NIH Update – FDP September 2009

Office of Policy for Extramural Research Administration

New NIH Director

- Francis S. Collins, M.D., Ph.D., was officially sworn in on Monday, August 17, 2009 as the 16th director of the National Institutes of Health (NIH). Dr. Collins was nominated by President Barack Obama on July 8, and was unanimously confirmed by the U.S. Senate on August 7. (Formerly served as Director of the National Human Genome Research Institute (NHGRI),NIH from 1993-2008.)
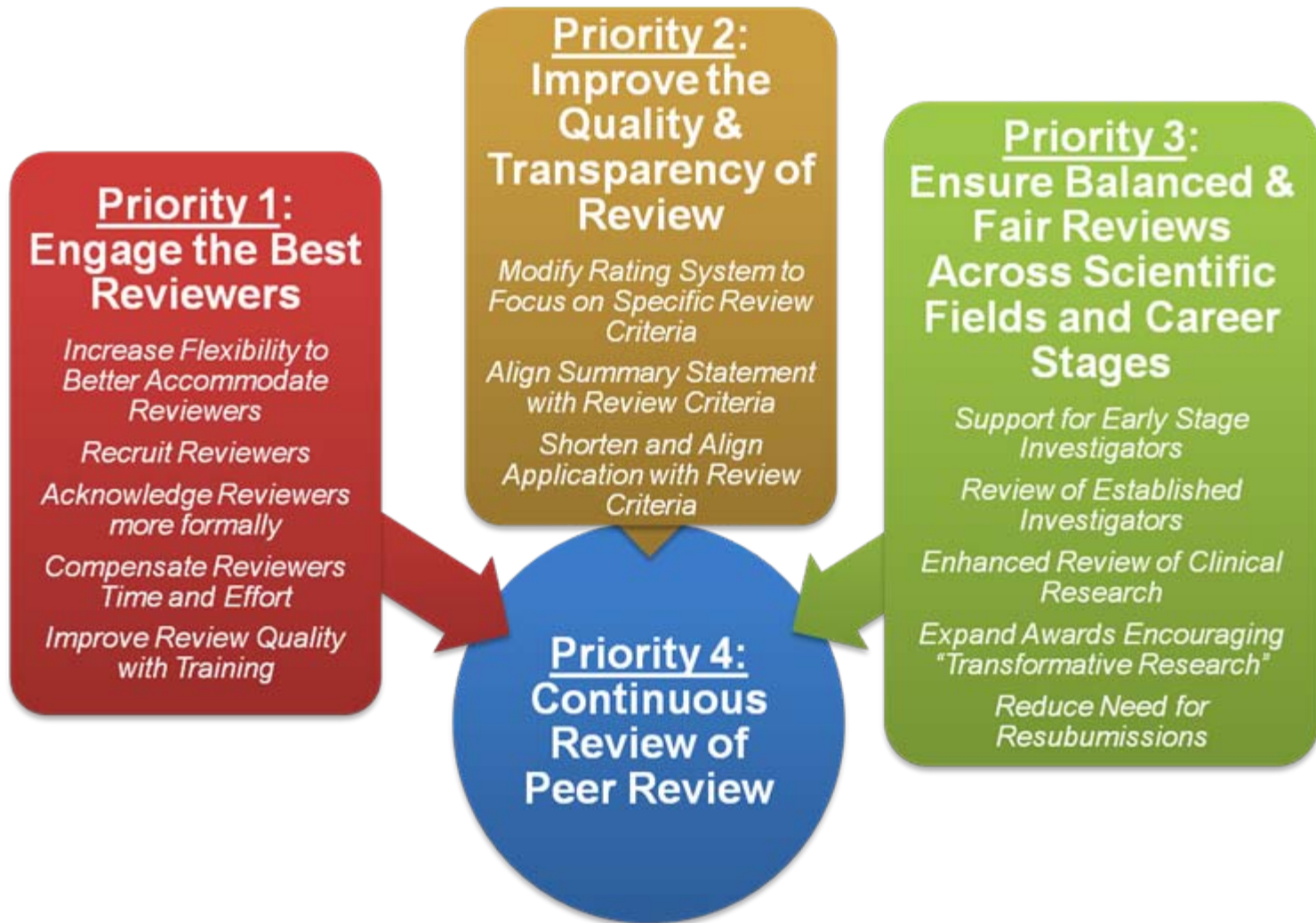
New Scientific and Grants Management Policies

Enhancing Peer Review: Summary of Recommendations

Priority 1:
Engage the Best Reviewers

Increase Flexibility to Better Accommodate Reviewers

Recruit Reviewers

Acknowledge Reviewers more formally

Compensate Reviewers Time and Effort

Improve Review Quality with Training

Priority 2:
Improve the Quality & Transparency of Review

Modify Rating System to Focus on Specific Review Criteria

Align Summary Statement with Review Criteria

Shorten and Align Application with Review Criteria

Priority 3:
Ensure Balanced & Fair Reviews Across Scientific Fields and Career Stages

