

NIH REGIONAL SEMINAR



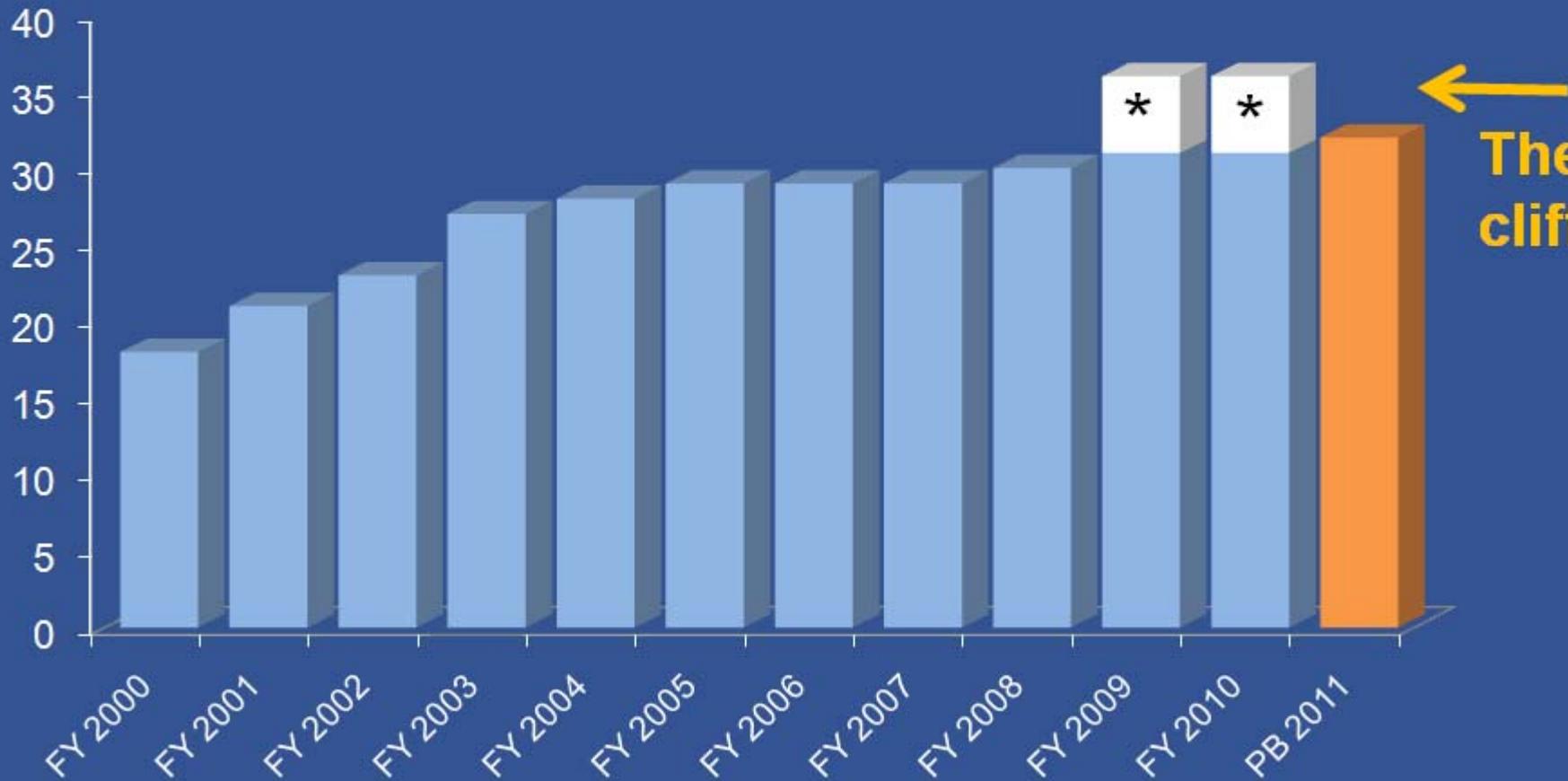
David Garcia

HIGHLIGHTS



NIH FY 2011 President's Budget Request \$32.2 Billion

Increase of \$1B or 3.2% over FY 2010 non-ARRA dollars



*ARRA Funding: \$5B for FY 2009, \$5B for FY 2010

Annual levels represent total budget authority, including special type 1 diabetes appropriation

