National Institute of General Medical Sciences

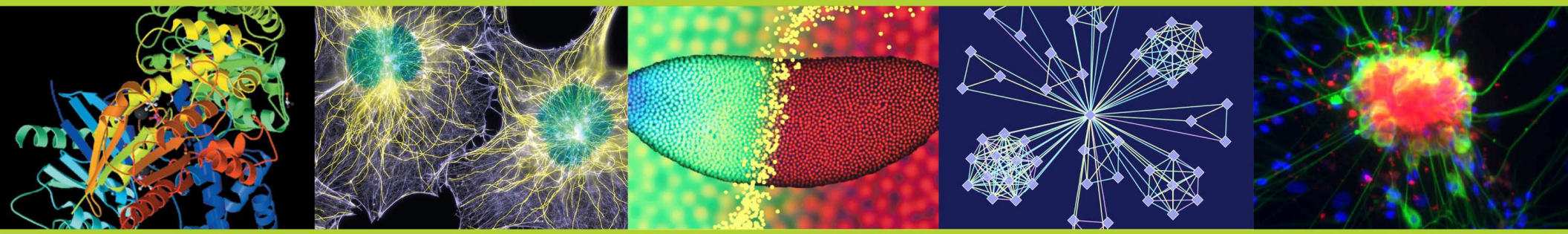
IDeA Post Award Management

Andrea Culhane

Grants Management Specialist

Grants Administration Branch

National Institute of General Medical Sciences, NIH



IDeA Post Award Management

- IDeA Policy Reminders
- Questionable Costs
- Prior Approvals
- Administrative Supplements
- Annual Performance Reporting Requirements
- NIH Updates and Policy Reminders

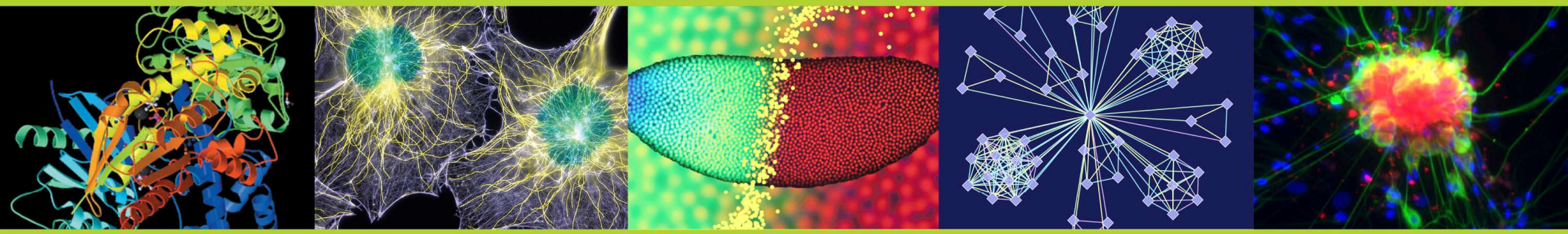
IDeA Policy Reminders

- Research Project Leaders (RPLs) and Pilot Project Leaders (PPLs) may not receive simultaneous research or pilot project support from the same or other IDeA grants.
- COBRE, INBRE, and IDeA-CTR PIs may not receive any research support from any COBRE, INBRE, or IDeA-CTR program.
- No IDeA grant funds awarded to an IDeA-eligible institution may be transferred via subcontract to a consortium partner institution in a non-IDeA state.
- IDeA funds may be used in other IDeA and non-IDeA states for fee-for-service type of activities that include activities associated with collaborative projects, research education and training, sample and data analysis, workshops, etc.

Questionable Costs

- **Honorarium** – unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium; a payment for services rendered is allowable
- **Stipends** – only allowable on training grants; unallowable on IDeA grants; "Compensation of Students" is allowable
- **Housing** – not allowable on NIH grants; Travel costs are okay
- **General Supplies** – only costs directly related to the grant and/or project are allowable as direct costs
- **Meals/Food** – only allowable as part of meeting necessary for disseminating information; must be consistently treated and reasonable; grantee must have a written meal policy in place
- **Scholarships** – not allowable on NIH grants
- **Costs with Poor Justification** – not including adequate detail or using confusing terms in the budget justification narrative

Prior Approvals



NIH Perspective

A few things to remember…

- We must support federal policy, to enforce applicable laws, cost principles and administrative requirements
- We must act as stewards of federal funds
- Some IC's have a relatively broad mission; others are (by comparison) relatively narrow
- The correct answer often really is... "it depends"

NIH Perspective

- Have we "listened" enough to really understand all the issues and objectives of the situation?
- What is in the best interest of the science?
- What will best serve the investment of the taxpayer in the project?
- Do we have the necessary funds to support the proposed arrangements?
- How would this play if presented on the evening news or the front page of .....?
- Is there an opportunity for a 'win/win'?
- Can we get to a "yes"

Prior Approvals

NIH Grants Policy Statement Sections

- 8.1 Changes in Project and Budget
  https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm
- 8.1.1 NIH Standard Terms of Award
  https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.1_nih_standard_terms_of_award.htm
- 8.1.2 Prior Approval Requirements
  https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.2_prior_approval_requirements.htm
- 8.1.3 Requests for Prior Approval
  https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.3_requests_for_prior_approval.htm

