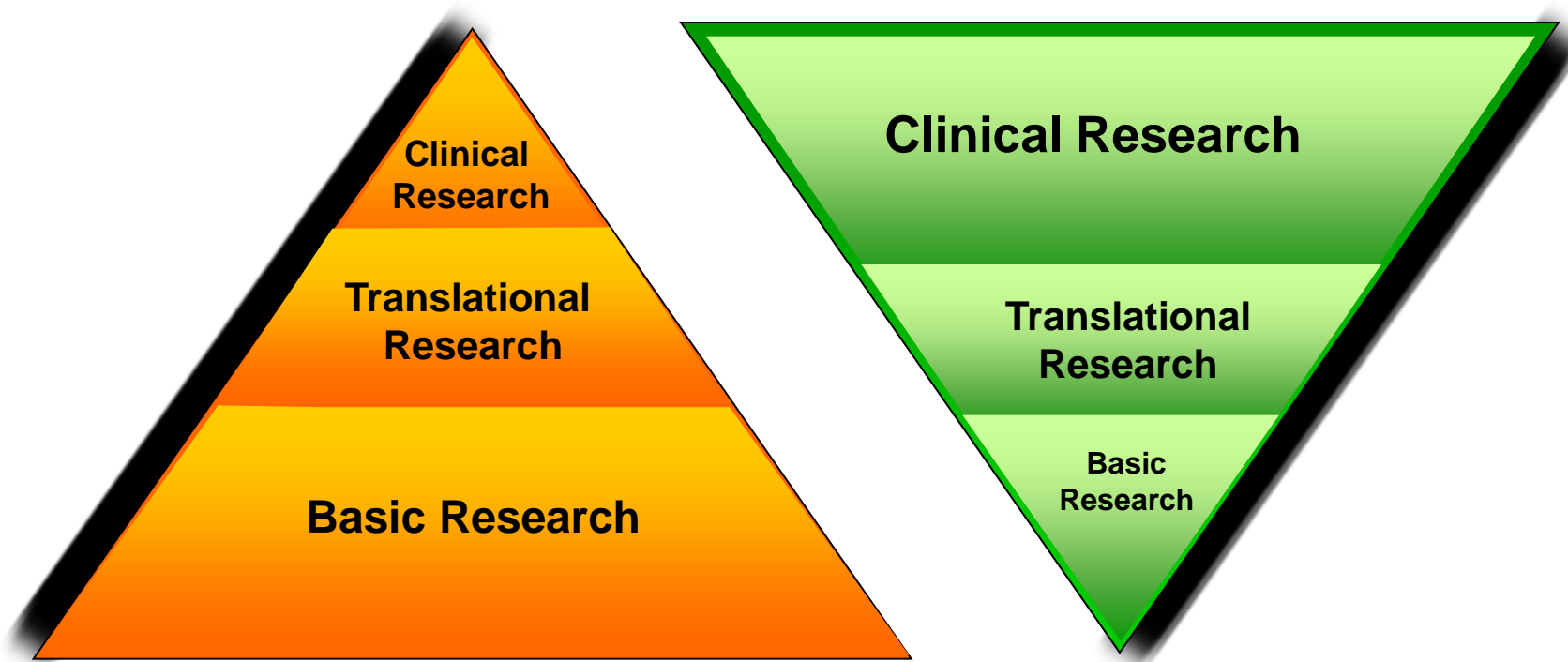
NIH produced \$68.035 billion in new economic activity – more than double the \$31 billion NIH invested in 2010.