Of the \$10 Billion appropriated directly to NIH*

- **Approximately \$6.3B has been awarded as of April 2010**
 - \$5.7B in grants to over 15,000 projects
 - \$565M in contracts to over 683 projects
- **2,346 new investigators**
- **Estimated job creation/retention: 50,000 over 2 years**





- **No “co-mingling” of ARRA T-3 and parent grant \$\$\$ allowed (assuming parent grant funded with regular appropriation \$\$\$)**
 - **Separate institution accounts and PMS drawdowns**
 - **ARRA T-3 budget/projects periods reflect that of T-3 only and not parent**
 - **No rebudgeting between parent and ARRA T-3**
 - **No carryover of ARRA T-3 balances into the parent**
 - **If ARRA award includes commitment for an ARRA-funded future year in FY10, grantees can carryover from FY09 into FY10.**



- **ARRA T-3 progress report included in annual progress report of parent grant**
 - **Special progress reporting for Summer Experience program**
- **Separate Targeted/Planned Enrollment and Inclusion Enrollment table for each clinical research protocol funded with ARRA funds and NIH Appropriations funds**
- **Separate Financial & Closeout Reports Required**
- **No-cost Extensions of ARRA-funded T-3s**
 - **ARRA T-3s are awarded under NIH Terms of Award and therefore are eligible for a one-time no-cost extension**
 - **This is separate from the parent record**
 - **<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-067.html>**
 - **Additional (prior approval) extensions will only be considered in limited circumstances**

ARRA Carryover examples



Unique Business Processes: Modified Carryover Authorities

Grant Number	Document Number	Notes
5 R01 AI123456-04	RAI123456A	Non-ARRA Funded
2 R01 AI123456-05	RAI123456Z	ARRA Funded
5 R01 AI123456-06	RAI123456Z	ARRA Funded
2 R01 AI123456-07	RAI123456B	Non-ARRA Funded

- 04 Yr funds **CANNOT** be carried forward into -05; -04 year financially closed
- 05 Yr funds **CAN** be carried forward into -06
- 06 Yr funds **CANNOT** be carried forward into -07
- 04 Yr funds **CANNOT** be carried forward into -07



Fiscal Policy update

- **Non-Competing Research Awards:** each IC will use its own discretion to implement compliance with the 2% inflation allowance provided in FY10.
- **Competing Research Awards:** each IC will manage its own portfolio, with average increase of 2% over FY09.
- **New Salary Cap Summary (equal to Executive Level I) is \$199,700 <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-041.html>**



Fiscal Policy update (cont.)

