






Current Issues at NIH Spring 2012

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NIH Budget and Recovery Act News

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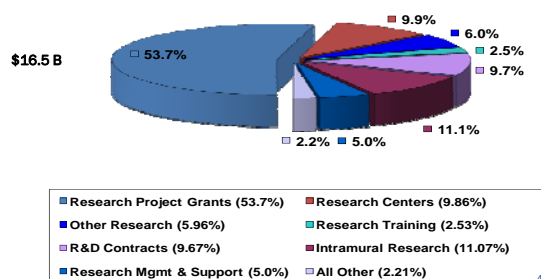
NIH Budget News

- President Obama signed into law H.R. 2055, the Consolidated Appropriations Act, 2012 on December 23, 2011.
 - Appropriates \$30.7 billion to NIH for FY2012;
 - Increase of less than 1% from FY 2011;
 - Reduces the salary cap to \$179,700 for all NIH grants;
 - Apply Executive Level (EL) II prospectively to all awards that were issued on or after the bill was signed (12/23);
 - Awards issued on or before 12/22, EL-I still applies for FY 2012—only. Future years must be adjusted to reflect EL-II.



More at: <http://officeofbudget.od.nih.gov/br.html> 3

Breakdown of FY 2012 Budget for NIH \$30.7 Billion



NIH Fiscal Policy for Grant Awards FY 2012

- **FY 2012 Funding Levels:**
 - Non-competing awards will be issued without cost of living/inflationary adjustments;
- **Inflationary Increases for Future Years:**
 - Will be discontinued for all competing and non-competing research grant awards issued in FY 2012;
- **Overall effort is to keep average size of grants consistent to the FY2011 levels or lower;**
- **NRSA:**
 - NIH will implement a two percent increase at all stipend levels.

More at: [NOT-OD-12-036](#)

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NIH Fiscal Policy for Grant Awards FY 2012 (cont'd)

- **New Investigators:**
 - NIH will continue to support new investigators on R01 equivalent awards at success rates equivalent to that of established investigators submitting new (Type 1) R01 equivalent applications.;
- **Salary Limits:**
 - Applies Executive Level II;
- **Additional Information:**
 - Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at <http://grants.nih.gov/grants/financial/index.htm>;

More at: [NOT-OD-12-036](#)

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NIH Salary Cap News

- Prior year awards (awards made in FY 2011, 2010, etc) are not impacted. No adjustments required;
- If the President signs a CR for any part of FY 2013, unless legislative language provides otherwise, the EL-II salary cap will apply regardless of what level was applied in FY 2012;
- Where applicable, grantees will be allowed to rebudget in an effort to accommodate the new salary cap limitations.

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NIH Salary Cap News (cont'd)

- Salary cap does not apply to payments made to consultants under a grant;
- Salary cap does apply to subawards/contracts for substantive work under a NIH grant;
- See Frequently Asked Questions website at http://grants.nih.gov/grants/policy/fy2012_salary_cap_faqs.htm

More at: [NOT-OD-12-035](#)

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Legislative Mandates in Effect for FY2012

FY 2011 Legislative Mandates
that remain in effect:

1. Acknowledgment of Federal Funding;
2. Restriction on Abortions;
3. Exceptions to Restriction on Abortions;
4. Ban on Funding Human Embryo Research;
5. Limitation on Use of Funds for Promotion of Legalization of Controlled Substances;
6. Certification of Filing and Payment of Taxes

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Legislative Mandates in Effect for FY2012 (cont'd)

Amended Legislative Mandates in effect:

1. Dissemination of False or Misleading Information;
2. Restriction on Distribution of Sterile Needles;
3. Salary Limitation;
4. Anti-Lobbying.

Additional Legislative Mandate in effect:

Gun Control

More at: [NOT-OD-12-034](#)

FY2013 President's Budget

- Requests \$30.9 billion for NIH; same as FY2012
- From the HHS FY2013 Budget in Brief:
 - Continued focus on resources for young, first time researchers;
 - Continued exclusion of inflationary allowances;
 - Reduce non-competing continuation grants by 1% below FY2012 level;
 - Manage competing awards to avoid growth in average award size;
 - Provide consideration by IC Advisory Councils of awards to PD/PIs with existing grants of \$1.5 million or more in Total Costs.

Closing out the Era of ARRA

- Timely Quarterly and Closeout Reports Required
 - All standard closeout documents apply to ARRA funded awards (Final Progress Report, Final Invention Statement, Final FFR), even if ARRA funded a Supplement to a non-ARRA parent;
 - Financial closeout requirements for multiple ARRA supplements: [NOT-OD-10-066](#).