Requests for Prior Approval

- Requests for actions that require prior approval must be submitted by an Authorized Organization Representative (AOR) to the NIGMS Grants Management Specialist and Program Officer no later than 30 days **before** the proposed change
- Prior approval requests can be sent via email, or for the following three types of prior approval requests, electronically through eRA Commons in the Prior Approval Module:
  - *Prior Approval Request for Change of PD/PI*
  - *Prior Approval Request for No Cost Extension (NCE)*
  - *Prior Approval Request for Carryover*
- NIGMS tries to respond to all prior approval requests within 30 days of receiving all necessary information from the grantee

If you aren't sure if prior approval is needed…

- Consult the following information sources **before** implementing the change or requesting prior approval:
  - Check the NIH Grants Policy Statement on Prior Approvals
  - Ask your Sponsored Programs Office / AOR
  - Ask your Program Officer
  - Ask your Grants Management Specialist

Prior Approvals

The following are some Prior Approvals frequently requested for IDeA grants:

- Carryover of Unobligated Balances
- Change of Key Personnel
- Change of Scope
- Addition of new research projects and changes to currently approved research projects
- Addition of new pilot projects and changes to currently approved pilot projects

Carryover of Unobligated Balances

- IDeA grants do NOT have automatic carryover
- Prior approval is required to use unobligated funds from a previous budget period during the current budget period
- Carryover is not guaranteed or needed every year
- Carryover requests must be for immediate needs that cannot be supported by rebudgeting funds from the current budget period

Carryover or Rebudget?

- Budget flexibility to rebudget within components AND across components.
- Underspent this year? Need additional funds within scope? REBUDGET!
- No extra funds this year? Need additional funds for an additional one-time expense like equipment or supplies? CARRYOVER!
- Previous year funds don't immediately disappear. You may not need carryover in Year 2 or Year 3 but do in Year 4. In this instance, WAIT! and request carryover in Year 4 from the cumulative balance available in the year 3 FFR.

Carryover Requests

A carryover request should include the following:

- Explanation of why there is an unobligated balance
- Justification of why carryover funds are needed in the current year. Confirmation all current year funds will be spent and can't be rebudgeted to meet current needs.
- If the request will generate recurring costs in future years, an explanation of how costs will be supported without future use of unobligated balances or new supplemental funding
- Summary Budget page (PHS398 or SF424)
- Budget and justification pages (PHS398 or SF424), for each component, including any subcontract sites.
- Summary Checklist page (PHS398 or SF424) for F&A costs
- Appropriate Just In Time (JIT) documents (e.g., biosketches for new key personnel, other support, human subjects education certification)
- Equipment quotes, if appropriate

Reasons Why Carryover Requests are Delayed or Rejected

- The Federal Financial Report (FFR) has not been received and approved by NIH
- The request was not signed by or sent through an Authorized Organization Representative (AOR)
- History of underspending
- Inadequate justification for carryover funds rather than rebudgeting current funds
- Requested costs duplicate costs in the current year's award
- Carryover request includes recurring costs in future years
- Unallowable costs were included
- Use of the carryover funds are not within the currently approved scope of the grant
- Carryover funds does not reflect immediate needs (Ex: TBD staff, TBD pilots)
- No plan to show funds can be spent in the budget period they are requested

Change of Key Personnel

- Prior approval is required for the following changes regarding the PI and any Key Personnel named on the Notice of Award:
  - Reduction in effort of 25% or more of the originally approved effort level
  - Reduction in effort that would bring the person below the required minimum effort level
  - Withdrawal from the project entirely
  - Be absent 3 months or more
  - Replacement of Key Personnel

If a Research Project Leader (RPL) is leaving and a replacement RPL has not been identified, you have to request the removal of the RPL who is leaving. You do NOT wait until you have a replacement RPL ready.

Change of Key Personnel

A request for changes to key personnel must include:

- The reason for the request (leaving/joining/replacing)
- Justification for selection of the person
- Level of effort and duties to be performed
- Explanation of any changes to the budget or scope of the grant
- Biographical sketch for new person
- Updated other support for new person
- Human subjects education certification (if applicable)
- Statement regarding any concerns related to safety and/or work environment – see NIH GPS: 8.1.2 Prior Approval Requirements (nih.gov)

Scope in NIH Grants

- Scope is the direction, aims, objectives, purposes, or type of research training, identified in the project
- Stated/identified in the original, peer-reviewed application
- Is the basis for which the budget is requested and awarded
- Unless negotiated otherwise, is approved with the award

Change of Scope

- As stated in the NIH Grants Policy Statement, section 8.1.2.5, a change in scope requires NIH prior approval

  In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope.

