NIH Extramural Program Update

BRP Grantees Meeting

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OFFICE OF EXTRAMURAL RESEARCH (OER)
THE NIH EXTRAMURAL NEXUS

Grants Policy & Guidance
Grants Compliance & Oversight
Peer Review Policy
Conflict of Interest
Intellectual Property

Research Integrity
Inclusion of Women, Minorities & Children
Human Subjects Protection
Animal Welfare

Program Coordination
Funding Opportunities
Extramural Activities Support

Invention Reporting
Data & Resource Sharing

Financial Operations Plan
Information Dissemination:
NIH Guide, Extramural Nexus, OER Insider
Natural Disaster Response

AREA
Loan Repayment Program
SBIR/STTR
Research Training
Workforce Diversity
Staff Training

Knowledge Management
eRA/Commons
Electronic Receipt of Applications

Multiple PI Initiative
New Investigators
Public Access

Other Initiatives & Issues

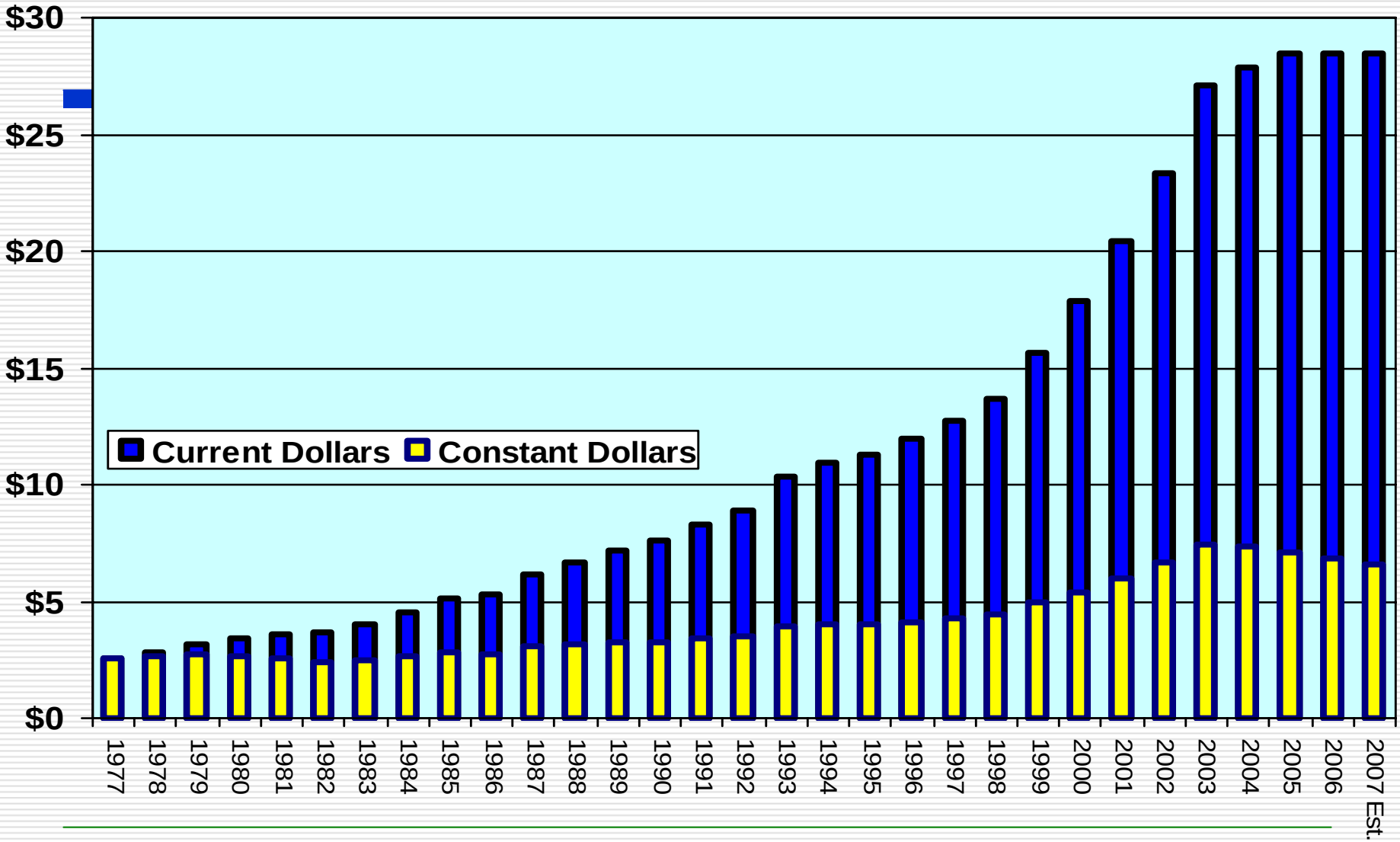
Budget
FY06; FY07

Where grants policy, program coordination, compliance and electronic research administration converge.

NIH Budget Authority FY 1977 – FY 2007

(Current vs. Constant 1977 Dollars Using BRDPI as the Inflation Factor)

(Dollars in Billions)



What is driving NIH's budgetary environment?

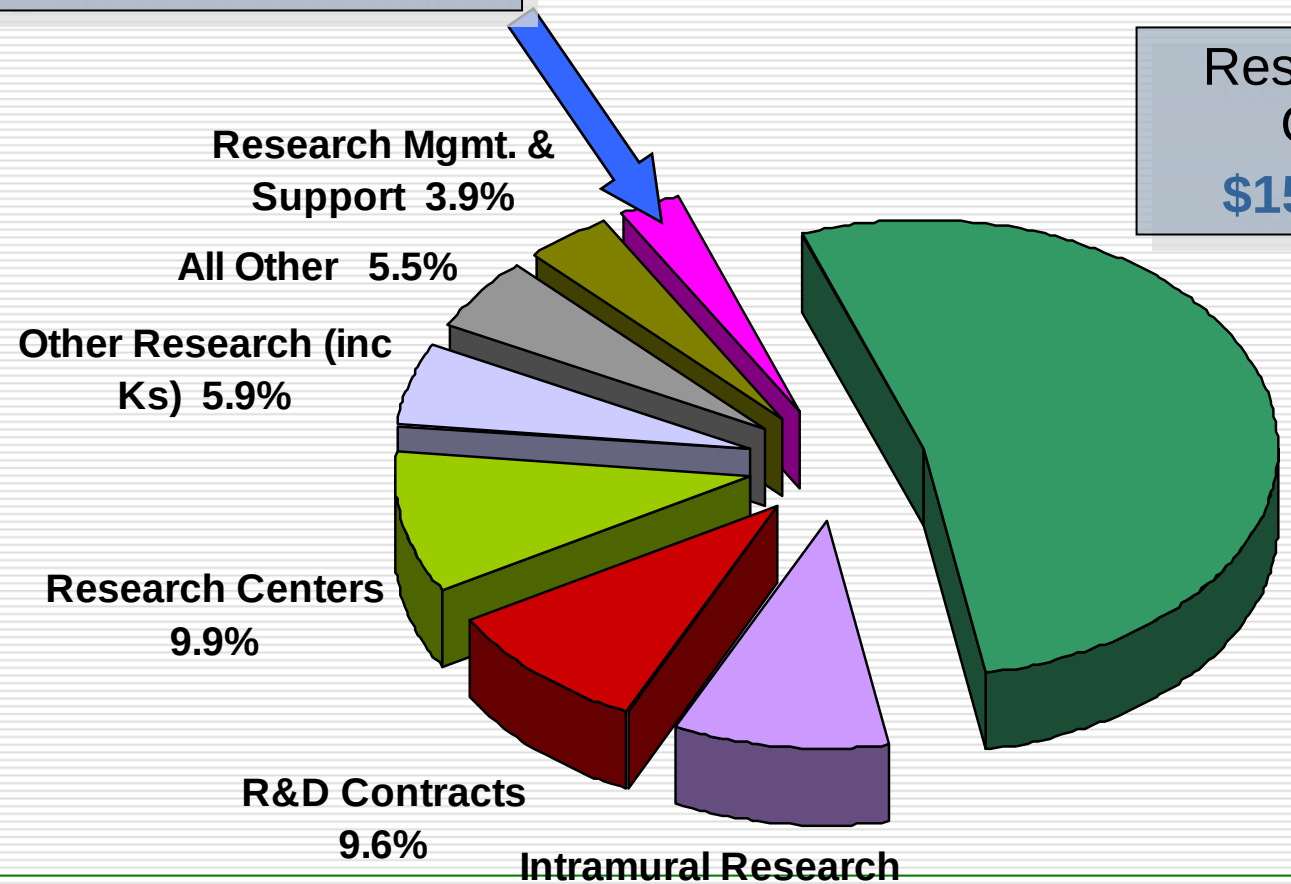
- "Perfect storm" scenario
  - Federal Deficit, Defense and Homeland Security priority requirements, Pandemic flu and domestic budget cuts
  - Sense in Congress that Doubling mission was accomplished and it is "other's turn"- Physical sciences for competitiveness
  - Biomedical research inflation is around 3-5%