More at: <http://www.grants.nih.gov/recovery/>

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Accelerating Unspent ARRA Awards

- [OMB Memorandum M-11-34](#) Issued 9/15/2011, directs agencies to assure ARRA funds are spent by 9/30/2013 and to “revise the terms of Recovery Act discretionary grant agreements, to the extent permitted by law, to provide for reclamation of funds that remain unspent after September 30, 2013, absent a waiver issued by OMB pursuant to this memorandum.”

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Accelerating Unspent ARRA Awards (cont'd)

- NIH issued on December 13, 2011, [NOT-OD-12-014](#), Notice of Revised Term of Award for All Recovery Act Awards to Ensure Project Completion by September 30, 2013. In summary:
 - 1) NIH is revising the terms and conditions on some active Recovery Act awards to amend the current automatic no-cost extension authority by limiting the ability for awardees to extend the final budget period of a project period to no later than 9/30/2013 without prior NIH approval. Commons Extension feature being modified accordingly;
 - 2) establishing a procedure for recipients to request prior NIH approval for waivers to extend beyond 9/30/2013; and
 - 3) describing process for those recipients unable to accept the revised terms of award.

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Accelerating Unspent ARRA Awards (cont'd)

- At this time NIH has not determined the need for waiver requests to OMB. NIH continues to strongly encourage grantees to accelerate expenditures for all active Recovery Act grants regardless of the current or projected project period end date.

More at: [NOT-OD-12-014](#)

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Financial Conflict of Interest (FCOI) Regulations

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Financial Conflict of Interest (FCOI) Regulations

- 42 CFR Part 50 Subpart F (grants and cooperative agreements);
- 45 CFR Part 94 (contracts)
Initial Regulation effective October 1, 1995
 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
 Revised Final Rule published on August 25, 2011
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

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Revised 2011 Regulation

- Revised regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*;
- Federal Register published August 25, 2011;
- Implementation no later than 365 days after publication of the final rule in the Federal Register, i.e., August 24, 2012. In the interim:
 - Institutions comply with 1995 regulations;
 - Institutions revise policies, establish procedures for compliance, train Investigators, and continue to report FCOIs to NIH;
- Basic FCOI framework remains the same regarding responsibilities and compliance.

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Major Changes to the Regulations

- **Significant Financial Interest (SFI)**
 - Minimum threshold of \$5,000 generally applies to payments and 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, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education;
 - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

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Major Changes to the Regulations (cont'd)

- **Investigator Disclosure**
 - All SFIs related to Investigators' institutional responsibilities;
 - Institutions responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI).

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Major Changes to the Regulations (cont'd)

- **Reporting to PHS Awarding Component (NIH)**
 - Previous requirements, (grant/contract number, name of PD/PI, name of Investigator with FCOI) and:
 - Name of the entity with which the Investigator has a FCOI;
 - Value of the financial interest;
 - Nature of FCOI, e.g., equity, consulting fees, honoraria;
 - A description of how the financial interest relates to PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research;
 - Key elements of the institution's management plan.

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Major Changes to the Regulations (cont'd)

• Public Accessibility

- The Institution's FCOI policy must be made available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site, the Institution shall make its written policy available to any requestor within five business days of a request;
- Before spending funds for PHS-supported research, an Institution shall ensure public accessibility of information on certain SFIs that the Institution has determined are related to the PHS-funded research and are FCOI, via a publicly accessible Web site or by a written response to any requestor.

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Major Changes to the Regulations (cont'd)

• Investigator Training

- FCOI training required for Investigators before engaging in PHS-funded research, every four years thereafter, and immediately under designated circumstances.

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Reporting FCOIs to the NIH eRA Commons

- FCOI reports for NIH grants and cooperative agreements must be submitted using the eRA Commons FCOI Module;
- Once the Institution is required to be in full compliance with the regulatory requirements, the additional reporting requirements must be met;
- Commons FCOI Module being updated;
- If the FCOI Module is not updated by the time this occurs, the FCOI report should include an attachment with the minimum elements of the FCOI report as provided in 42 CFR 50.605(b)(3). Existing FCOI Module will accommodate this uploaded material.

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New FCOI Reporting Requirements

- **Annual FCOI reports**
 - Update status of existing FCOI;
 - Describe changes to management plan.
- **Mitigation Reports will only be submitted when the Institution has determined that any NIH-funded research, or portion thereof, was biased in the design, conduct or reporting of the research.**

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Resources

- **Mailbox for inquiries**
 - FCOICompliance@mail.nih.gov
- **OER FCOI Web Site**
 - <http://grants.nih.gov/grants/policy/coi/>
 - FAQs posted on 9/30/2011. See NIH Guide Notice [NOT-11-121](#)



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Other Policy Updates

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NIH Reorganization

- On 12/23/11, P.L.112-74 dissolved NCRR, created the National Center for Advancing Translational Sciences (NCATS), and created a new Office of Research Infrastructure Programs within the NIH OD;
- All NCRR Programs, Awards, and Pending Applications are being transferred to Other NIH ICs, including NCATS;
- An initial listing of NCRR programs being transferred to other ICs can be found at <http://www.ncrr.nih.gov/>.