- It is the grant recipient's responsibility to initially assess whether a plan will result in a change in scope that requires approval
- Change in Scope is a change in direction, type of training, or other area that constitutes a significant change from the aims, objectives, or purpose of the originally approved project
- A change of scope always requires prior approval

Change of Scope

Potential indicators of a change in scope:

- Change in the specific aims approved at the time of award
- Change from the approved involvement of human subjects
- Change from the approved involvement of human subjects that would result in an increased risk (which has a number of situations!)
- Change from the approved use of live vertebrate animals
- Substitution of one animal model for another
- Shifting research emphasis from one disease area to another
- Applying a new technology; i.e., changing assays from those approved to a different type of assay
- Transfer of performance of substantive programmatic work to a third party
- Change in other senior/key personnel not specifically named in the NoA
- Significant rebudgeting of 25% or more in a single direct cost budget category
- Purchase of a unit of equipment exceeding $25,000

Changes of Human Subjects and Vertebrate Animals Involvement

- Changes of human and vertebrate animal involvement are usually a change of scope and therefore require prior approval
- For IDeA grants, changes to human subjects and vertebrate animals involvement are usually due to research and pilot projects
- The required prior approval items for both human subjects and vertebrate animals are submitted as part of the prior approval request for research and pilot projects
- The enrollment table for projects involving human subjects/clinical trial must be submitted in the Human Subjects System (HSS).

IDeA Research and Pilot Projects

Official approval from NIGMS is required prior to the commencement of any new research project or pilot project

- COBRE I and II: research and pilot projects
- COBRE III and IDeA-CTR: pilot projects only
- INBRE: research and pilot projects

*NOTE: new research and pilot projects that require prior approval are not eligible for pre-award costs as they must be approved PRIOR to expenditure of funds for these projects

Addition of Research Projects – COBRE I and II

Prior to the commencement of any new research project, the following documentation must be submitted to NIGMS staff:

- Research project proposal. Using PHS398 forms and instructions, only the following sections have to be submitted:
  - Face Page
  - Project Summary (Page 2)
  - Research Strategy Section
- External Advisory Committee (EAC) or Advisory Committee (AC) approval approval - communication from the EAC/AC chair (at a minimum) indicating that the EAC/AC concurs with supporting the research project
- An institutional letter of support from a Dean or higher official outlining the faculty appointment of the research project PI and support for his/her research program (check parent grant FOA for applicability)
- Biographical Sketch of Research Project Leader
- Updated other support of Research Project Leader
- Detailed Budget with justification
- Checklist Format Page with F&A cost breakdown
- Human Subjects and Clinical Trials Information Form (using the current FORMS version at time of submission), IRB approval, documentation of the human subjects education for those involved in the design and conduct of human subjects research and creation of new enrollment report in HSS (if applicable)
- IACUC approval and Vertebrate Animal Section (if applicable)

Addition of Pilot Projects – COBRE I, II, III, and IDeA-CTR

Prior to the commencement of any pilot project, the following documentation must be submitted to NIGMS staff:

- Pilot project proposal. Using PHS398 forms and instructions, only the following sections have to be submitted:
  - Face Page
  - Project Summary (Page 2)
  - Research Strategy Section
- Biographical Sketch for Pilot Project Leader (PPL)
- External Advisory Committee (EAC) or Advisory Committee (AC) approval - communication from the EAC/AC chair (at a minimum) indicating that the EAC/AC concurs with supporting the pilot project.
- Human Subjects and Clinical Trials Information Form (using the current FORMS version at time of submission), IRB approval, documentation of the human subjects education for those involved in the design and conduct of human subjects research and creation of new enrollment report in HSS (if applicable)
- IACUC approval and Vertebrate Animal Section (if applicable)

Addition of Research and Pilot Projects – INBRE

UPDATE

Effective February 14, 2023, developmental research projects and pilot projects that **do not** involve HS or VA research will only require official notification to NIGMS with appropriate documentation at least 14 calendar days before the projects begin. Prior approval by NIGMS is no longer required to initiate these projects.

Addition of Research and Pilot Projects – INBRE

INBRE developmental research projects and pilot projects **that DO NOT involve human subjects or vertebrate animals research** will require official notification:

- E-mail from AOR to GMS, PO and NIGMS Post Award Projects
- Addendum

- AOR will receive a confirmation from NIGMS that the required documentation was received. If the AOR is not contacted by NIGMS for additional information within 14 calendar days after submission, the developmental research project or pilot project may start.
- If the AOR is contacted by NIGMS for additional information, the project may not start until NIGMS receives the additional information.

This change applies to Developmental Research Projects and Pilot Projects for all the INBRE FOAs: PAR-23-100; PAR-20-102; PAR-18-262; and PAR-17-160.

Addition of Research and Pilot Projects – INBRE

INBRE developmental research projects and pilot projects **that involve human subjects or vertebrate animals research** will continue to require NIGMS prior approval before the projects can begin, the following documentation must be submitted to NIGMS staff:

- Developmental Research Project/Pilot Project proposal. Using PHS398 forms and instructions, only the following sections have to be submitted:
  - Face Page
  - Project Summary (Page 2)
  - Research Strategy Section
- EAC/AC External Advisory Committee (EAC) or Advisory Committee (AC) approval - communication from the EAC chair (at a minimum) indicating that the EAC/AC concurs with supporting the developmental research project/pilot project.
- Human Subjects and Clinical Trials Information Form (using the current FORMS version at time of submission), IRB approval, documentation of the human subjects education for those involved in the design and conduct of human subjects research and creation of new enrollment report in HSS (if applicable)
- IACUC approval and Vertebrate Animal Section (if applicable)