An Economic Engine

Report by United for Medical Research



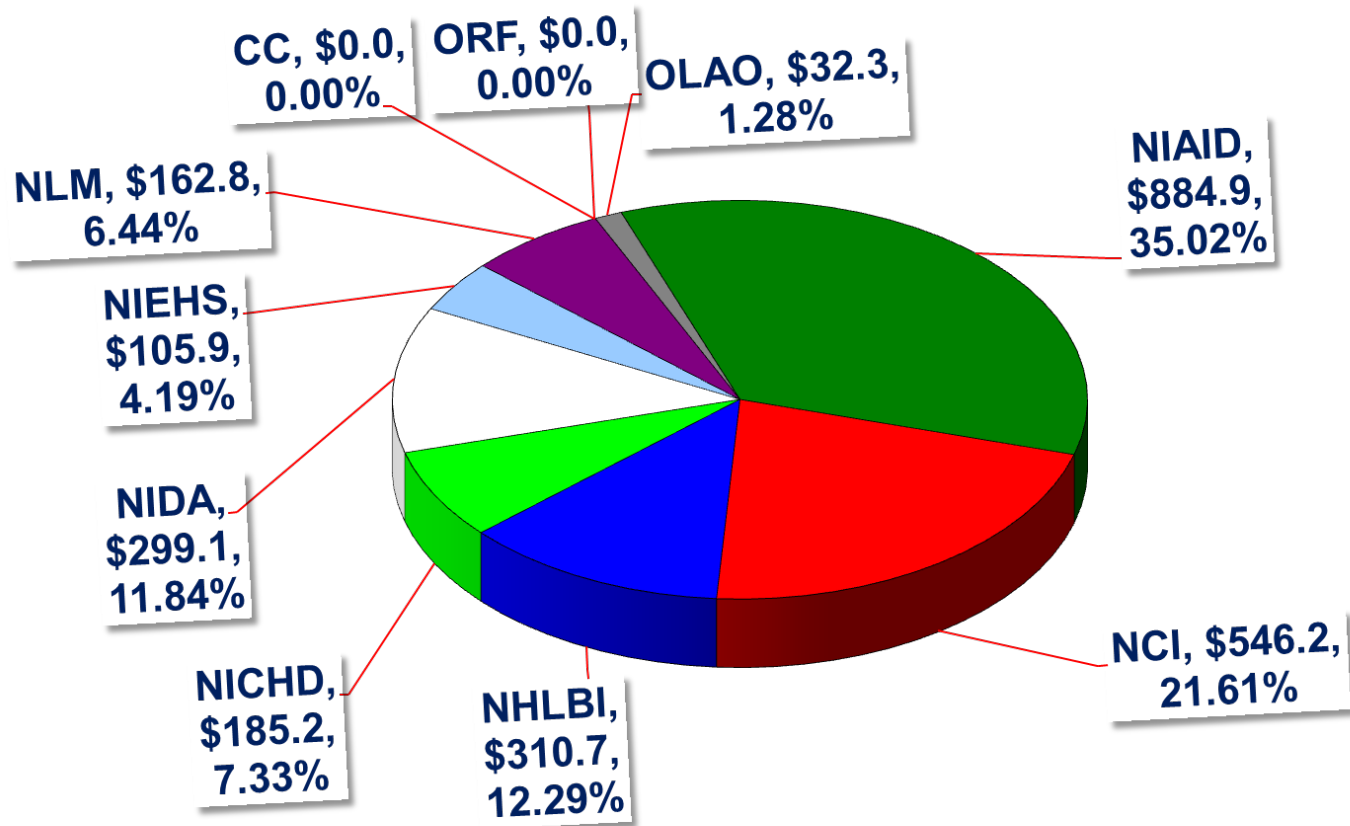
NIH Complements Biotech and Pharma Efforts



**NIH - \$31B
(Government)**

**Private Sector - \$59B
(Biotech and Pharma)**

NIH FY 2011 R&D Contracts: \$2,527.1 Million



Shows dollars in millions and percentages of total dollars. Excludes micropurchases, deobligations. Includes zero dollar actions. Data from the NIH Office of Acquisitions and Logistics Management



NIH Small Business Research Grants in FY 2012

Small Business Research Grants (SBIR)

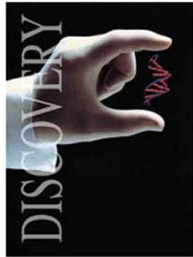
- \$632 Million -- 2.6% of the NIH budget.

Small Business Technology Transfer Grants (STTR)

- \$85 Million -- 0.35% of the NIH budget.