More at: [NOT-OD-12-026](#) and [NOT-OD-12-027](#)

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NIH Research Involving Chimpanzees

- NIH will not fund any new projects for research involving chimpanzees while the Agency considers and issues policy implementing the Institute of Medicine's (IOM) recommendations regarding the necessity of using chimpanzees in biomedical and behavioral research.
- NIH will assemble a working group of the NIH Council of Councils to provide advice on implementation of the IOM recommendations, and to consider the size and placement of the active and inactive populations of NIH-owned or -supported chimpanzees.

More at: [NOT-OD-12-025](#)

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Revised Multiple-PD/PI Policy Allows PD/PI Change with Prior Approval

- Revised policy acknowledges that it may not be essential to require peer review to change from single- to multiple-PD/PI award, or from a multiple- to single-PD/PI award;
- Requires a prior approval request sent to the IC GMO by the AOR;
- Justification must be based on scientific needs of the project; request will not be considered if based on administrative convenience;
- Revised policy is consistent with prior approval requirements for a change in PD/PI (see Grants Policy Statement, Section 8.1.2.6);
- Guide NOT-OD-11-118 specifies the information to be included in the prior approval request;
- Change may not be implemented without GMO approval and revised NoA.

More at: [NOT-OD-11-118](#)

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Appeals Policy

Effective with Competing Applications submitted on/after 1/25/2011; (i.e., October 2011 Council Round)

- Formal appeal letter must be submitted by the Authorized Organization Representative (AOR) or document concurrence of the AOR; requests to withdraw an appeal letter must likewise include AOR concurrence;
- ICs can establish deadlines for appeals; however no letter can be accepted before the summary statement has been made available to the PD/PI or later than 30 calendar days after the relevant Council meeting.

More at: [NOT-OD-11-101](#); [NOT-OD-11-064](#) ³¹

Appeals Policy (cont'd)

An appeal letter will only be accepted if the letter:

- 1) Describes flaws in the review process for application in question;
 - 2) Explains reason for the appeal;
 - 3) Is based on one or more of the following issues
 - Evidence of bias on the part of one or more peer reviewers;
 - Conflict of interest on the part of one or more peer reviewers (see 42 CFR 52h.5);
 - Lack of appropriate expertise within the Scientific Review Group (SRG);
 - Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially;
- Appeals based solely on differences of scientific opinion will not be accepted;
 - Questions on the Notice should be directed to ReviewPolicyOfficer@mail.nih.gov.

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Mandating Use of the Commons to Submit No-Cost Extension Notifications

- Effective October 1, 2011, NIH required grantees to use the No-Cost Extension feature in the eRA Commons to notify NIH when they exercise their one-time authority to extend, without additional funds, the final budget period of a grant.
 - Once the eRA Commons link is closed, such an action becomes a prior approval request and must be submitted for consideration to the Grants Management office of the NIH awarding component;
 - Link opens 90 days before project end date;
 - Contact your Grants Specialist if you feel there is a problem with the link being open.

More at: [NOT-OD-11-098](#) ³³

Change in the NIH Continuous Submission Policy for Reviewers with Recent Substantial Service

•NOT-OD-11-093 announced the lengthening of the window of time during which peer reviewers who have served six times in 18 months (recent substantial service) can submit their applications under the NIH continuous submission policy;

•Previous window was 10/1 – 9/30;

•Effective July 8, 2011: For peer reviewers in this category, the window is adjusted to begin on August 16th and extend to September 30th of the next year.

More at: [NOT-OD-11-093](#); [NOT-OD-08-026](#); [NOT-OD-09-114](#); [NOT-OD-09-155](#); [NOT-OD-10-090](#); & [NOT-OD-11-035](#)

Modification of Eligibility Criteria for Ruth L. Kirschstein National Research Service Awards (NRSA) for Individual Postdoctoral Fellows (Parent F32)

- As of 7/15/2011, instructions under “Eligible Organizations” for the NIH Postdoctoral Fellowship program, Ruth L. Kirschstein National Research Service Awards (NRSA) for Individual Postdoctoral Fellows (Parent F32) ([PA-11-113](#)) were modified (updated) as follows:

- The fellowship is designed to support research training experiences in new settings in order to maximize the acquisition of new skills and knowledge. In most cases, therefore, the sponsoring institution should be a site other than where the applicant fellow has trained as a graduate student. However, if the applicant fellow is proposing postdoctoral training at his/her doctoral institution, the application must carefully document the opportunities for new research training experiences specifically designed to broaden his/her scientific background. In addition, the application should propose research experiences that will allow the fellow to acquire new knowledge and/or technical skills that will enhance his/her potential to become a productive, independent investigator.