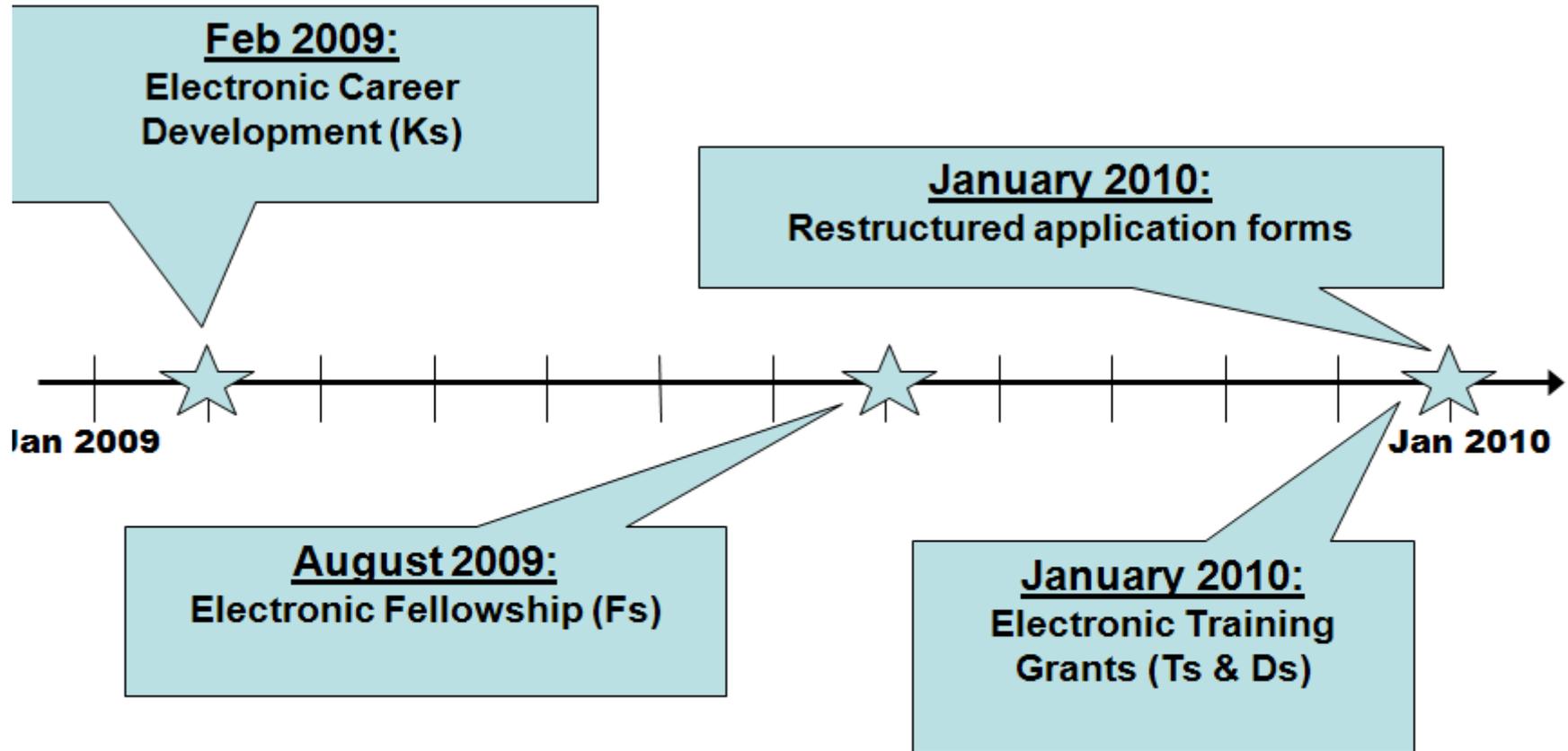
- **New NRSA Stipend levels**

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-047.html>

- **Policy for Tuition, Fees, and Health Insurance on Training Grants and Fellowships finalized: See**

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-073.html>

eSubmission Milestones



All “non-complex” mechanisms now require electronic submission.

Error Correction Window

NIH currently provides a two-day “error correction window” following a submission deadline to correct eRA-identified errors/warnings as long as:



- Initial submission made “on time”
- All registrations completed before deadline
- AOR enforces that changes are restricted to fixing errors/warnings
- Proof of “on time” submission and description of changes documented in cover letter

NIH is currently in talks to potentially eliminate the error correction window. Stay tuned for a related guide notice.

- Grants.gov security enhancements targeted for late summer/early fall
 - New “Change My Password” and “I Forgot My Password/Unlock My Account” features
 - Stronger passwords
 - At least 8 alphanumeric characters with at least one upper and one lowercase letter
 - Forced password change every 90 days
 - Lock-out after three failed login attempts
 - Session timeouts reduced from 60 to 15 minutes
 - After one year of inactivity accounts will be locked
 - Can unlock account
 - E-biz POC must reinstate AOR authority





- xTrain allows users to electronically process required paperwork associated with awarded training and career development grants. xTrain use will be required in Jan. 2011.
 - Create, route and submit appointments, re-appointments, amendments and termination Notices
 - Track the status and timing of training actions

Mandating xTrain NIH guide notice posted at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html>





Types of grants X-Train supports

- Kirschstein-NRSA Undergraduate Institutional Training Grants (**T34**)
- Kirschstein-NRSA Pre-doctoral and Post-doctoral Institutional Training Grants (**T32, T35, T90, TL1, TU2**)
- Kirschstein-NRSA Fellowships (**F30, F31, F32, F33**)
- NLM Institutional Training Grants (**T15**)
- Research Education Awards (**R25, R90**)
- Institutional Career Development Grants (**K12, KL2, KM1**)

xTrain instructions & training resources available at:
http://era.nih.gov/training_career/index.cfm



Financial Conflict of Interest

- “NIH Requests Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”
 - NOT-OD-09-099
- Federal Register (Vol. 74, No. 88) May 8, 2009
- 60-day comment period
- All comments are posted at:
 - <http://www.regulations.gov/search/Regs/home.html#ocketDetail?R=NIH-2008-0002>



FCOI (cont.)