And yet, on the plus side…

  - Overall support for NIH is still strong

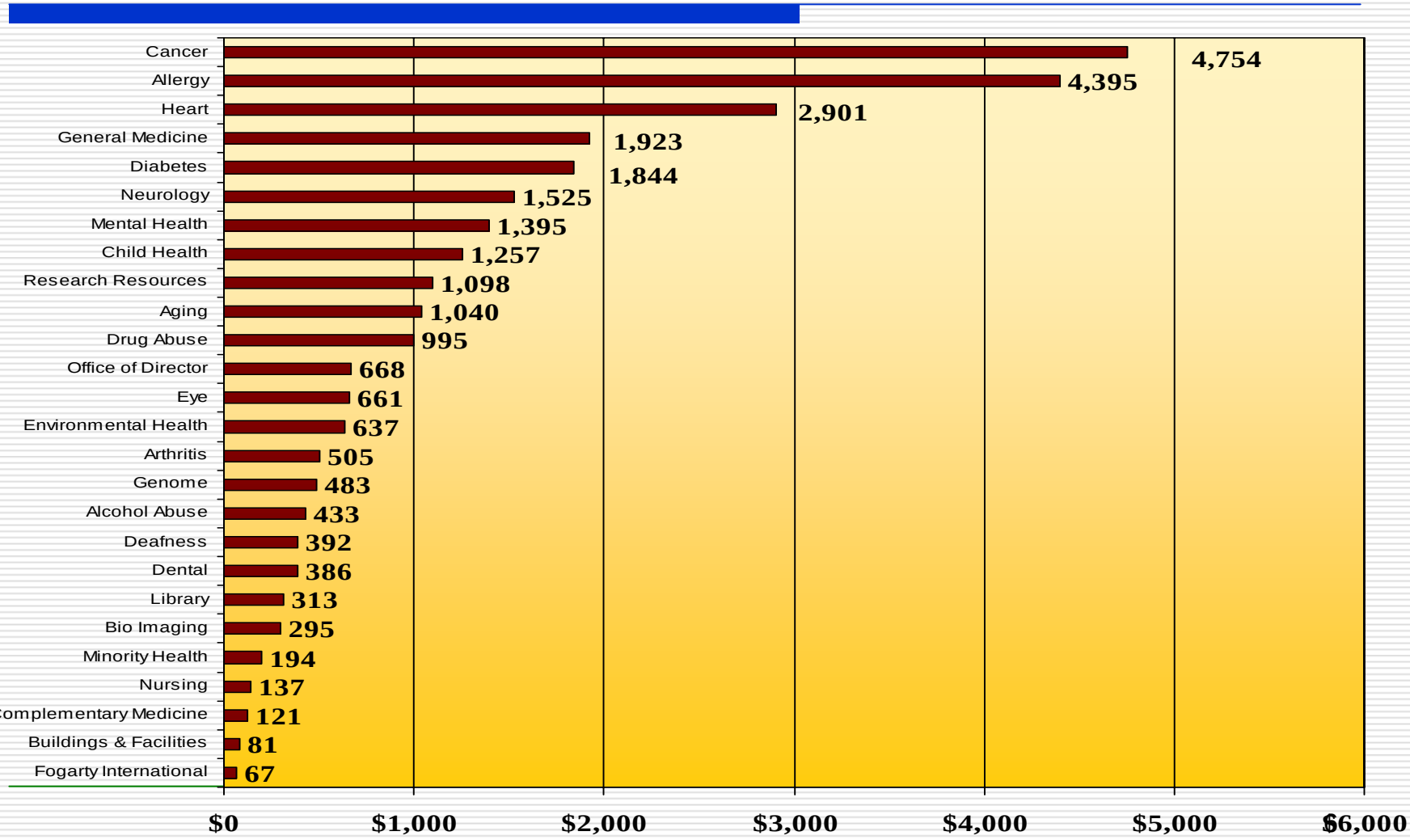
FY 2007 Estimate
Total NIH Budget Authority
$28.578 Billion

Training 2.7% $760.5 Million



NIH Funding in FY2007: $28.6 Billion

(dollars in millions)



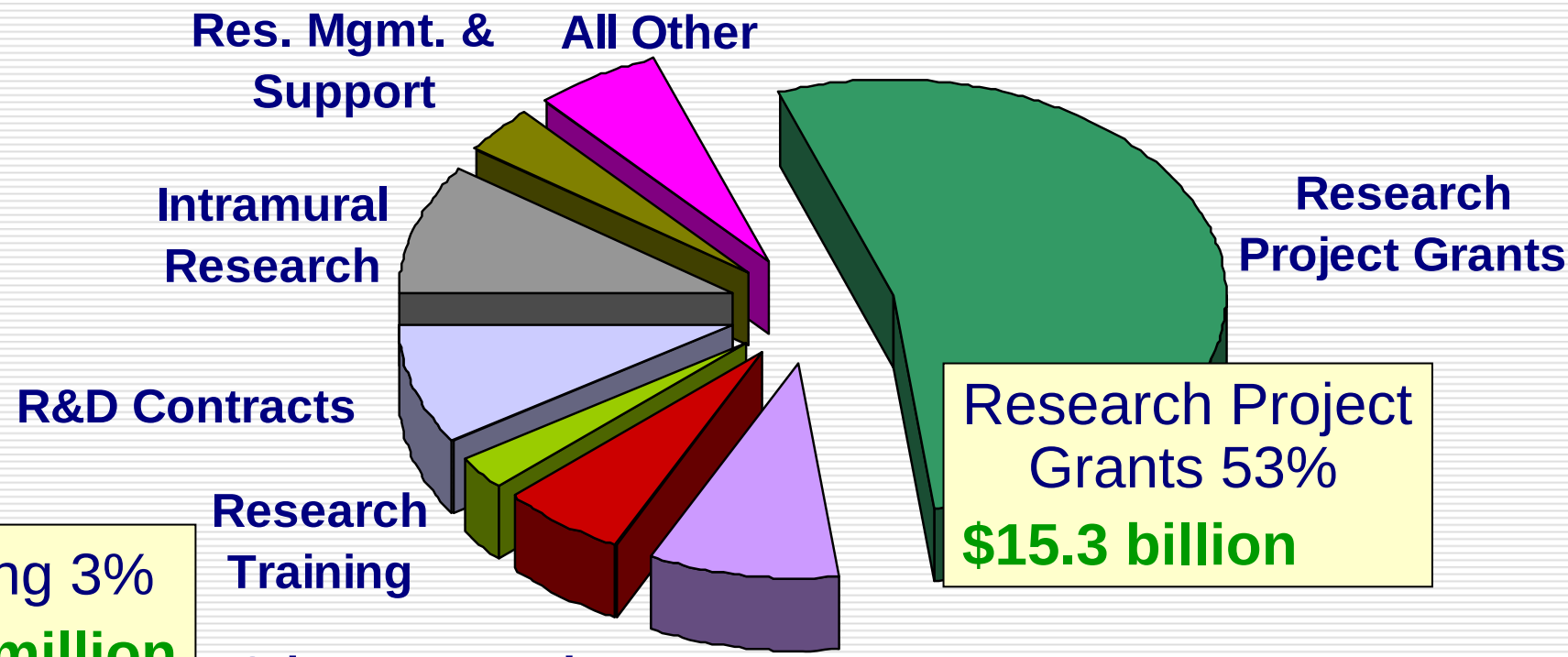
Priorities Included in the FY 2007 Budget