More at: [NOT-OD-11-097](#)

New NRSA Stipend Levels for FY 2012

- For FY 2012 Kirschstein-NRSA awards for undergraduate, predoctoral, and postdoctoral trainees and fellows;
- Tuition and Fees, Training Related Expenses for trainees, and the Institutional Allowance for individual fellows remain unchanged;
- Effective with all Kirschstein-NRSA awards made on or after October 1, 2011;
- For additional information see: Questions and Answers Related to NRSA Tuition, Fees, and Health Insurance Policies: http://grants.nih.gov/training/nrsa_tuition_q&a.htm & [NOT-OD-12-033](#).

NRSA & Other Fellowship Applications: New Policy on Post-Submission Information on Sponsor's Research Funding

- Information will be allowed as post-submission material to update the Sponsor(s)' funding information in the originally submitted application;
- Must not exceed 1 page; limited to the project title, funding source (e.g. NIH grant number); a brief description of specific aims, & relevance to the fellowship application under review;
- Due no later than 30 days prior to the meeting of the review committee.

More at: [NOT-OD-12-022](#)

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New HHS Policy on Efficient Spending

- **New HHS policy modifies grantee use of NIH funds for conferences, meetings, food, promotional items, and printing and publications.**
 - Applies to NIH Grants and Cooperative Agreements where the primary purpose of the grant is to support a Conference and/or Scientific Meeting (i.e., R13s and U13s);

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New HHS Policy on Efficient Spending (cont'd)

- **Implications for Grants**
 - Effective with awards issued on or after 01/27/12, a new term and condition prohibiting food/meal costs from being supported by or charged to NIH-supported conference grants will be included on all competing and noncompeting NIH R13 and U13 awards:
"Direct charges for meals/food and beverages are unallowable charges to this project."

More at: [NOT-OD-12-041](#) and [NOT-OD-12-048](#)

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New HHS Policy on Efficient Spending (cont'd)

- **Implications for Applications**
 - Applications for the April 12, 2012 and subsequent due dates must comply with this new policy;
 - The parent conference grant FOA and other active R13/U13 FOAs have been revised to reflect the new term and condition.
- **Implications for Grants Not Specifically to Support Conferences**
 - The policy does not apply.

More at: [NOT-OD-12-041](#) and [NOT-OD-12-048](#) 40

NIH Grants Policy Statement Revision - FY2012

- **Effective October 2011, revision superseded the October 1, 2010 version**
 - Incorporates policy changes since 10/01/10, public policy changes, clarification of existing policies;
 - Incorporates new business process changes, minor edits for clarity in response to user input, and updated URLs when applicable.

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Fed-wide Streamlining Efforts

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Research Performance Progress Report (RPPR)

- OMB mandated format standardizes interim progress reports submitted to agencies;
- NIH will implement as a module in Commons; will replace PHS 2590, including eSNAP, and 416-9;
- Includes standard fed-wide questions and NIH-specific data elements;
- Initial pilot, with limited institutions, April 2012;
- Mandated use of the new RPPR module is expected for all SNAP and all Fellowship awards made in Calendar Year 2013;
- Schedule for complex mechanisms and non-SNAP to be determined.

More at: <http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp>

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What's new about it?

- Format is different from eSNAP, but the information requested is similar;
- SNAP awards will still not require budget;
- Publications from PI's MyNCBI will indicate Public Access Policy compliance status;
- Will include live links to Notice of Award;
- Streamlines ClinicalTrials.gov reporting;
- Content will vary depending on activity code.

Significant Differences

- New data collection on foreign components, dollars to foreign countries, and foreign affiliation of personnel
- Effort for all participants must be rounded to nearest whole person month
- Other support only required if change
- Clarifies when report may be used to request prior approval (ONLY for reduction in level of effort for PD/PI or Senior/Key listed in NoA)

OMB Notice on Potential Reforms to Federal Grants Policy

- Published in Federal Register 2/28/2012:
<http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4521.pdf>
- Includes ideas that would standardize information collection, adopt a risk-based model for single audits, & provide new administrative approaches for determining & monitoring allocation of Federal funds;
- Ideas of Interest:
 - Exploring time & effort reporting alternatives;
 - Charging allocable admin support costs directly;
 - Including computing device costs as allowable direct costs;
 - Consolidating cost principles into single document;
 - For F&A costs, using flat rates instead of negotiated rates.

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Looking Ahead

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Changing Payment Process for Foreign Grantees

- Transitioning Payment of Foreign Grantees from a manual quarterly check to drawdowns through Payment Management System;
- Will align payment and FFR reporting processes with those for domestic grantees;
- Anticipated Date = October 2012 (FY2013 awards);
- Stay tuned for Guide Notice on details.