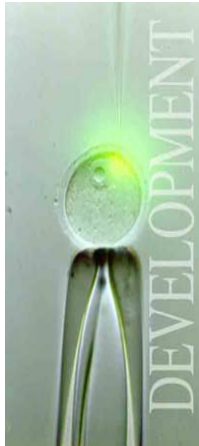
<http://grants.nih.gov/grants/funding/sbir.htm>

NIH SBIR/STTR: 3-Phase Program



PHASE I Feasibility Study

- Budget Guide: \$150K (SBIR); \$150K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)

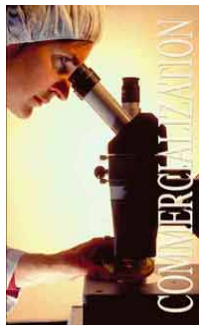


PHASE II Full Research/R&D

- \$1M (STTR), \$1M (SBIR) over two years

PHASE IIB Competing Renewal/R&D

- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~\$1M/year; 3 years

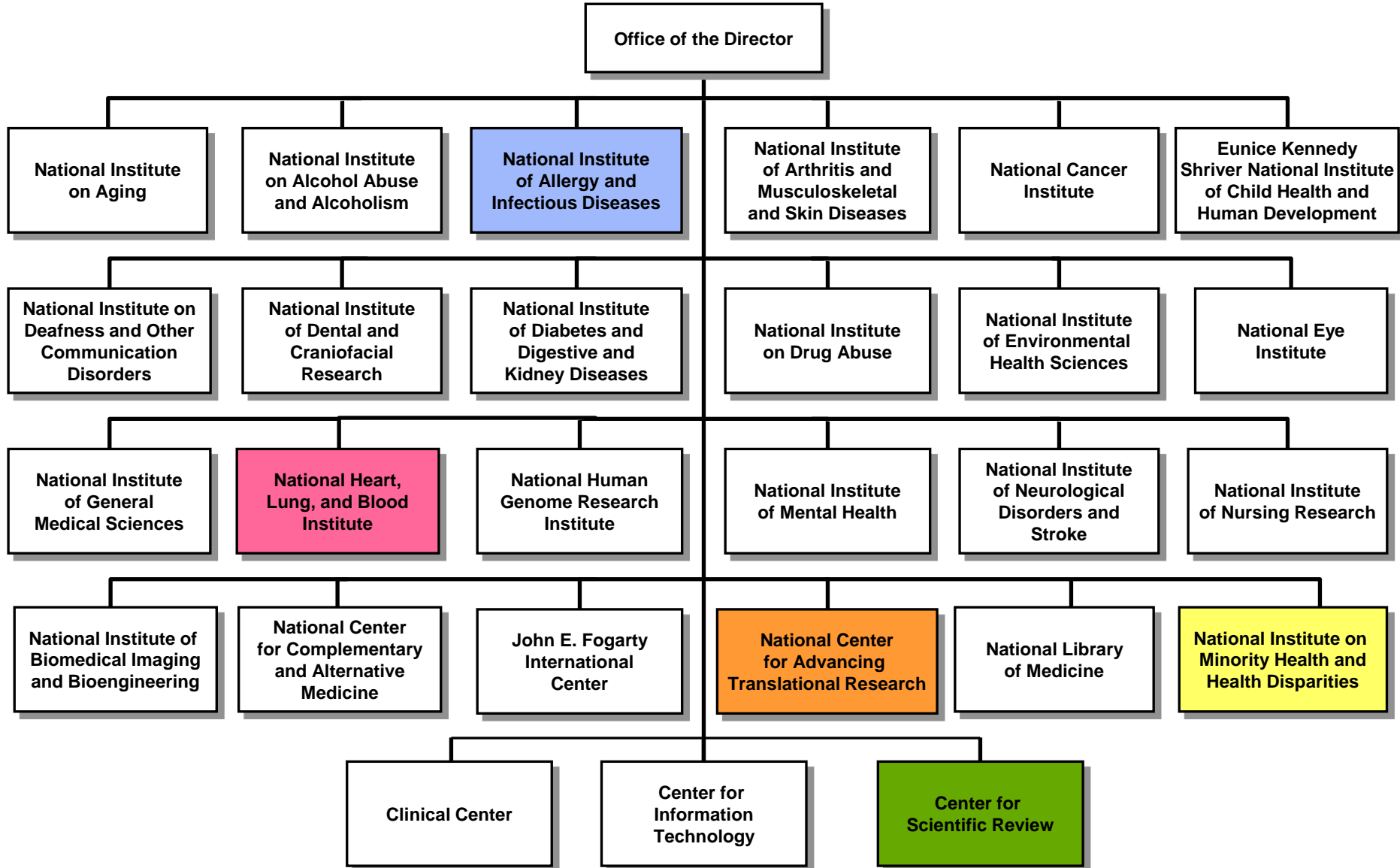


PHASE III Commercialization Stage

- NIH, generally, not the “customer”
- Consider partnering and exit strategy early