- Enhanced Support for New Investigators -- Pathway to Independence Program $15M
- Roadmap - increase of $113M; total included $443M
- Biodefense-related activities – increase of $110M in the NIH Office of the Director for Advanced Development; Total Biodefense $1,891M
- Pandemic Influenza – an increase of $17M to support specific initiatives; total included $34M.
- Genes, Environment and Health initiative – $40M for this multi-year initiative.

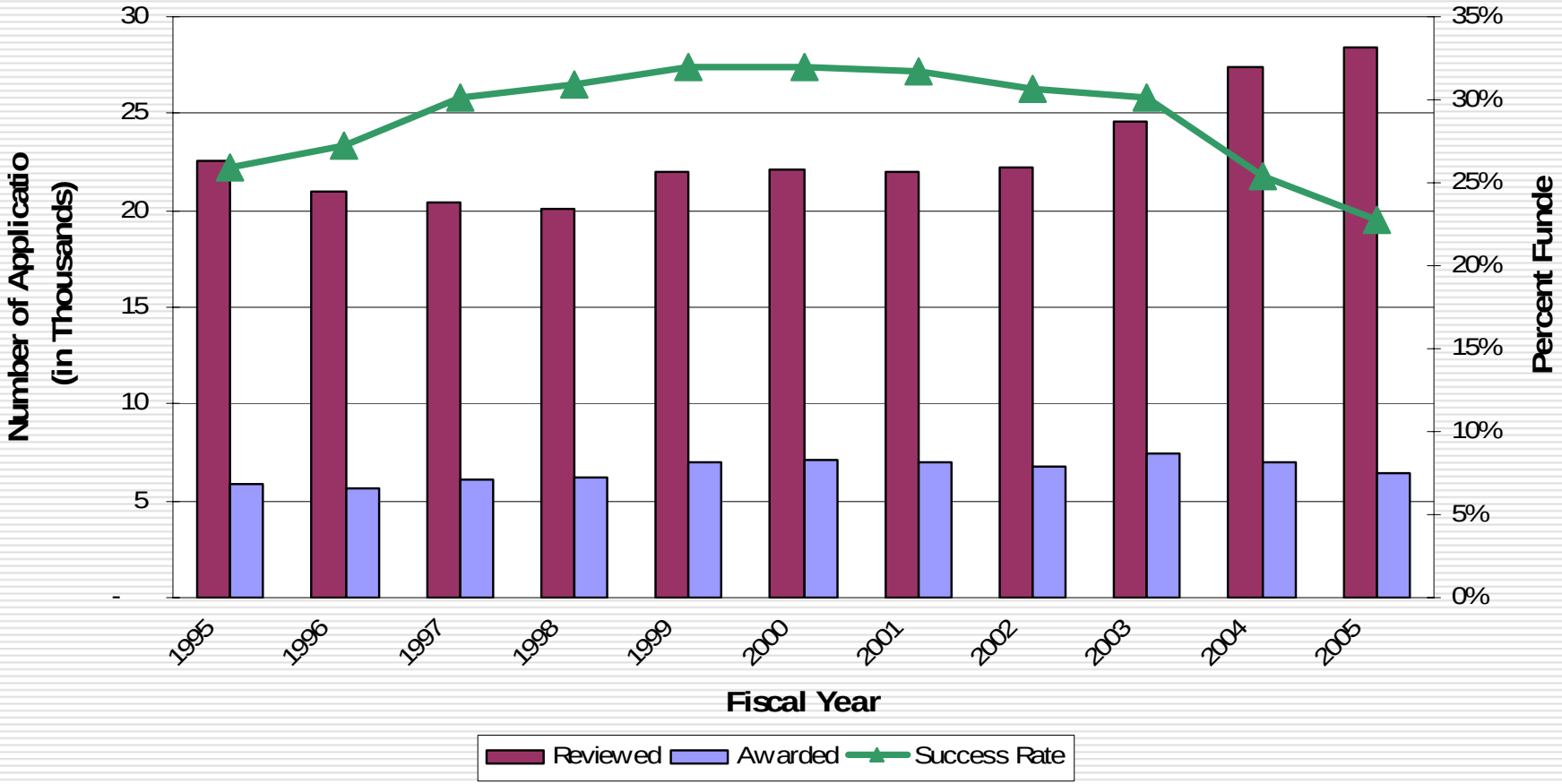
FY 2007 Budget's Impact on Research Project Grants (RPGs)

- 37,671 Total RPGs
  - a decrease of -656 from the FY 2006
  - a decrease of -1,237 from FY 2005.
- 9,337 Competing RPGs
  - an increase of +275 over FY 2006
  - a decrease of -262 from FY 2005.
- Success rate ~ 19%,
  - about the same as FY 2006
  - a decrease from the 22% for FY 2005.

FY 2006 Budget
$28.6 Billion



Number of NIH Competing R01 Equivalent* Applications, Awards and Percent Funded (Success Rate)



R01 Equivalent* Includes R01, R23, R29 and R37

Why are success rates so low?!