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Policy Reminders

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Transparency Act Subaward Reporting

- Where is information on subawards reported?
 - To FFATA Subaward reporting system (FSRS) fsrs.gov;
 - FSRS.gov also used for the executive compensation of subawardees when information not available in CCR;
 - XML Upload available;
 - Information made publicly available at USASpending.gov;
 - FSRS User support through the Federal Service Desk www.fsd.gov;
- Where can I get more information?
 - Direct questions concerning reporting on NIH grants to: GrantsPolicy@mail.nih.gov;
 - FAQs: [Federal Funding Accountability and Transparency Act](#).

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Transparency Act—Subrecipient Reporting Reminder

- Previously, requirement for Subrecipient Reporting only applied to “New” (Type 1) grants issued in FY2011 and beyond;
- In FY2012 and beyond, this expands to MOST awards where the Type 1 was awarded after October 1, 2010. This includes:
 - Non-competing Type 5 and Type 7 awards (that follow an FY2011 T-1); and,
 - Type 2s competing continuations when the original Type 1 was awarded on or after October 1, 2010.
- Beginning in FY2012, awards will have more definitive “Yes/No” award term for this requirement.

More at: [NOT-OD-12-010](#)

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Need Assistance with the NIH FFATA Requirements?



- Visit the NIH FFATA/Public Accountability Web Page
 - http://grants.nih.gov/grants/public_accountability/ffata.htm;
 - Includes Frequently Asked Questions;
- Send your NIH-specific questions by e-mail to GrantsPolicy@mail.nih.gov.

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Common Problem: Can't Find Grant in FSRs to Report

- **Trouble-Shooting:**
 - Is it truly part of the FFATA reporting requirement?
Confirm that the award is a Type 1 award issued on or after October 1, 2010 or subsequent award to such a Type 1;
 - Are you using the correct identifier? The FAIN for NIH awards is based on the NIH award number but only the activity code, IC, and serial number. Example: NIH award 1R01CA987654-01A1 appears as FAIN R01CA987654;
 - Is the award in USASpending? Do a grant search at <http://www.usaspending.gov/advanced-search>. If your award is listed on USASpending.gov it should also appear in FSRs.gov.

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Multi-year Funded (MYF) Award Progress Reports

- MYF awards are not funded incrementally (1 yr at a time), but have a budget period and project period that are the same, and are longer than 1 year;
- Traditionally multi-year funded:
 - C06, DP2, DP3, R15;
- Standardization of submission and content of progress reports for multi-year funded awards;
- Supports monitoring of progress and enforcement of terms of award.

More at: NOT-OD-11-010

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Multi-year Funded (MYF) Award Progress Reports (cont'd)

- Progress reports due on or before anniversary date of award;
- Report is a PDF uploaded through eRA Commons (NOT eSNAP);
- Instructions for Grantees on how and what to submit:
 - <http://grants.nih.gov/grants/policy/myf.htm>;
- Reporting period is calendar year preceding anniversary date of the award;
- Notifications
 - PD/PI receives eNotification two months prior to anniversary date of the award stating when progress report is due;
 - Subsequent eNotification sent when report is past due.

More at: [NOT-OD-11-010](#)

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Audit Requirements

All NIH Grantees that expend \$500,000 or more within a year in Federal awards are subject to an audit requirement.

- Audits are due within the earlier of 30 days after receipt of the auditor's report(s) or 9 months after the end of the grantee's audit period.
- Grantees delinquent in submitting audits risk the imposition of sanctions and potential loss of Federal funds.

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Summary of Audit Requirements

Grantee Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	OMB Circular A-133 45 CFR Part 74.26	Online to: http://harvester.census.gov/fac/collect/ddeindex.html Questions: 1-800-253-0696
Colleges & Universities		
Non-Profits		
Hospitals		
For-Profits	45 CFR Part 74.26 (d)	HHS Office of Inspector General HHS Office of Audit Services National External Audit Review Center 1100 Walnut Street, Suite 850 Kansas City, MO 64106-2197 Phone: 800-732-0679/816-426-7720
Foreign	NIH GPS, uses 45 CFR Part 74.26(d)	(same as For-Profits)

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Closeout Final Reports

Grantees are strongly encouraged to submit closeout documents electronically through the eRA Commons!

- Failure to submit timely reports may affect future funding to the organization;
- Documents are due within 90 days of project period end date:
 - **Final Federal Financial Report (FFR) SF-425 Expenditure Data** (submitted through eRA Commons);
 - **Final Inventions Statement & Certification;**
 - **Final Progress Report;**
- Grantees must ensure there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FFR cash transaction data in the Payment Management System.