National Institutes of Health





National Center for Advancing Translational Sciences (NCATS)

Approved by U.S. Congress in 2011
Created in 2012

MISSION: To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

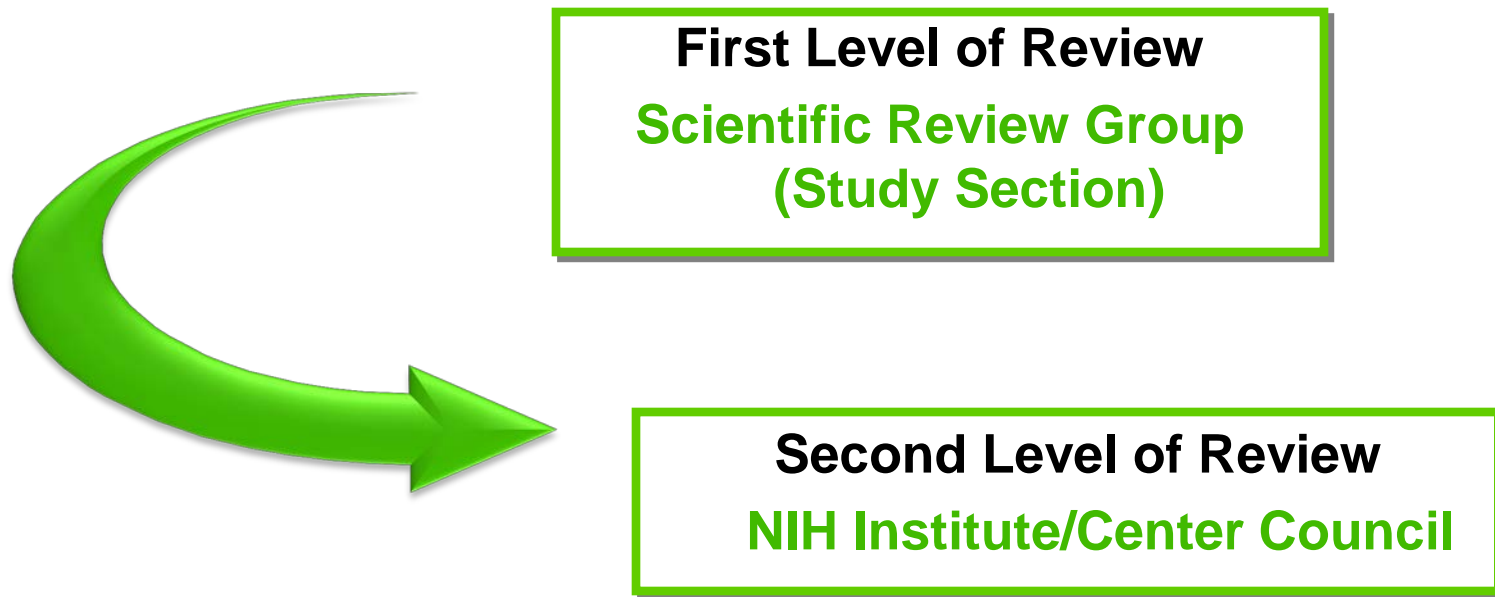


Why Has NIH Been So Successful?

Peer Review

- Focus is on funding ideas not institutions.
- Ideas spring from local researchers.
- Researchers must compete – like capitalists – for funding.
- Scientific experts do the judging.
- Institutions receive funds only when their scientists submit successful applications.
- NIH program and review staff are separated.
- Scientists manage the peer review process.

NIH Peer Review System for Grant Applications



About 80,000 applications and 18,000 reviewers



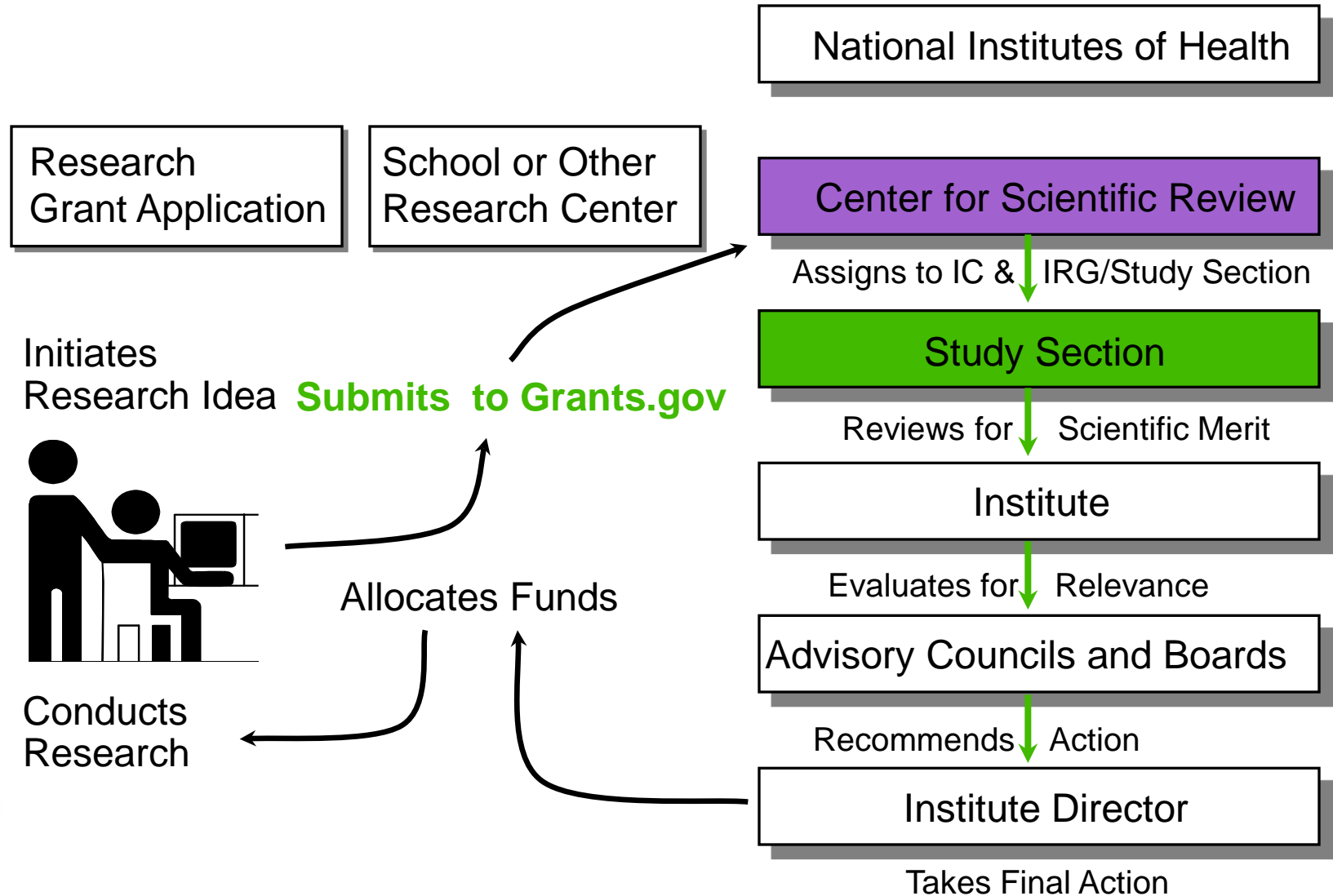
CSR's Mission

To see that NIH grant applications receive **fair, independent, expert, and timely reviews** – free from inappropriate influences – so NIH can fund the most promising research.

CSR reviewed 70% of NIH grant applications in 2011



Review Process for a Research Grant





View the Video



Get a front-row seat at a NIH review peer review meeting.

<http://www.csr.nih.gov/video/video.asp>