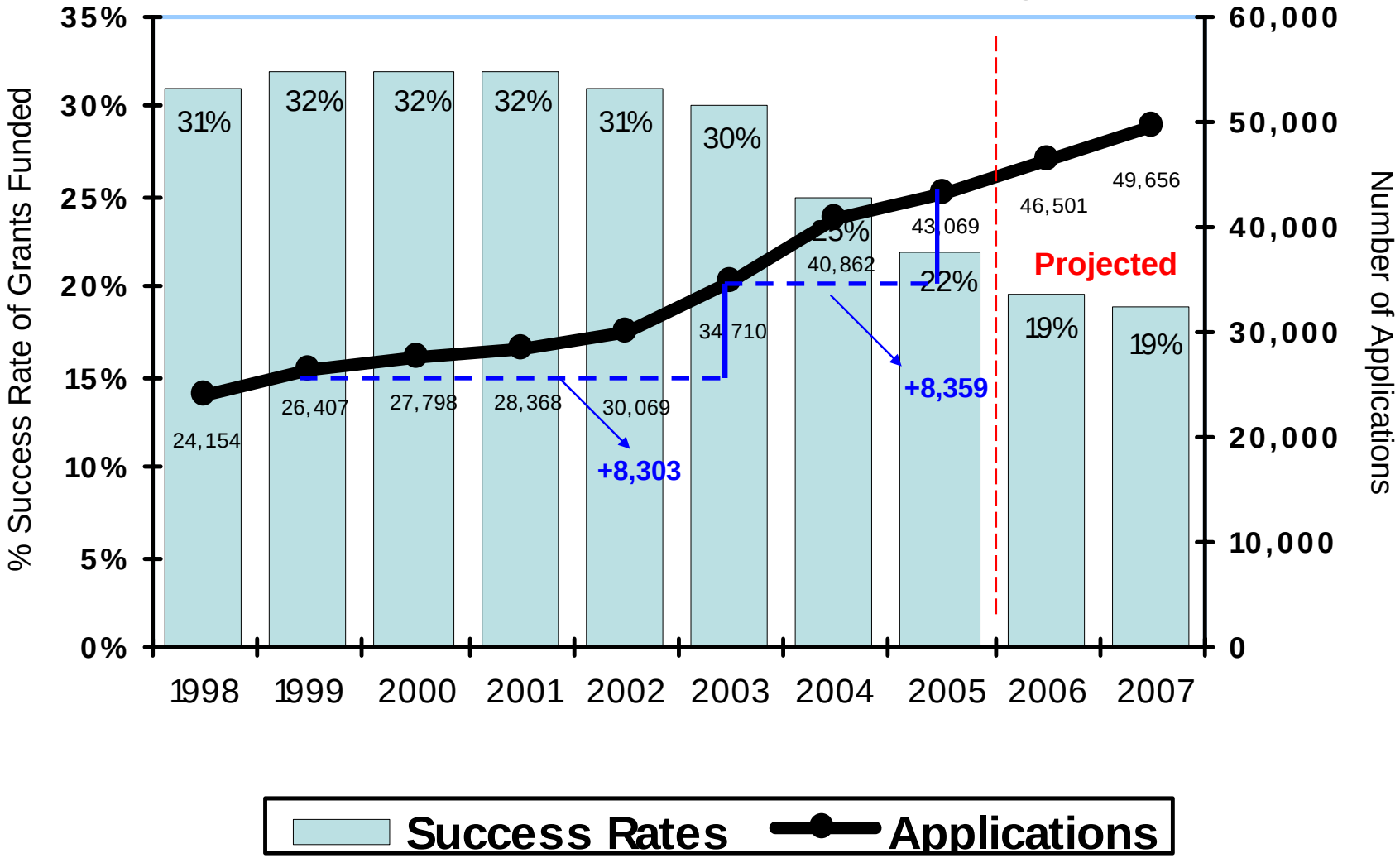
- Urban legends:
  - Too much emphasis on translational science away from basic science!?
  - It must be that big projects and initiatives (RFAs) are taking money away from unsolicited grant applications!?
  - It must be the Roadmap!?

- The reality:
  - NIH Investment in Extramural Research and Training Programs (http://grants.nih.gov/grants/news.htm#20060526)
  - NIH Award Data http://grants1.nih.gov/grants/award/award.htm)
  - "NIH at the Crossroads: Strategies for the Future" - (http://www.nih.gov/about/director/acd/060206slides/index.htm)

Success rates are low because…

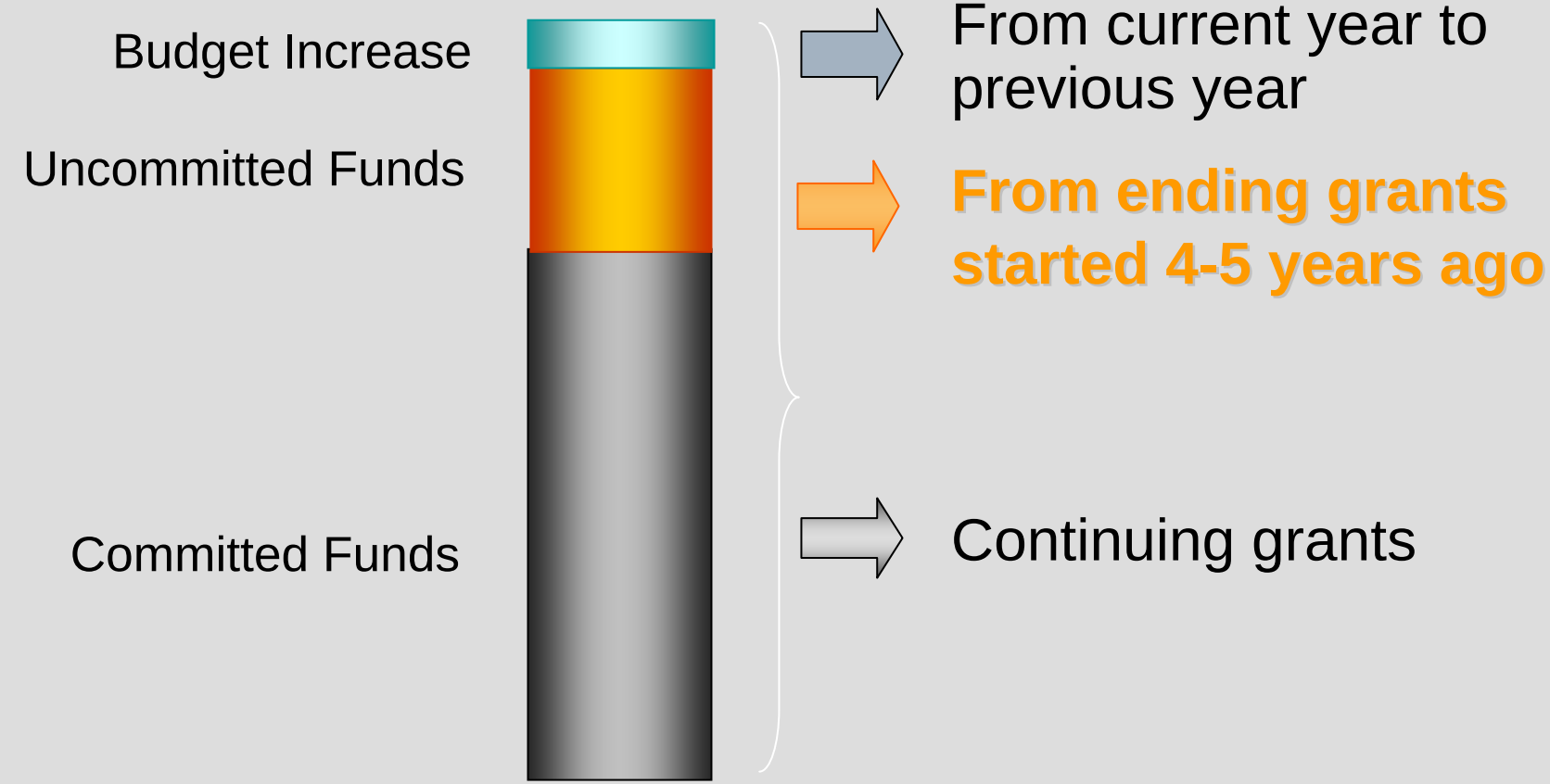
Demand is outstripping supply

How Does the % of Grant Applications Funded (or "Success Rate") Compare with the Number of New Ideas (Applications) Coming In?