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Closeout NIH Centralized Processing Center

- **Centralized office accepts receipt of all non-financial, paper-based closeout documents;**
 - **Final Progress Report;**
 - **Final Invention Statement and Certification.**
- **If not using eRA Commons Closeout Module, mail closeout documents to the Central NIH unit at:**

NIH Centralized Processing Center
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail only)

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Non-Competing Continuation Progress Reports

- Failure to submit complete and timely progress reports may affect future funding to the organization;
- Non-SNAP annual progress reports are due two months prior to the anniversary date (paper submission);
- SNAP progress reports (e-SNAP) are due 45 days prior to the anniversary date (electronically submitted through eRA Commons eSNAP Module);
- All grantees have access to a searchable list to determine which progress reports are due at:
http://era.nih.gov/userreports/pr_due.cfm

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Requirements and Compliance Assistance for OHRP / OLAW

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Office for Human Research Protections (OHRP)

- **Mission:** Provide leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS);
- Provide clarification and guidance;
- Design educational programs and materials;
- Maintain regulatory oversight;
- Provide advice on ethical and regulatory issues in biomedical and behavioral research;
- Website revised and streamlined 1/2/11.

More at: <http://www.hhs.gov/ohrp>

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News from the Office for Human Research Protections

- **OHRP Posts New/Updated Guidance and Clarification:**
 - Revisions to Federalwide Assurance document and processes – 6/20/2011;
 - Guidance on Written IRB Procedures – updated 7/5/2011;
 - OHRP & FDA Draft Guidance on Exculpatory Language - 9/7/2011;
 - OHRP Correspondence on “Non-engaged” Scenarios – 9/22/2011;

More at: <http://www.hhs.gov/ohrp/newsroom/index.html>

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News from the Office for Human Research Protections (cont'd)

Advance Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule

In the July 25, 2011, Federal Register, HHS published an advance notice of a proposal to Improve Rules Protecting Human Research Subjects. HHS sought the public's input on an array of issues related to the ethics, safety, and oversight of human subjects.

- Seven specific significant reforms were proposed in the ANPRM along with a request for comments on more than 70 questions regarding various parts of the current regulations and proposed changes;
- To view the ANPRM and for more information see: <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>
- The comment period closed October 26, 2011.

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Office of Extramural Research Human Subjects Program

- **Mission:** Provide expert advice and leadership in the areas of policy development, evaluation and implementation for human subjects protection issues related to the NIH Extramural research programs;
- Help ensure the compliance of NIH grantees with Federal regulations regarding the protection of human subjects in research;
- Assess and approve resolution of human subjects concerns noted by NIH review groups for fundable applications;
- As a public service, the NIH Office of Extramural Research offers a free tutorial on [Protecting Human Research Participants](#). This training is also available in Spanish.

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Office of Laboratory Animal Welfare (OLAW)...

...provides guidance and interpretation of the PHS Policy, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported research.

New in 2012: The NIH has determined that it will adopt the 8th Edition of the *Guide for the Care and Use of Laboratory Animals* effective 1/1/12. In OLAW's judgment, the 8th Edition empowers continued advancement in the humane care and use of vertebrates in research, training, and testing. Assured institutions have until 12/31/12 to conduct at least 1 semiannual program review using the 8th Edition. Details on OLAW website.

More at: <http://grants.nih.gov/grants/olaw/2011positionstatement.htm>

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OLAW Educational Outreach

- FAQs at <http://grants.nih.gov/grants/olaw/faqs.htm>;
- OLAW online free quarterly webinars series:
 - OLAW Online <http://grants.nih.gov/grants/olaw/e-seminars.htm>;
 - Recordings of past webinars http://grants.nih.gov/grants/olaw/educational_resource_s.htm.



<http://olaw.nih.gov>

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Upcoming OLAW-supported Workshops

May 9-10, & Oct 3-4, 2012	Beltsville, MD	Meeting the Information Requirements of the Animal Welfare Act: A Workshop
Apr. 30, 2012	Baltimore, MD	SCAW IACUC Training
May 30-31, 2012	Denver, CO	IACUC Administrators' Best Practice Meeting
June 13-14, 2012	VA Beach, VA	IACUC 101/201 PLUS
Sept. 19-20, 2012	Baltimore, MD	IACUC 101/201 PLUS
Oct. 4, 2012	San Diego, CA	SCAW IACUC Training
Dec. 3-4, 2012	San Antonio, TX	SCAW 2012 Winter Conference

<http://grants.nih.gov/grants/olaw/workshop.htm>

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Update on Electronic Submission & eRA Commons

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Update on eRA Commons: LikeThis

A Thesaurus-Based Search Tool

LikeThis provides a powerful and integrated search tool in a user friendly interface. With the ability to find similar projects and publications, PIs can more quickly and efficiently:

- find out new ideas for research based on what NIH has awarded in the past;
- see what NIH is doing in his or her area of interest;
- use the information as a decision tool to determine if they need to come up with a fresh research idea;
- and figure out in which study section his or her application should be reviewed.