Clinical Trials

- If there is a research or pilot project on an IDeA award that proposes a clinical trial, additional information and documentation will be required when it is submitted for prior approval to NIGMS
- Terms specific to each clinical trial will be included on the NoA
- It is critically important to ensure all regulatory requirements of clinical trials are met.
  - NOT-OD-16-149: All NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will ensure that their NIH-funded clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting
  - NOT-OD-19-050: For NIH-funded or supported clinical trials, informed consent documents must be posted on a public federal website after recruitment closes and no later than 60 days after the last study visit

When Prior Approval is Not Needed

Changes to the Budget

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, **unless the incurrence of costs is associated with or is considered to be a change in scope.**

- Incur pre-award cost up to 90 days before the beginning date of the initial budget period of a competing or non-competing award
- Initiate a one-time extension of the final budget period of a previously approved project period without additional funds (a.k.a First No-Cost Extension)
- Rebudget among budget categories
- Rebudget between direct and F&A costs
- Add, change, or remove a domestic consortia site
- Provide subawards based on fixed amounts, provided that the subawards meet the requirements for fixed amount awards in 45 CFR 75.201

When Prior Approval is Not Needed

8.1.2.5 Change of Scope section of the NIH GPS includes a list of **potential** indicators of a change in scope

- Transfer of the performance of substantive programmatic work to a (domestic) third party through a consortium agreement, by contract, or any other means
- Change in other senior/key personnel not specifically named in the NoA
- Significant rebudgeting, whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded (does not apply to modular grants)
- Purchase of a unit of equipment exceeding $25,000

If there is no change of scope, then prior approval is NOT required

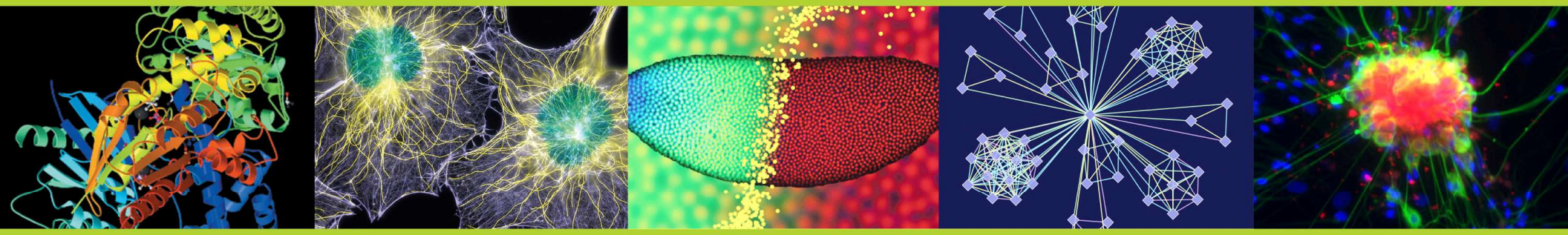
When Prior Approval is Not Needed

Level of Effort Changes do not require prior approval if:

- The personnel are not named on the Notice of Award
- The personnel are not required to maintain a minimum level of effort (e.g. Pilot Project PIs)
- The departure or addition of personnel does not result in a change of scope

You don’t need prior approval for these changes but you should report on those changes in the RPPR.

Administrative Supplements



Administrative Supplements

An administrative supplement is a non-competing award that provides additional funding to a currently funded grant to meet increased costs that are within the scope of the approved project, but that were unforeseen when the new or competing renewal application was awarded.

There are ongoing administrative supplement opportunities as well as short term opportunities that are announced via a Notice of Special Interest (NOSI).

Requirements for Submitting

- Submit a request for supplemental funding before the awarded grant expires.
- Consult with the NIH grants management officer and program official assigned to your award before submitting a request for an administrative supplement.
- Review the awarding institute and center's (IC) web site for any IC-specific submission deadlines or eligibility criteria before submitting an administrative supplement request.
- Identify an appropriate funding opportunity by searching the NIH Guide to Grants and Contracts. Using the advanced search feature, use the activity code field and select "Admin Supp" (activity code will show as "333").
- Find the application package linked from the funding opportunity that is appropriate for the parent award.
- Complete all required fields in the application package that you would for a competing revision (including an Introduction) unless the funding opportunity specifies otherwise.
- Provide additional information justifying the supplemental dollars as described in the funding opportunity.

Budget Considerations

- Administrative Supplements will fall within the current budget period of the parent grant
- Any costs requested (personnel, supplies, other expenses) must fit within the budget period of the parent grant
- Provide adequate justification for new funds rather than utilizing available unobligated balance
- Review the NOFO carefully for budget guidance

Budget Considerations

If your parent grant's budget period is 4/1/23 – 3/31/24:

1. No matter when the supplement application is submitted, the supplement budget will end on 3/31/24
2. Calculate the start date of the supplement application based on the due date supplied in the NOSI
3. Do not request personnel costs that will extend beyond the budget period end date of the parent grant
4. Ensure the budget justifications are clear that no costs will extend past the parent budget period

Supplement Reporting

Progress on all supplements is required for the first year when the supplement was awarded, and any following year when the supplement's research activities continue into the next funding period.

Report progress in Section B.3 Competitive Revisions/Administrative Supplements - include information on scientific accomplishments and any related grants submitted/awarded

Use Section C to report publications and other products.

Supplement FAQs

What happens if my supplement isn't done by the end of the budget period?