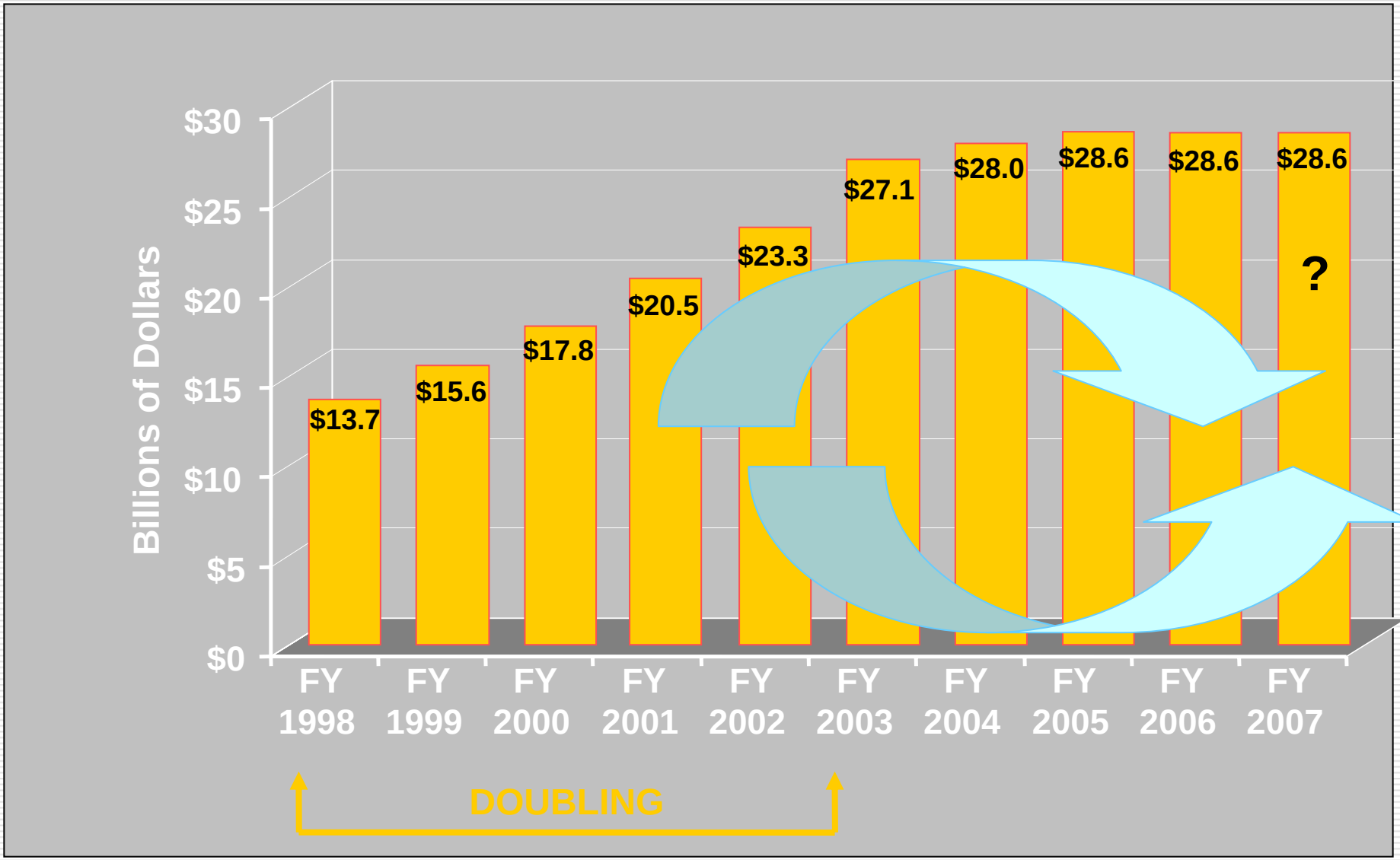


The Budget Cycling Phenomenon:

What Funds are Available in any One Year?



NIH Congressional Appropriations



The Bottom Line:

Demand for Grants "Took Off" Just as NIH Budget Was "Landing!"

- Post doubling "boom" in applications has led to a ***supply/demand imbalance***
- Success rate drop is due to
  - Near 100% increased demand for grants
  - 40% increased costs of grants
  - Decrease in inflation adjusted budget
- Budget cycling effect will slightly improve supply vs. demand of grants in 2007 and beyond

So, where do we go from here?

- Protect the future: New Investigators
- Protect core values and mission: Discovery and New Knowledge
- Manage the key drivers (supply and demand of grants)
- Proactive communication
- Promote NIH's vision for the future

NRSA Training

Ruth L. Kirschstein
NRSA Research Training Award Program

	FY 2005 Actual	FY 2006 Appropriation	FY 2007 President's Budget
Individual Fellowships	$119.2 M	$120.3 M	$119.8 M
Institutional Awards	$636.9 M	$640.5 M	$640.7 M
Total	$756.1 M 17,638 FTTPs	$760.8 M 17,459 FTTPs	$760.5 M 17,499 FTTPs

FY 2006

- 4% stipend increase for level 0 and 1 postdocs
- $500 health insurance increase for postdoctoral fellows

FY 2007

- No stipend increase
- Implement new tuition, fees and health insurance policy

NRSA Tuition, Fees, and Health Insurance Policy

Issue

- NRSA costs associated with T/F/HI are estimated to be increasing annually by 7% for predoctoral T32 trainees & 11% for postdoctoral T32 trainees
- Requested costs exceed available funds
- Continuation of trend will result in a significant decrease in the number of NRSA supported training positions and programs

Actions

- T/F/HI expenses frozen for FY 2006 T32 competing renewals
- Town Hall Meeting (November 2005)
- Feedback considered, options modeled
- Posted DRAFT policy for comment (May 2006)
- Evaluating feedback

Current vs. Proposed Institutional Training Grant (T32) Policy

	Predoc	Postdoc
Stipend	$20,772	$36,996 - $51,036
Tuition/Fees/Health Insurance (per Trainee Formula) Move Health Insurance to TRE	~~$3,000 + 60% above~~ 60% up to $16,000 for predocs 60% up to $21,000 for dual-degree M.D./Ph.D. 60% up to $4,500 for postdocs 60% up to $16,000 for postdocs seeking degree	
Training Related Expenses* (Per Trainee) Health Insurance and TRE	$2,200 (+$2,000)=$4,200	$3,850 (+$2,000)=$7,850
Trainee Travel (Per Trainee)	$400 - $1000	
F&A	8% (excludes tuition/fees/health insurance, equipment)	

*Training Related Expenses are intended to help defray the costs of training such as research supplies, equipment, consultant costs, staff travel, and appropriate administrative costs

Current vs. Proposed Individual Training Grant (F30, F31, F32) Policy

	Predoc	Postdoc
Stipend	$20,772	$35,568 - $51,036
Tuition/Fees (Formula) Move health insurance for predocs to institutional allowance similar to current postdoc practice	$3,000 + 60% above (includes health insurance) 60% up to $16,000 60% up to $21,000 for dual-degree	$3,000 + 60% above (does not include health insurance) 60% up to $4,500 60% up to $16,000 for those seeking additional degree
Institutional Allowance* ➢ Public/Private Inst. ➢ Federal/For Profit Inst.	 $2,750 (+$1450)=$4200 $1,650 (+$1450)=$3100	 $7,000 (+$850)=$7,850 $5,900 (+$850)=$6,750

*Institutional allowance is intended to help defray costs of training such as research supplies, equipment, health insurance (postdocs only), fellow's travel to scientific meetings & appropriate administrative costs

Teamwork – Multiple PIs

Why Multiple PI's?

As the nature and conduct of science changes to become more integrative and multi- and interdisciplinary, so must its tools

- Traditional single-PI model does not always work for multidisciplinary efforts and collaboration
- Growing consensus that team science would be encouraged if more than one PI could be recognized on individual awards
- Overarching goal: maximize the potential of team science efforts, responsive to the challenges and opportunities of the 21st century.

Why Multiple PI's?