Support for Early Stage Investigators

Review of Established Investigators

Enhanced Review of Clinical Research

Expand Awards Encouraging "Transformative Research"

Reduce Need for Resubumissions

Priority 4:
Continuous Review of Peer Review

More at: http://enhancing-peer-review.nih.gov

Priorities and Goals Implemented Thus Far

- Phase-out of A2 resubmission applications
- New and early stage investigator policies
- Continuous submission process for study section members expanded to include NIH Advisory Group members
- Enhanced peer review criteria
- New 1-9 scoring system
- Scoring of individual review criteria
- Templates for structured reviewer critiques
- Score order review (Ranking)
- Clustered review of new and ESI investigator R01 applications

More at: http://enhancing-peer-review.nih.gov

Coming Soon: Restructured Applications and Instructions

- Implementation of goal: *Align the structure and content of applications with review criteria, and shorten the length of applications*

- Three sections of application instructions to be revised:
  - Research Plan
  - Biographical Sketch
  - Resources and Facilities

- Shorter Page Limits

- *For additional information see NIH Guide Notice NOT-OD-09-149 issued 09/16/09. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html)

More at: http://enhancing-peer-review.nih.gov

Research Plan Changes

- New **Research Strategy** section will replace 3 sections of the current Plan (Background and Significance, Preliminary Studies/Progress Report, and Research Design and Methods).

- **Research Strategy** will have 3 subsections:
  - **Significance**
  - **Innovation**
  - **Approach**
    - Preliminary studies for new applications
    - Progress report for renewal/revision applications

More at: http://enhancing-peer-review.nih.gov

Biographical Sketch Changes

- *Personal Statement:* Tell us why your experience and qualifications make you particularly well-suited for your role in the project

- *Publications:* Include no more than 15, and make selections based on recency, importance to the field, and/or relevance to the application

- *Page limit remains at 4*

More at: http://enhancing-peer-review.nih.gov

Facilities and Resource Changes

- Provide a description of how the scientific environment will contribute to the probability of success of the project

- For ESIs describe the institutional investment in the success of the investigator

- In Select Agent Section of Research Plan describe the biocontainment resources available at all performance sites

Shorter Page Limits

Introduction Except Intro to Resubmission for Ts and K12	1 page
Specific Aims	1 page
Research Strategy R03, R13/U13, R21, R36, R41, R43, Fs, SC2, SC3	6 pages
Research Strategy R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	12 pages
Candidate Information + Research Strategy Career Development Awards (Ks, except K12)	12 pages
Research Training Program Plan Including NRSA (Ts), K12 and R25	25 pages

Restructured Application Forms/Instructions **must** be used for due dates on/after **January 25, 2010**

- New FOAs are being posted without electronic application packages

- By December, new application packages will be posted, along with new Parent Announcements, and updated active FOAs

- You must return to the FOA to download the new forms and instructions for 1/25/10 due dates

- Resubmissions must use new application forms and instructions (and shorter page limits)

More at: http://enhancing-peer-review.nih.gov

New Assurance & Reporting for Graduate Training Awards

- Applies only to doctoral degree granting institutions receiving: D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

- Assurance that institution will disclose to doctoral applicants:
  - % of students admitted who attained a doctoral degree
  - Average time until receipt of doctoral degree

- Report same info to NIH on Table 12A of Institutional Research Training Data Tables

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-141.html

Revised Progress Report

- Use required as of 10/01/2009
- eSNAP changes released 10/09/2009
- Policy changes:
  - All Personnel Report (PD/PIs & all > 1 person month)
  - Assurance for Institutions with Awards for Grad Student Training for Doctoral Degrees
  - Describe any change to innovative potential
  - Biosketch (peer review initiative change)
  - Question regarding hESC change

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-139.html   and

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-150.html

eRA Commons ID Required for Postdocs on Progress Reports

- All Personnel Report implemented as part of Progress Report (effective 10/01/2009)
- Report those in a postdoctoral role for one person month or more
- Provide Commons ID for postdocs

Note for Commons Account Administrators: *help your postdocs establish eRA Commons accounts using the new Commons Postdoctoral role*

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-140.html

NIH Recovery Act News

American Recovery and Reinvestment Act (ARRA)

- NIH Recovery Act Web site **www.nih.gov/recovery**

- $10 billion appropriated directly to NIH
  - Stimulate and accelerate biomedical research with existing mechanisms
  - Expand science with new programs

Special ARRA Terms and Administrative Requirements

- In addition to the standard NIH terms of award, all NIH ARRA awards will include special ARRA terms
  - http://grants.nih.gov/grants/policy/NIH_HHS_ARRA_Award_Terms.pdf (updated July 8, 2009).