- **NIH has considered the 78 comments submitted in response to the ANPRM and on behalf of the Department of Health and Human Services and the Public Health Service has prepared a NPRM which proposes changes to the regulations**
- **The NPRM is under review and clearance**
- **NPRM will be published in the Federal Register for public comment**
- **A Final Rule is expected to be published this year**



Major Proposed Changes to PHS FCOI Regs

<i>Topic</i>	<i>Current</i>	<i>Proposed</i>
Significant Financial Interests (SFI) definition	- De minimis threshold of \$10,000 for disclosure generally applies to payments or equity interests - Exclusions include income from seminars, lectures, or teaching, and service on advisory committees or review panels, for public or nonprofit entities	- De minimis threshold of \$5,000 for disclosure generally applies to payments and/or equity interests - Includes any equity interest in non-publicly traded entities - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels, for government agencies or institutions of higher education
Investigator disclosure requirements	Only SFIs related to PHS-funded research as determined by the Investigator	- SFIs include financial interests that are related to an Investigator's institutional responsibilities - Institutions responsible for determining whether SFI relates to PHS-funded research and is a FCOI
Public disclosure	No requirement	Before spending funds for PHS-supported research, an Institution shall post on a publicly accessible web site information on certain SFIs that the Institution determines are related to the PHS-funded research and are FCOI < \$20K; <\$50K; , \$100K; <\$250K and >\$250K
Management of an identified FCOI by the Institution	Manner of compliance with regulation not specified (manage, reduce or eliminate are indicated as options)	- For all identified FCOI, Institutions must develop and implement a management plan (may include reduction or elimination of the SFI) - If FCOI is one that was not disclosed or reviewed in a timely manner, the Institution must also implement a mitigation plan which shall include review and determination as to whether any PHS-funded research conducted prior to identification and management of the FCOI was biased
Information on an identified FCOI reported by the Institution to the PHS funding component	- Grant/Contract number - Project Director/Principal Investigator (PD/PI) or Contact PD/PI - Name of Investigator with FCOI - Whether FCOI was managed, reduced, or eliminated	Current requirements, plus: - Value of the financial interest \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-\$100K by increments of \$20K or statement that a value cannot be readily determined. - Nature of FCOI , e.g., equity, consulting fees, travel reimbursements, honoraria, and description of how FCOI relates to PHS-funded research - Key elements of the Institution's management plan
Timing of reporting of an identified FCOI to the PHS-funding component	- Prior to the Institution's expenditure of any funds under the award - Within 60 days for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award	Current requirements, plus annual updates on any previously-identified FCOI for the duration of the research project
Scope of the regulation	Does not cover Small Business Innovation Research/Small Business Technology Transfer Research (SBIR/STTR) Phase I applications	Includes SBIR/STTR Phase I applications
Investigator training	No requirement	FCOI training required for Investigators before engaging in PHS-funded research, and every two years thereafter
HHS authority to inquire about FCOI	The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research	Clarifies that HHS authority applies before, during, or after an award with regard to any Investigator disclosure of financial interests, whether or not the disclosure resulted in the Institution's determination of a FCOI



Coming Soon!!

- **Use of eSNAP will be required for all SNAP awards**
 - **Effective August 1, 2010**
 - **Paper progress reports will not be accepted for SNAP awards**
 - **See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-093.html>**
- **Integration of My Bibliography feature of NCBI with PD/PI eRA Commons Profile**
 - **Helpful to PD/PI citing publications in eSNAP**
 - **Many PD/PIs already have My Bib accounts**

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Summary of Helpful NIH Web Pages

- Office of Extramural Research (OER) Web Page
<http://grants.nih.gov/grants/oer.htm>
- NIH Searchable Database of RFAs, PAs, and Guide Notices
<http://grants.nih.gov/grants/guide/index.html>
- NIH Grants Policy Statement (Rev. 12/03)
http://grants.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Extramural Nexus – Monthly newsletter (previously bimonthly) for the extramural community
<http://grants.nih.gov/grants/nexus.htm>
- RePORTER - Search to analyze an Institute's portfolio of funded projects, research areas, and more <http://projectreporter.nih.gov/reporter.cfm>
- Grant Application Basics http://grants.nih.gov/grants/grant_basics.htm
- Intellectual Property Policy
<http://grants.nih.gov/grants/intell-property.htm>