More at:

http://era.nih.gov/services_for_applicants/like_this/likethis.cfm

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Update on eRA Commons: Streamlining Delegations

- New Delegation Tab added to Commons;
- Found on the Admin tab after logging into eRA Commons;
- Allows scientists to delegate administrative tasks;
 - Status;
 - Progress Reporting;
 - Publications;
 - And More.
- SOs will be able to delegate authority from the *Delegate Progress Report* and *Delegate Sponsor* links on their *My Delegates* screen

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Update on eRA Commons: Password Reminder

•Password policy

- eRA Commons passwords now expire every 90 days;

- Change was *required* for compliance with security policies;

- Details of the password policy:

http://era.nih.gov/files/NIH_eRA_Password_Policy.pdf

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Tips for eSubmission Success

Remember to use the latest forms available for your funding opportunity announcement (FOA)

- Identify form version by Competition ID.
- Competition ID ADOBE-FORMS-B2 currently used for most new FOA postings
 - Older FOAs still use ADOBE-FORMS-B1.
 - B2 forms include: fix for modular budget issue, updated construction budget form and support for up to 30 subaward budgets.
- Fellowship, Training and a few other programs will continue to use ADOBE-FORMS-B1.

FAQs: http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#find1 73

Tips for eSubmission Success

• Register Early!

- Registration with both Grants.gov (organizations only) and eRA Commons (organizations & PD/PIs) must be completed before the submission deadline
- Allow 4 weeks to complete new registrations.

• Keep registrations active

- Central Contractor Registry (CCR) information must be updated at least every 12 months to remain active;
- As of August 2011, Grants.gov rejects submissions from applicants with expired CCR;
 - Use your organization's DUNS to view your CCR registration status at <http://www.bpn.gov/CCRSearch/Search.aspx>

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Tips for eSubmission Success

• Carefully follow the specific guidelines found in the Application Guide and the Funding Opportunity Announcement (FOA)

- Instructions in the FOA trump those found in the Application Guide;

• Check your application for common errors before you submit

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm.

• Submit early!

- Think days, not hours or minutes before deadline.

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Tips for eSubmission Success

- **Correct any errors **before** the application due date**
 - If errors are found in the submission process, you must submit a changed/corrected application before the submission deadline.
- **View your application in Commons**
 - YOU are responsible for verifying that your error-free application is viewable in the eRA Commons and correctly reflects your submission.
 - If you can't VIEW it, NIH can't REVIEW it!
- **Remember, NIH eliminated the 5-day grace period for receipt of letters for reference for Ks (as of 6/1/2011) and Fs (as of 4/08/2011)**
 - Letters of reference are due by the application due date.

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Electronic Post Award Administration

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Use of xTrain Required

- xTrain required to prepare and submit appointments (PHS 2271) and terminations notices (PHS 416-7) for research training grants, institutional career development awards, individual fellowships, and research education awards;
- A new role of "Sponsor," similar to PD/PI role, exists for termination of fellowships;
- See xTrain overview presentations, FAQs and quick reference sheets.
 - New resources can be found at: http://era.nih.gov/training_career/index.cfm

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Electronic Administrative Supplements

- Electronic submission of admin supplement pilot began February 1, 2012.
 - Optional for all single project grantees
 - Complex, multi-project grants not included in pilot;
 - Parent FOA PA-12-100 used for submission
 - Can submit through the eRA Commons
 - To take advantage of pre-population of fields;
 - OR
 - Can submit through Grants.gov
 - For schools who have built systems to interact directly with Grants.gov.
- Contact IC or review IC web site before submitting.

See: [NOT-OD-12-024](#)

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Electronic Submission for Organization Changes

- An electronic business process for post-award Change of Grantee Institution (T-7s) and Successor-in-Interest (T-6) applications
 - April 2012 pilot
 - Restricted to post award actions
- Process:**
1. Old institution submits relinquishing statement through the Commons.
 2. New institution receives notification of relinquishing statement from the Commons.
 - Open to all institutions
 3. New institution submits application through Grants.gov
 - Uses new change of grantee application parent FOA
 - Available for applications currently submitted through Grants.gov
 - Selects appropriate application package from parent FOA for the activity code

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Electronic Submission for Organization Changes (cont'd)

- An electronic tool for applications routinely submitted on paper;
- Paper-based process still allowable
- Grantees should discuss potential organization changes with the awarding IC prior to submitting application

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Upcoming Just-In-Time Changes

Effective April 20, 2012

- Opening link broadly for all; decoupling this from any impact score/percentile;
- Modifying eRA-generated eNotifications to tighten up for which applications these will be sent.
- Mandating Use.