- ARRA requires recipients to account for, track, monitor, report on, provide for audit of, and closeout ARRA funding separately from non-ARRA awards
  - Unique business processes established
  - Guide Notice NOT-OD-09-080 describing ARRA features; updated in Notice NOT-OD-09-120
  - Special Quarterly Reporting Requirements

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-120.html

Reporting and Accountability

- The opportunity afforded by the ARRA also carries enhanced accountability and transparency.
  - Grantees must fulfill detailed quarterly budget reporting requirements, consistent with section 1512(c) of the ARRA by October 10, 2009.
  - Reports will summarize total amount of ARRA funds received that quarter and how those funds were expended.
    - This includes a detailed list of all projects or activities and an estimate of the number of jobs created or retained through those projects and activities.
- *OMB posted Guidance Memo M-09-21 on June 22, 2009 http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-21.pdf*
- *OMB clarified this document through Q&As: http://www.whitehouse.gov/omb/recovery_faqs/*

Recipient Reporting

- Reports will be entered at www.FederalReporting.gov and will be publicly available at www.recovery.gov
  - Includes web based form, MS Excel template and XML schema options for report submission
- OMB Data Model v.3.0
  - OMB released the Recipient Reporting Data Model v3.0 for ARRA, Quarter Ending September 30, 2009.
  - Includes a Data Dictionary describing the data elements specifically required for recipient reporting
  - Additional NIH guidance (*based on the OMB Data Model*): http://grants.nih.gov/recovery/Data_Dictionary.xls.

Recipient Reporting

- NIH FAQs address ARRA recipient reporting NIH-specific concerns: http://grants.nih.gov/recovery/faqs_recovery.html

- ARRA Quarterly Report Sample Templates: http://grants.nih.gov/recovery/sample_quarterly_reports.html

- ARRA Data Reports: http://report.nih.gov/recovery/index.aspx
  (*includes most data needed for quarterly reports*)

Accessing ARRA $$$ in the Payment Management System (PMS)

- Unique "P" accounts for ARRA funds require a new process to access those funds.

  - Cash pooling is not permitted. When a grantee requests ARRA funds, the grantee must separately account for those funds by subaccount/grant document.

  - If a grantee has more than one "P" account, the grantee MUST request funds by subaccount (grant document).

  - Existing PMS users can access the "P" accounts using already established login & password.

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html

- When a grantee processes its quarterly 272 Federal Cash Transaction Reports, if the grantee received ARRA funds the previous quarter, the grantee will see two different reports. One report for their "G" account and one report for their "P" account.

- Each 272 must be submitted or a hold will be placed on their Division of Payment Management (DPM) account.

Unique Document Number Schema

- All HHS agencies required to adopt a unique Document Number Schema for ARRA awards.

  - For NIH, core schema traditionally used will remain intact; except the last character will be "Z" for initial awards.

  - Example: Grant Number= 1 R01 AI123456-01; ARRA Doc # = RAI123456Z

  - Transfers (T-7s): Transfer "competitive segment" for ARRA grants will be denoted with "Y", "X" or "W" when applicable.

Administrative Supplements & Competing Revisions

- Need to accommodate the "separation" and accountability required by ARRA while maintaining a programmatic connection to the parent grant
  - ARRA T-3 budget/projects periods reflect that of the T-3 only and not the parent
  - ARRA T-3s issued in FY2009 may be for a single budget/project period up to 24 months.
  - ARRA T-3s issued in FY2010 will be no more than a 12-month budget/project period
  - Specific information on ARRA additional funding must be included in annual progress report of the parent grant.
- 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

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html

Administrative Supplements & Competing Revisions (cont.)

- No "co-mingling" of ARRA T-3 and parent grant $$$ allowed (assuming parent grant funded with regular appropriation $$$)
  - Separate institution accounts and PMS drawdowns
  - No rebudgeting between parent and ARRA T-3
  - No carryover of ARRA T-3 balances into the parent
  - If an ARRA award includes a commitment for an ARRA-funded future year in FY2010, grantees will be able to carryover from the FY2009 budget period into FY2010.
  - No carryover allowed between ARRA funding budget periods and budget periods funded by non-ARRA fund
- Separate Financial & Closeout Reports Required