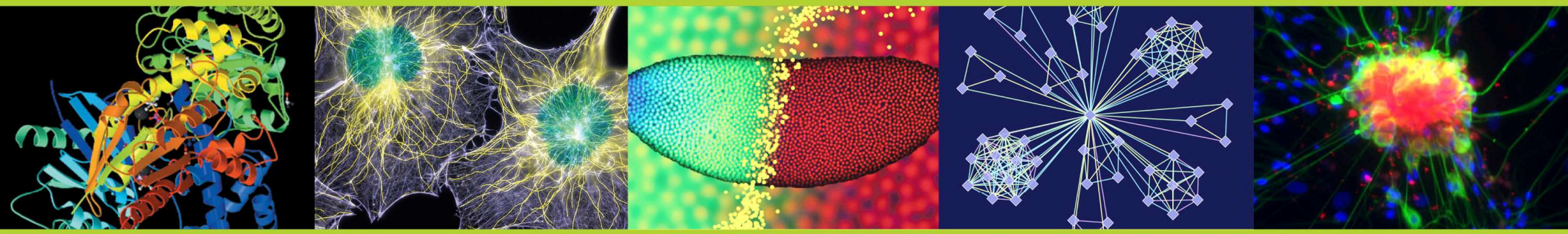
- Administrative supplements are within the scope of the parent grant – therefore you may continue the supplement activity into the next budget period if additional time is necessary
- The supplement will not be extended but parent grant funds can be rebudgeted to cover the activity
- Any unobligated funds from the supplement will be reported on the parent grant's FFR and will be available to request for carryover in later budget periods

Supplement FAQs

What happens if I have an unobligated balance larger than 25% and apply for an administrative supplement?

- It depends on the justification provided for the need for new funds rather than rebudgeting available funds
- Based on the amount of available unobligated balance:
  - The administrative supplement request could be funded partially with carryover and partially we new funds via an administrative supplement award
  - The administrative supplement request could be funded via a revised NoA that authorizes the use of unobligated funds via a carryover for the entire amount of the administrative supplement

Annual Performance Reporting Requirements



Annual Performance Reporting Requirements

Research Performance Progress Report (RPPR)

- Annual progress reports for non-SNAPs are due two months (60 days) prior to the cycle date
- Failure to submit complete and timely progress reports may affect future funding to the organization
- Grantees may access a list of progress reports that are due by using
  - The Status page in eRA Commons, and selecting the Tab "List of Applications/Grants"
  - Enter your IPF number on this site - https://public.era.nih.gov/chl/public/search/progressReportByIpf.era

Annual Performance Reporting Requirements

Research Performance Progress Report (RPPR)

- Must include the overall section and separate components for each core and research project
- Pilot project reporting can either be done in individual components or as part of the narrative of the administrative core – see parent grant FOA for instructions
- Each component in the RPPR
  - Reports on the progress of that particular core, research project, or pilot project (as applicable) during the current budget period
  - Requests funds to be used during the next budget period
    - If you are only reporting progress because the research or pilot project has ended, you do not include a budget for that component
- Decimals in Effort Reporting

RPPR Instructions Section 7.6 Multi-Project RPPRs:
https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf

Annual Performance Reporting Requirements

****UPDATE****

Per NOT-GM-23-046, effective October 1, 2023, Supplemental Annual Reports through the Scientific Information Reporting System (SIRS) is no longer required

eRA Human Subjects Systems (HSS)

The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects and clinical trials to NIH; and for NIH agency staff to monitor and manage the data.

- Automatically populated by data entered by the PI on the *Human Subjects and Clinical Trial Information* form in applications submitted for due dates of January 25, 2018 and beyond
- All inclusion records migrated to the HSS module on June 9, 2018

System Access:

- *Human Subjects* link in the *Status* section of eRA Commons
- *Human Subjects* link in the *RPPR* section of eRA Commons

eRA Human Subjects Systems (HSS)

- Add/update study information
- Create new enrollment reports or view/edit/update existing enrollment data
- Make off-cycle corrections or updates after application or Research Performance Progress Report (RPPR) submission
- Convert a delayed onset study to a full study record, once detailed study information is available
- Provide interim data as requested by NIH staff, in the funding opportunity announcement, or in the terms and conditions of award
- Inform NIH of ClinicalTrials.gov registration
- Export Human Subjects/Clinical Trial (HSCT) study records in XML format and upload to ClinicalTrials.gov.

eRA Human Subjects Systems (HSS)

- Check your records!
  - Ensure everything matches up
- NIH has a great resources out there!
  - https://era.nih.gov/files/HSS_user_guide.pdf
  - Participant-Level Data Template Tip Sheet
  - HSS Error and Warning - PI and SO Quick Guide
- Best advice...remember to populate HSS with what you have in CT.gov before you submit the RPPR (see p.17 of the User Guide)
- IMPORTANT!!!! It is critical that the registration in CT.gov is done in compliance with the regulations!

Invention Reporting

- NIH recipients must file the HHS 568 at the conclusion of an NIH competitive award segment
- All subject inventions reported on the HHS 568 must be reported in iEdison.
- Failure to report all inventions may result in your organization's loss of rights in the invention or other actions as appropriate.

- See NOT-OD-16-066 and NIH Intellectual Property Policy

iEdison Transitioned from NIH eRA to NIST

Management of the iEdison system has transitioned from the NIH eRA to the National Institute of Standards and Technology (NIST), U.S. Dept. of Commerce (DOC). The new iEdison by NIST was launched August 9, 2022.