More at: [NOT-OD-12-101](#)
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2012 NIH Regional Seminars for administrators and researchers new to NIH

- April 16-18, 2012 – Indianapolis, Indiana
- June 20-22, 2012 – Washington, DC (Registration Now Open);
- Faculty: NIH policy officials, grants management, program and review staff, eRA Commons trainers, OHRP, OLAW
- * Optional NIH eRA computer workshops are offered the day prior to the 2-day seminar. These ½ day workshops are designed for administrators and investigators, providing attendees with hands-on experience utilizing the eRA Commons and the overall electronic grants process.

More at: [NOT-OD-12-040](#)
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Helpful NIH Resources

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Frequently Asked Questions

- **FAQs include questions about:**
 - Application/progress report preparation, funding initiatives, policies, human subjects, animals, disaster response, etc...
http://grants.nih.gov/grants/frequent_questions.htm
 - NIH Salary Cap in FY 2012
http://grants.nih.gov/grants/policy/fy2012_salary_cap_fags.htm
 - Key word search

More at: http://grants.nih.gov/grants/frequent_questions.htm 85

Tools to Search NIH Funding

- **Research Portfolio Online Reporting Tools (RePORT) <http://report.nih.gov>**
 - Provides access to reports, data and analysis of NIH research activities, including ARRA-specific data queries, and more;
 - Quick links to "Frequently Requested Reports," FAQs.
- **RePORT EXPENDITURES & RESULTS (RePORTER) <http://projectreporter.nih.gov/reporter.cfm>**
 - Tool used to search information from NIH project databases and funding records, PubMed abstracts and full-text articles, and invention reporting (iEdison, Interagency Edison);
 - Replaces CRISP.

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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 Grants Policy Statement (Rev. 10/11)**
http://grants.nih.gov/grants/policy/nihgps_2011/index.htm
- **NIH Extramural Nexus – newsletter for the extramural community**
<http://nexus.od.nih.gov/all/nexus-by-date/>
- **Rock Talk**
<http://nexus.od.nih.gov/all/rock-talk/>
- **Grant Application Basics**
http://grants.nih.gov/grants/grant_basics.htm

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Summary of Helpful NIH Web Pages

- **Applying Electronically**
<http://grants.nih.gov/grants/ElectronicReceipt/index.htm>
- **Annotated SF424 (R&R) Application Forms (General and Small Business)**
<http://grants.nih.gov/grants/ElectronicReceipt/communication.htm#forms>
- **Ten Checks to Help Avoid Common Application Errors**
http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm#10checks
- **Do I have the right electronic forms for my NIH application?**
http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf

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Summary of Helpful NIH Web Pages

- **NIH Extramural Response to Natural Disasters**
http://grants.nih.gov/grants/natural_disasters.htm
- **eRA Commons Web pages**
<http://era.nih.gov/>
- **Updated (8-6-2010) eSNAP User Guide**
http://era.nih.gov/docs/eSNAP_UG_v2.25.0.0_041210.pdf
- **Updated (1-24-2012) Commons User Guide**
http://era.nih.gov/Docs/COM_UGV2630.pdf
- **Self Help Resources page:**
http://era.nih.gov/help/self_help.cfm
- **Intellectual Property Policy**
<http://grants.nih.gov/grants/intell-property.htm>

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NIH OER Listservs

- **NIH Guide for Grants and Contracts:**
 - Official publication for NIH Grant Policies, Guidelines & Funding Opportunities
 - <http://grants.nih.gov/grants/guide/listserv.htm>
- **Office for Human Research Protections (OHRP):**
 - <http://www.hhs.gov/ohrp/>
- **Office of Laboratory Animal Welfare (OLAW):**
 - <http://grants.nih.gov/grants/olaw/references/list.htm>
- **eSubmission:**
 - Separate listservs available for scientists and administrators
 - <http://era.nih.gov/ElectronicReceipt/listserv.htm>

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**Grants Information:
Who to Contact**

- **General Application Questions:**
 - E-Mail: GrantsInfo@nih.gov
 - Phone: 301-435-0714
- **Grants.gov Customer Support:**
 - E-Mail: support@grants.gov
 - Webpage: <http://grants.gov/>
 - Phone: 800-518-4726
- **eRA Commons Helpdesk:**
 - Webpage: <http://ithelpdesk.nih.gov/era/>
 - Phone: 301-402-7469 or 800-504-9552

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**Grants Information:
Who to Contact (cont'd)**

- **Division of Grants Policy:**
 - E-Mail: GrantsPolicy@mail.nih.gov
 - Phone: 301-435-0949
- **Division of Grants Compliance & Oversight:**
 - E-Mail: GrantsCompliance@mail.nih.gov
 - Phone: 301-435-0949

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Thank You!

Any Questions?

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