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html

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

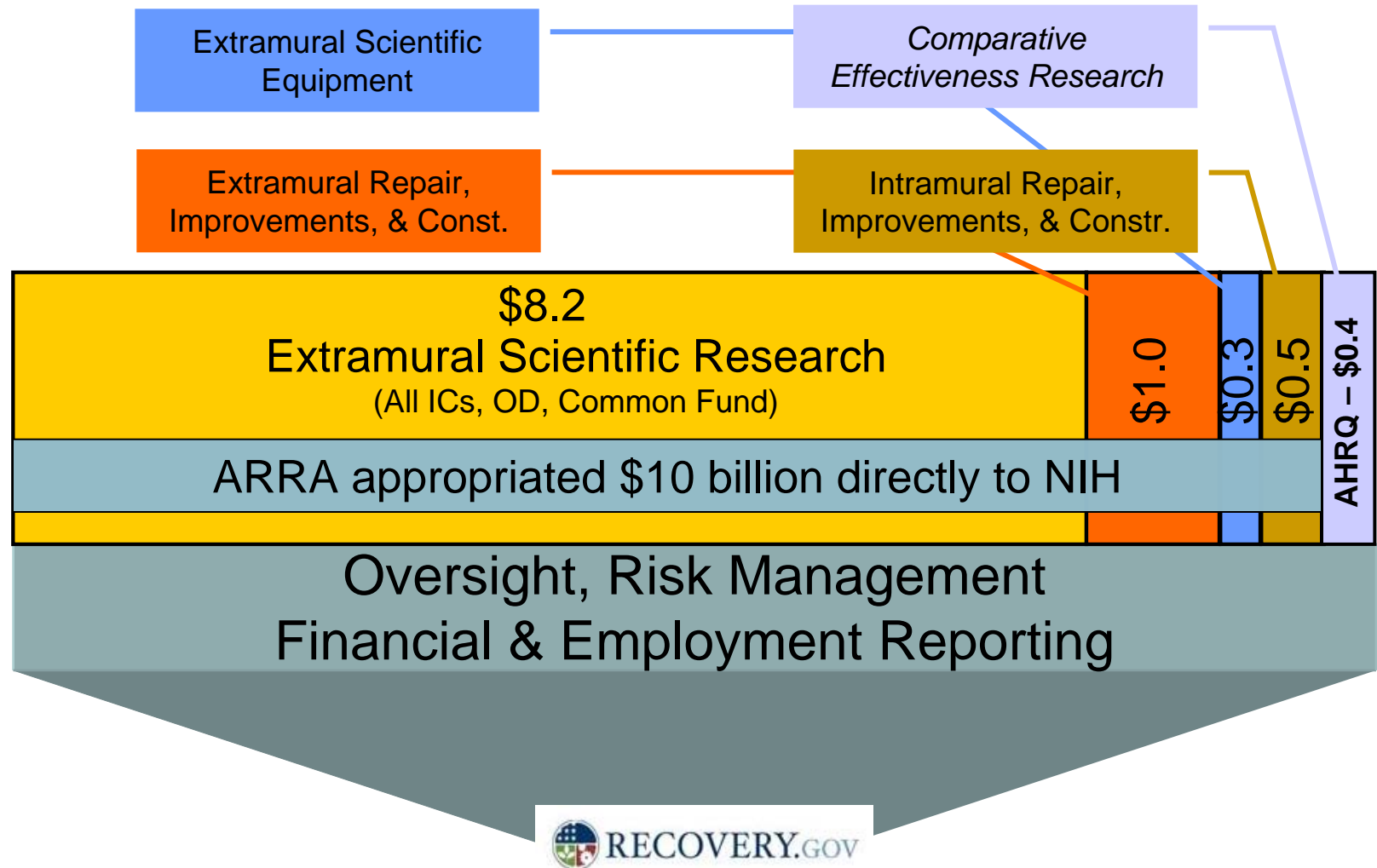- -04 Yr funds **CANNOT** be carried forward into -07

ARRA Grant Compliance (Same as non-ARRA)

- The applicant organization certifies in the grant application that it is obligated to comply with the terms and conditions of any resulting grant award

- Acceptance of a grant award is signified by drawdown of funds which then obligates the grantee to comply with all standard and special terms and conditions of award (e.g., based on statute, regulation, policy, program requirement)

- Failure to comply may cause NIH to take one or more enforcement actions, depending on the severity and duration of the non-compliance.

  – Enforcement actions may include special conditions, closer monitoring, withholding of support, recovery of funds, suspension, or termination

NIH Allocation of ARRA Funds
Dollars In Billions

Extramural Scientific Equipment

Comparative Effectiveness Research

Extramural Repair, Improvements, & Const.

Intramural Repair, Improvements, & Constr.

$8.2
Extramural Scientific Research
(All ICs, OD, Common Fund)

$1.0

$0.3

$0.5

AHRQ – $0.4

ARRA appropriated $10 billion directly to NIH

Oversight, Risk Management
Financial & Employment Reporting

RECOVERY.GOV

Thank You!

Any Questions?