The transition included several new capabilities and enhancements, including:

- Ability to initiate discussions with the agency staff within an invention record using two-way communications.
- Integration with the U.S. Patent and Trademark Office (USPTO) database to ensure accuracy and reduce recipient reporting burden.
- Optional real-time email notifications to both recipient and agency users for notifications regarding certain required reporting and reviewing actions.
- Enhanced security through Login.gov.

All existing data and any attachments associated with individual invention and patent reports has been transferred to the new iEdison system. In addition, existing and active iEdison accounts have been associated with the new system.

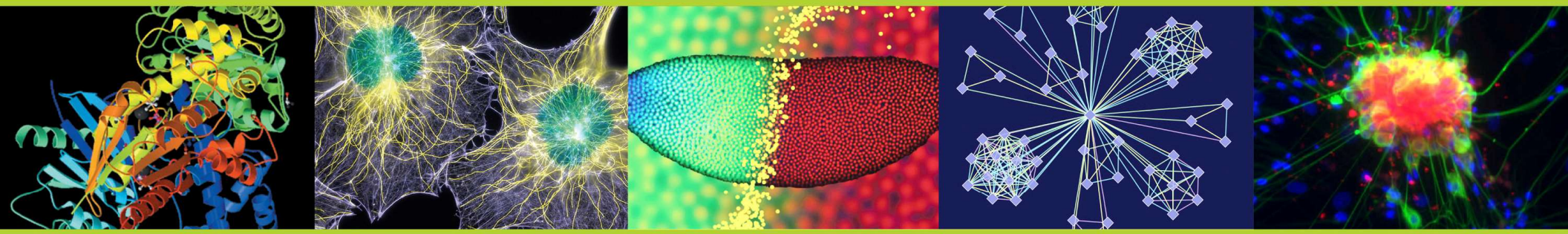
Reminder: There will be **no** changes to the longstanding NIH requirements for invention and patent reporting under the Bayh-Dole Act. The only change is the new iEdison system interface and associated Login.gov requirements for access.

See NOT-OD-22-100 and NOT-OD-22-158

Closeout Requirements

- NIH continues to require and enforce longstanding closeout requirements.
- Recipients must submit timely, accurate closeout reports
- Reports are LATE after 120 calendar days
- Recipients are required to electronically submit the final FFR through the Payment Management System
- There must be no discrepancies between the Federal share of expenditures reported on the final FFR and the net cash disbursements reported in PMS on the Transactions section of the FFR. It is the recipient's responsibility to reconcile reports **prior** to submission to PMS and to the NIH awarding IC
- When recipients fail to submit timely reports, NIH will initiate unilateral closeout.

NIH Updates & Policy Reminders



Budget News & Fiscal Policy Updates

- On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (Public Law 117-328), into law.
- NIH has issued several important fiscal policy Guide Notices:
  - NOT-OD-23-071: Notice of Fiscal Policies in Effect for FY 2023
  - NOT-OD-23-056: FY 2023 Salary Cap ($212,100)
    - Increased salary limitations for NIH grants and cooperative agreements and extramural research and development contract awards.
  - NOT-OD-23-072: Notice of Legislative Mandates in Effect for FY 2023
  - NOT-OD-23-076: NRSA Stipend Levels for FY 2023

Expiration of the COVID-19 Public Health Emergency

- NOT-OD-23-095: the HHS declared public health emergency for COVID-19 was terminated on May 11, 2023.
- Effective May 12, 2023, NIH will no longer issue Emergency Notices of Funding Opportunity (NOFOs) related to COVID-19.
- Ongoing emergency awards will not be impacted and will retain all existing emergency flexibilities for the remainder of the current competitive segment.
- NOT-OD-23-097: NIH will no longer be able to grant single IRB (sIRB) exceptions for multi-site research that is subject to the revised Common Rule cooperative research provision under the Office for Human Research Protections (OHRP) Determination of "Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

New Data Management and Sharing Policy

- See: NOT-OD-21-013 and NOT-OD-23-053
- Effective for competing grant applications submitted January 25, 2023 and later, the DMS Policy will require researchers to prospectively plan for how scientific data will be preserved and shared through submission of a DMS Plan (replaces 2003 Data Sharing Policy).
- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.
- The DMS Policy requires:
  - Submission of a DMS Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations
  - Compliance with the awardee's plan as approved by the NIH Institute and Center (IC).