- Recommendations from 2003 NIH Bioengineering Consortium (BECON) Symposium, "Catalyzing Team Science"
- NIH Roadmap 2005 initiative to stimulate interdisciplinary science http://nihroadmap.nih.gov/interdisciplinary/
- Directive from Office of Science and Technology Policy (OSTP); 2005.
- Request for Information (RFI) issued by the NIH to solicit input on policies and issues of special interest to the health-related research community; 2005.

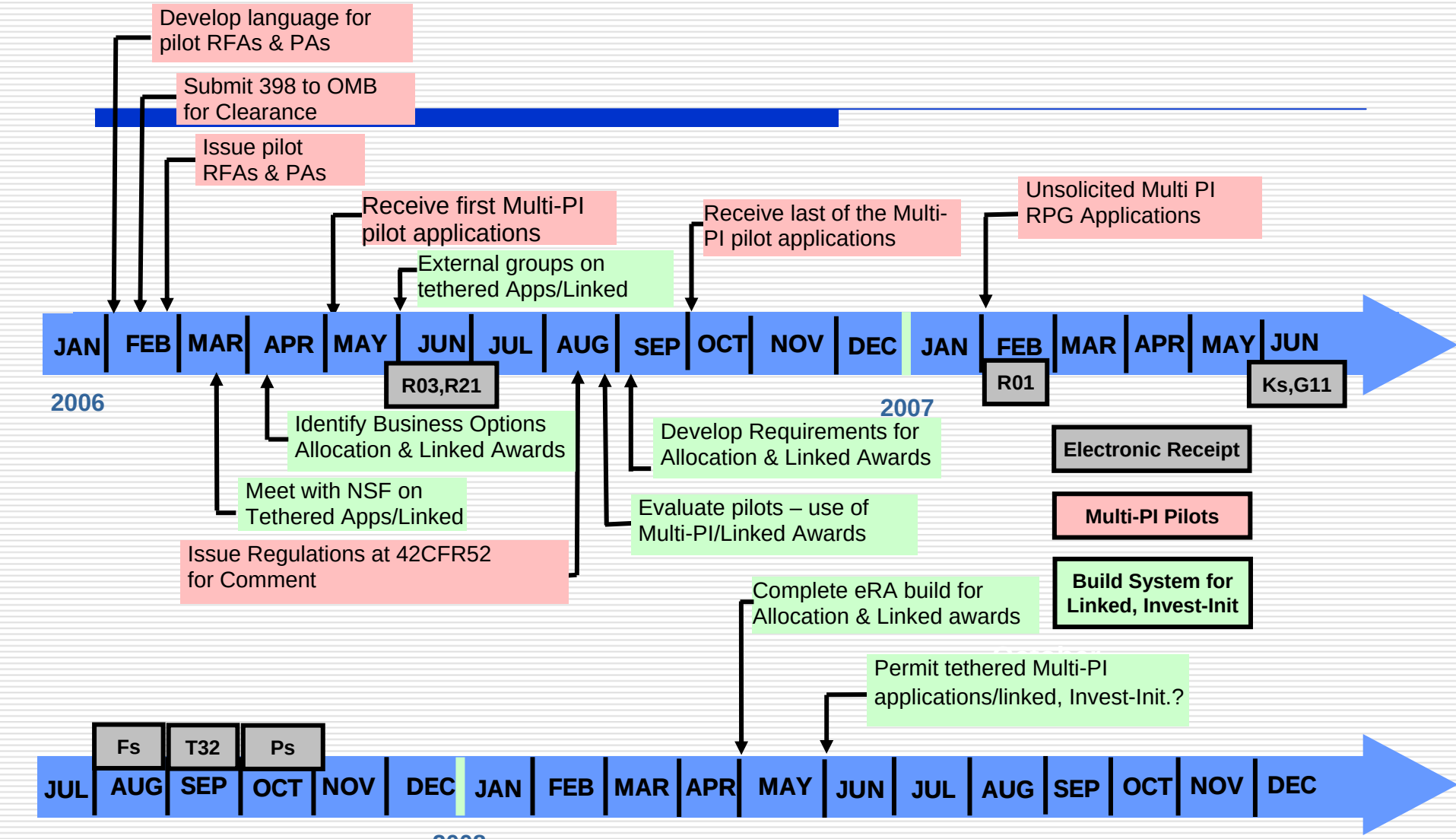
Federal-Wide Definition of Principal Investigator

- "The individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant organization may designate multiple individuals as PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PI is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program including the submission of all required reports."
- The presence of more than one identified PI on an application or award diminishes neither the responsibility nor the accountability of any individual PI.

Multiple PI Pilot Programs

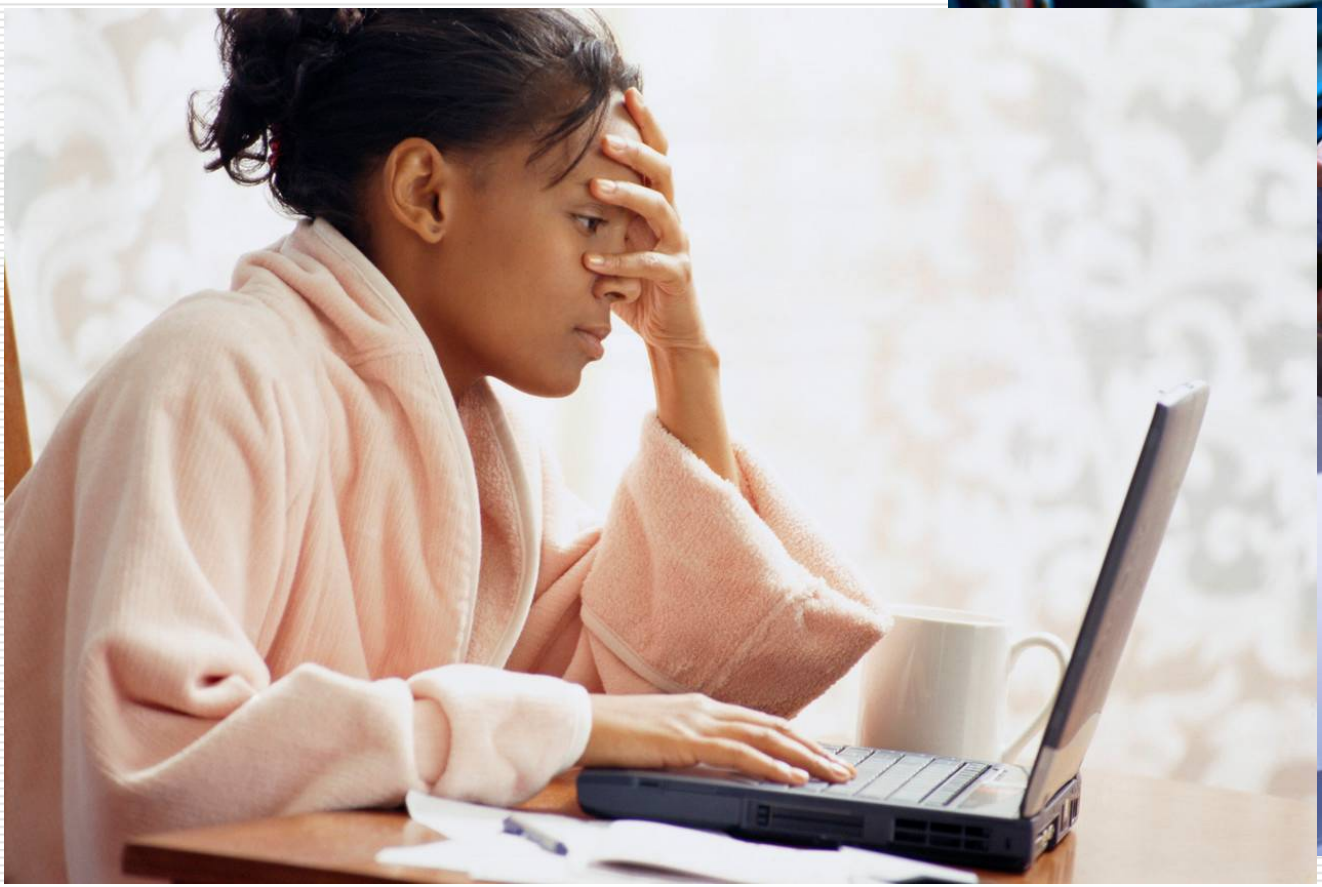
IC	Notice, Program Announcement or RFA	Name of Program	Mechanism	Linked Awards Permitted?	Electronic Applications	Application Receipt Date	Number of projects /applications	Number of Multi-PI Applications
NIDDK	http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-05-014.html	The Obese and Diabetic Intrauterine Environment: Long-term Metabolic or Cardiovascular Consequences in the Offspring	R01, R21	Yes	No	May 11, 2006	70 projects 74 apps	19 multies 4 linked
NCI	http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-004.html	Small Animal Imaging Resource Program	U24	No	No	May 18, 2006	33 projects 33 apps	17 multies (&6 more that may be but are missing info)
NLM	http://grants.nih.gov/grants/guide/pa-files/PA-06-094.html	NLM Research Grants in Biomedical Informatics and Bioinformatics:	R01	Yes	No	June 1, 2006		
NCCAM	http://grants.nih.gov/grants/guide/pa-files/PAR-06-108.html	Developmental Centers for Research on Complementary and Alternative Medicine: Phase I	U19	No	No	August 11, 2006		
NCCAM	http://grants.nih.gov/grants/guide/rfa-files/RFA-AT-06-001.html	Developmental Centers for Research on Complementary and Alternative Medicine: Phase II	U19	No	No	August 11, 2006		
NCI	http://grants.nih.gov/grants/guide/pa-files/PAR-06-406.html	In Vivo Cellular and Molecular Imaging Centers (ICMICs)[P50]	P50	No	NO	August 16, 2006		
NCI	http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-06-505.html	Cancer Research Network	U19	No	No	August 16, 2006		
NIMH	http://grants.nih.gov/grants/guide/pa-files/PAR-06-389.html	Basic and Translational Research Opportunities in the Social Neuroscience of Mental Health (R01) [SF424 (R&R)]	R01	No	Yes	September 25, 2006		

Tentative Multi-PI Timeline

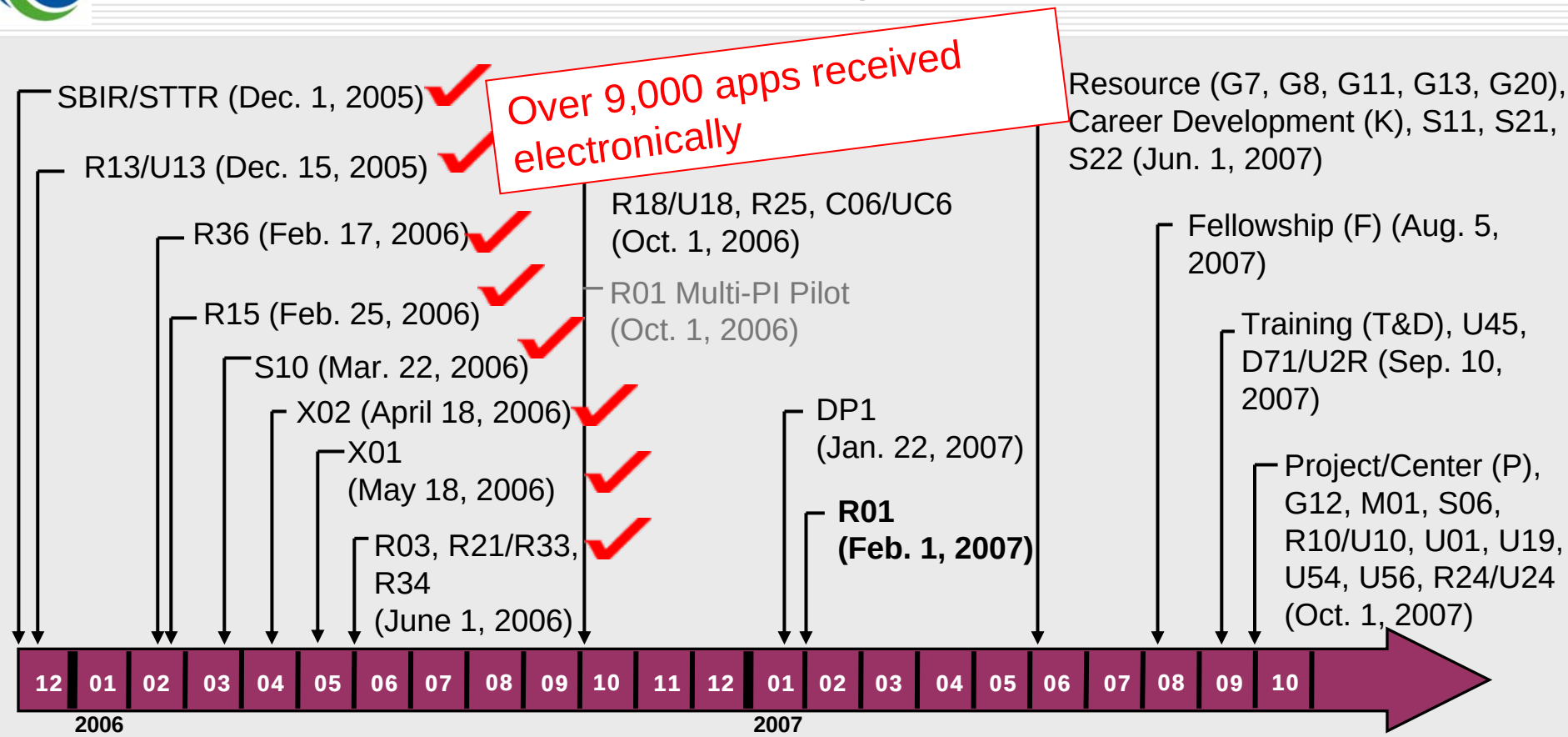


Multi-PI Timeline as of June 1, 2006

e-Submission



eSubmission Is Becoming a Reality for NIH



Current as of February 2, 2006. Visit the Web site for the latest version: http://era.nih.gov/ElectronicReceipt/

Mechanism Abbreviation Key:

C06/UC6	Research Facilities Construction Grants	R21/R33	Exploratory/Development Research
DP1	NIH Director's Pioneer Award Program	R24/U24	Resource Related Research Projects
D71/U2R	International Training Cooperative Agreement/ Phase 2 of FIC mechanism D71	R25	Education Projects
		R34	Clinical Trial Planning Grant Program
		R36	Research Dissertation Grant Program
R01	Research Project Grant Program	SBIR	Small Business Innovation Research
R03	Small Grant Programs	STTR	Small Business Technology Transfer
R10/U10	Cooperative Clinical Research Grants	S06,S10,S11	Biomedical Research
R13/U13	Support for Conferences & Scientific Meetings	S21,22	Health Disparities Endowment Grants
R15	Academic Research Enhancement Awards (AREA)	U	Cooperative Agreement Awards
R18/U18	Research Demonstration and Dissemination Projects	X02	Preapplication

Electronic Submission Progress to Date

- NIH has received over 9,000 unique electronic applications through Grants.gov since December
- Over 4,700 unique small grant applications received for the June 1 and July 1 submission dates combined
- NIH submissions account for over 50% of all applications submitted to Grants.gov this year

Advice from Experience

- Read and follow all application instructions
- Review available resources
- **http://era.nih.gov/ElectronicReceipt/** - information on registration requirements, submission process, avoiding common errors, tips on preparing applications for electronic submission

- Register now to be prepared
- Allow time for corrections
- **Take time to review the assembled application image in eRA Commons**
- When seeking support, be prepared to provide identifying information for your application and organization

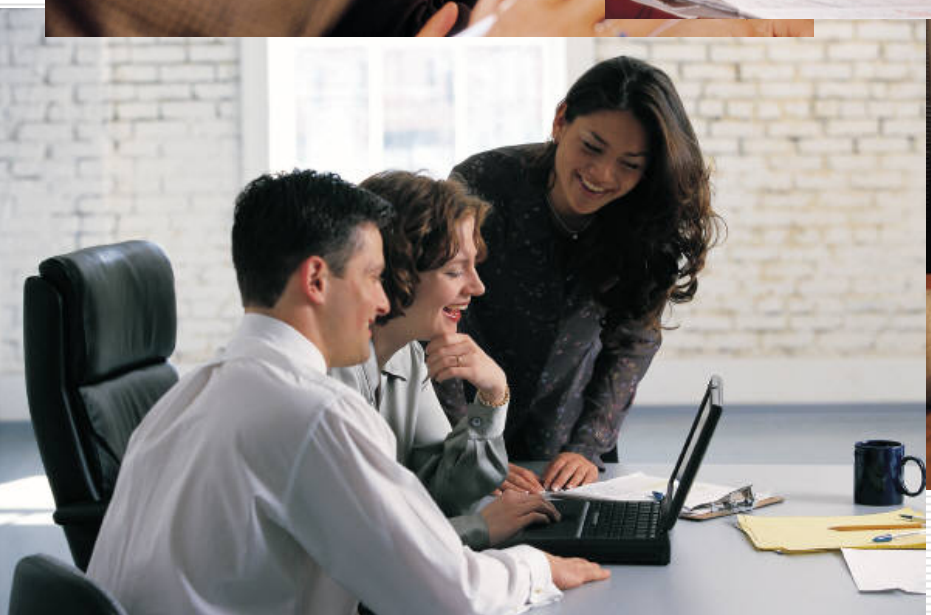
Next Steps: NIH

- Help desk support
- Educating NIH staff
- Outreach to the applicant community
- Continue to prepare for R01s
- Refine plans to transition more complex funding mechanisms

Next Steps: Applicants and Grantees

- Review eSubmission website: http://era.nih.gov/ElectronicReceipt/
- Familiarize yourself with the forms and application guide(s)
  - Application guides and sample versions of application packages are available at: http://grants1.nih.gov/grants/funding/424/index.htm
- Review available training resources: brochures, video library, video webcasts: http://era.nih.gov/ElectronicReceipt/training.htm
- Share experiences: 1) Network at mtgs; 2) Listservs
  Determine implementation plans for *your* Institution
  - How will your internal review & approval processes change?
  - How will you share applications in progress?
  - How will you manage last minute queue at Sponsored Programs rather than airport FedEx drop box?
- Assemble a team to tackle this—faculty, administration and technical representative
- Spread the word—The SF424 (R&R) & electronic submission through Grants.gov are here!

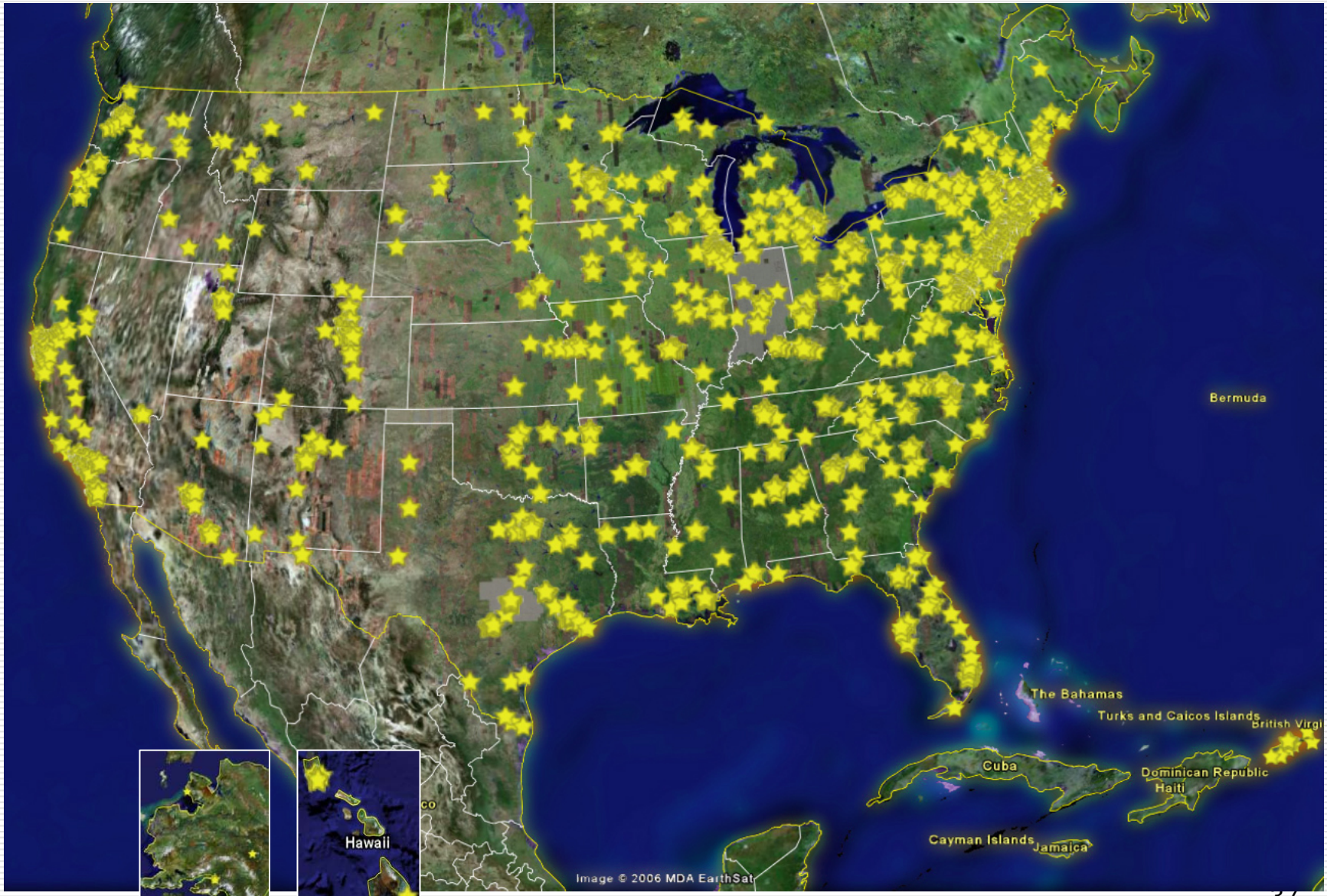
Upcoming changes in Peer Review



Changes in Peer Review – Coming up, Pilots, and Under Consideration

- Coming up – August submission date
  - Streamlining of individual postdoctoral (F32) applications (~40%)
- Pilots
  - Shortening the time from submission to receipt of summary statement (new investigators)
  - Other ideas?
- Under consideration
  - Shorten the application
  - Limit or abolish use of appendices
  - Increase use of electronic communication technology
  - Other ideas?

Thank you very much for your attention!



NIH Funding Across U.S.