NIH Data Management and Sharing Policy

- DMS Plans should describe how data will be managed and appropriately shared. See Writing a Data Management & Sharing Plan for details, sample Plans, and an optional format page which includes six elements recommended to be included in a Data Management and Sharing Plan. Guidance on planning and budgeting and selecting a data repository are available on the NIH Scientific Data Sharing website. Application Guide instructions have been updated to provide instructions for DMS policy implementation.
- Ultimately, the new DMS Policy promotes transparency and accountability in research by setting a minimum set of expectations for data management and sharing. This means that other NIH policies or NIH Institutes, Centers, Offices, or programs may build upon these expectations, for instance, by specifying scientific data to share, relevant standards, repository timelines, and/or shorter data sharing timelines for meeting programmatic needs, the DMS Policy sets a consistent baseline across NIH.
- In preparing for DMS Policy implementation, NIH has developed a number of helpful resources that we encourage investigators and institutions to review:
  - DMS Policy Overview
  - DMS Policy FAQs
  - Learning Resources including 2-part webinar series on DMS Policy
  - Statements and Guide Notices

Update – Process for Requesting Drawdowns Outside of the Liquidation Period

- NOT-OD-23-086
- Recipients must submit timely, accurate grant expenditure reports, and reconcile cash transaction reports submitted to the PMS with expenditure reports submitted to NIH.
- Recipients may request payments from the Payment Management System (PMS) up to 120 days past the period of performance end date of the PMS subaccount.
  - This is only for PMS subaccounts that are in Open or Pending Closed Status.
  - NIH will only consider late draw requests on closed PMS documents if they are related to a public health emergency, natural disaster, or similar event.

Update – Process for Requesting Drawdowns Outside of the Liquidation Period

- In circumstances where recipients are unable to complete drawdowns in a timely manner, the recipient must submit a prior approval request to the IC GMS **BEFORE** to submitting the payment request in PMS.
  - The request must provide the PMS subaccount (e.g. award document number), NIH grant number, the amount of funds being requested, and a justification for the late payment request. The recipient must also describe what action is being taken by the recipient to preclude similar situations in the future.
  - The IC will review the request and if it is determined that the justification is adequate, will notify the recipient of the approval. Once approved, the recipient may submit the payment request in PMS.
- Requests will be reviewed and considered on a case-by-case basis. Recipients remain responsible for ensuring that information submitted to NIH in Federal Financial Reports (FFR) is accurate, complete, and consistent with the recipient's accounting system (see NIHGPS Section 8.4.1.5.2). When submitting the FFR through PMS, the Authorized Organization Representative (AOR) or the individual designated to submit this report on behalf of their institution, certifies that the information in the FFR is correct and complete and that all outlays and obligations are for the purposes set forth in grant documents, and represents a claim to the Federal government.

NIH Forms

NOT-OD-23-012: NIH "FORMS-H" Grant Application Instructions Available for Due Dates On or After 01/25/2023

- **For NIH,** as part of the implementation of the 2023 NIH Data Management and Sharing (DMS) Policy, a new “Other Plan(s)” attachment field has been added to the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form. Applicants must attach the required Data Management and Sharing Plan in this new field in FORMS-H applications. See NOT-OD-21-013 and NOT-OD-22-189 for more information

Make sure you use the current forms for applications and post award requests.

On or after January 25, 2023, including: • Applications submitted for due dates on or after January 25, 2023 • All application types (New, Resubmission, Renewal, Revision) • Applications submitted early for intended due dates on or after January 25, 2023	FORMS-H application package

Financial Conflict of Interest (FCOI) and Other Support (NOT-OD-22-210)

- Per the FCOI regulation (42 CFR Part 50 Subpart F) the following requirements are in place for recipient institutions:
  - Develop a FCOI policy
  - Post the FCOI policy on their website and submit it to NIH
  - Ensure Investigator disclosure of both foreign and domestic Significant Financial Interests (SFI)
  - Report any FCOIs to NIH
  - Train Investigators on FCOI requirements
- Complete and accurate Other Support information must be submitted per NOT-OD-21-073 and NOT-OD-21-110

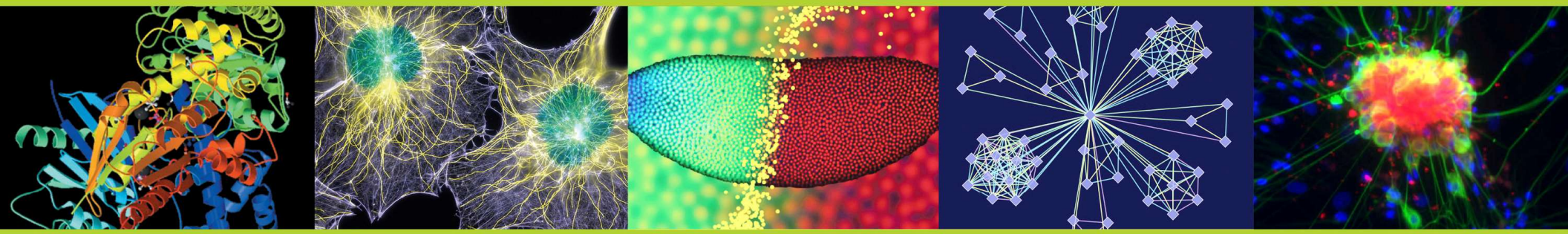
Implementation of Changes to the Biographical Sketch and Other Support Format Page

- NIH requires applicants and recipients to use the updated Biosketch and Other Support format for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs).
  - Effective January 25, 2022, electronic signatures and supporting documentation are required.
  - Failure to follow the appropriate formats may cause NIH to withdraw applications from or delay consideration of funding.
- Applicants and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used.
  - Learn more: NOT-OD-21-110
  - Learn More: Biosketch FAQs & Other Support FAQs
  - Send inquiries to: nihosbiosketch@nih.gov

Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel

- NOT-OD-21-109: Extension of the existing eRA Commons ID requirement to include all senior/key personnel
- An eRA Commons ID must be entered in the "Credential, e.g. agency login" field for all Senior/Key Personnel listed on the R&R Senior/Key Person Profile (Expanded) Form
- Senior/Key Personnel (NIH defined in NIH GPS 1.2)
  - The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.
- Applicants will encounter an eRA system validation if the "Credential, e.g. agency login" field is blank or does not contain a valid eRA Commons ID. Currently, this is a warning.

Final Thoughts



Notice of Award (NoA)

- Review the NoA carefully, including SECTION IV – GM Special Terms and Conditions
  - Specific requirements, restrictions, and policies that pertain to that particular award
- The grantee indicates acceptance of the terms and conditions of the award by drawing down funds against the grant from the Payment Management System

Notice of Award (NoA)

- **PLEASE read your NoA!**
- The NoA is the official notification of funding but it is more than just money
- The NoA is a legally binding document that contains:
  - Award Data & Fiscal Information
  - Grant Payment Information
  - Terms and Conditions
    - 45 CFR Part 75
    - NIH Grants Policy Statement
    - Program legislation and program regulations
    - Federal Award Performance Goals
    - Special terms and conditions as cited in NoA

Questions Specific to Your Grant

- Before you contact NIH staff, review the following sources of information as they will likely contain the answers to many of the questions you may have:
  - The Terms and Conditions in the NoA for your grant
  - The specific program announcement that your application was submitted under
  - The NIH Grants Policy Statement
  - Your AOR in your institution's sponsored programs office
  - The NIH grants management specialist or scientific program officer listed in the in eRA Commons

NIGMS Contacts

NIGMS GAB DRCB Team

Christy Leake	Christy.Leake@nih.gov	GAB DRCB Team Leader
Grants Management Specialists		*IDeA State Assignments*
Andrea Culhane	Andrea.Culhane@nih.gov	Delaware, Maine, New Mexico, Vermont
Arina Kramer	Arina.Kramer@nih.gov	Mississippi, Montana, Oklahoma
Barinaadaa Kara	barinaadaa.kara@nih.gov	Individual grants as assigned
Brian Iglesias	Brian.Iglesias@nih.gov	Alaska, North Dakota, Rhode Island
Courtney Tardd-Wright	Courtney.Tardd-Wright@nih.gov	Idaho, Nebraska, West Virginia
Emily Tran	Emily.Tran@nih.gov	Kansas, New Hampshire, South Carolina
Lisa Hildred	Lisa.Hildred@nih.gov	Arkansas, Hawaii, Nevada, South Dakota
Samantha Farrell	Samantha.Farrell@nih.gov	Kentucky, Louisiana, Puerto Rico, Wyoming

Questions?

Helpful NIH Resources

RPPR Resource

- RPPR Webpage: http://grants.nih.gov/grants/rppr/
- Includes links to:
  - RPPR Guide
  - RPPR Guide Notices
  - Frequently Asked Questions
  - Training
  - Contacts

Frequently Asked Questions

- FAQs –searchable websites for:
  - Application/progress report preparation, funding initiatives, policies, human subjects, sIRB, clinical trials, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc.…
  - http://grants.nih.gov/grants/frequent_questions.htm

Summary of Helpful NIH Web Pages

- Office of Extramural Research (OER) Web Page:
  - http://grants.nih.gov/grants/oer.htm
- NIH Grants Policy Statement:
  - http://grants.nih.gov/grants/policy/nihgps/
- NIH Extramural Nexus – newsletter for the extramural community:
  - http://nexus.od.nih.gov/all/nexus-by-date/
- Grant Application Basics:
  - http://grants.nih.gov/grants/grant_basics.htm
- eRA Training: Video Tutorials
  - http://era.nih.gov/era_training/era_videos.cfm

Summary of Helpful NIH Web Pages

Application Instructions

- How to Apply - Application Guide:
  - http://grants.nih.gov/grants/how-to-apply-application-guide.htm
- Annotated SF424 (R&R) Application Forms (General and Small Business and Multiproject):
  - https://grants.nih.gov/grants/how-to-apply-applicationguide/resources/annotated-form-sets.htm
- How we check for application completeness:
  - https://grants.nih.gov/grants/how-to-apply-application-guide/submissionprocess/how-we-check-for-completeness.htm
- Self Help Resources page:
  - http://grants.nih.gov/support/index.html

Summary of Helpful NIH Web Pages

- eRA Commons Web pages:
  - http://era.nih.gov/
- eRA Commons User Guides:
  - http://era.nih.gov/commons/user_guide.cfm
- Intellectual Property Policy:
  - http://grants.nih.gov/grants/intell-property.htm
- Research Portfolio Online Reporting Tools (RePORT):
  - http://report.nih.gov
- RePORT Expenditures & Results (RePORTER):
  - http://projectreporter.nih.gov/reporter.cfm

OLAW Educational Outreach

OLAW free quarterly webinars series:

http://grants.nih.gov/grants/olaw/e-seminars.htm

- Recordings of past webinars: http://grants.nih.gov/grants/olaw/educational_resources.htm

Disaster planning resources:

http://grants.nih.gov/grants/olaw/disaster_planning.htm

- Disaster planning webinar & FAQs

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://olaw.nih.gov/

- eSubmission:
  Separate listservs available for scientists and administrators
  - http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm