Agenda

• NIH Update
  – Continuing Resolution NOT-OD-16-002
  – Vertebrate Animals NOT-OD-16-006
  – xTRACT Research Training Tables NOT-OD-16-007
  – Implementing Rigor and Transparency in Career Development Applications NOT-OD-16-012

• Financial Services Update
  – Grant Purchasing and Procard Expenditure Approval Procedure

• Uniform Guidance Update

• Continuous Submission – Study Section Status

• Proposal & Progress Report Statistics
NIH Notices

• NIH Operates under Continuing Resolution
  – NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level).
  – All legislative mandates that were in effect in FY 2015 remain in effect under this CR, including the salary limitation set at Executive Level II.

NIH Notices

• Vertebrate Animals NOT-OD-16-006

These requirements, will take effect for all grant applications except Fellowship (F series) and Training (T series) grants for due dates on or after January 25, 2016, and will take effect for all applications for due dates on or after May 25, 2016.

Please share this info with your PI’s
NIH Notices

• Vertebrate Animals NOT-OD-16-006
  Summary of Changes
  – Description of veterinary care is no longer required.
  – Justification for the number of animals has been eliminated.
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NIH Notices

• xTRACT Research Training Tables NOT-OD-16-007
  – xTRACT is expected to be available for users to access via the eRA Commons beginning October 16, 2015.
  – Reduces the number of tables from 12 to 8
  – Minimizes the reporting of individual-level information
  – Existing data will be used to prepopulate the xTRACT system, including trainee names and selected characteristics, institutions, grant numbers
• xTRACT Research Training Tables NOT-OD-16-007
  – New training data table formats must be used for RPPRs due prior to December 1, 2015, and applications submitted for due dates prior to May 25, 2016
  – The xTRACT system is being piloted as an option for creating data tables for T32, TL1, T90/R90, and T15 applications and RPPRs, and will not be required for FY 2016
  – Upload features are planned and are expected to be introduced gradually, beginning in late January 2016.

• Implementing Rigor and Transparency in Career Development Applications NOT-OD-16-012
  – Will take effect for most Career Development Award applications submitted for due dates on or after January 25, 2016. (excludes K02, K05, and K24)
  – Revisions to application guide instructions for preparing your research strategy attachment
  – Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
  – Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications.
NIH Notices

• Implementing Rigor and Transparency in Career Development Applications NOT-OD-16-012

These updates focus on four areas deemed important for enhancing rigor and transparency:
1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

Please share this with your PI’s

Financial Services Update

Grant Purchasing and Procard Expenditure Approval Procedure
Expense Verification Report

- Request was made by some Administrators to have an easy report for PI’s to approve expenditures charged to their grants.

- Developed report in SUMMIT that can be printed (PDF only) and has a signature line.

- Report provides ability for dept to run one report for a chartstring or for all at the same time – page breaks on chartstring.

Info about using the report

- If use Expense Verification report must be signed by PI within 30 days of the close of the month.

- Depts. will keep these reports in their files for support should their be an audit – period of 3 years from submission of the final financial report.

- Not required to use, however University policy requires that PI approve all expenditures charged to grant funds.

- If dept chooses not to use must continue to have signed copies of requisitions, etc.

- Does not replace Procard procedures – Cardholder/Authorized Account Signers must still sign monthly statements.
Financial Services Update

New Summit Report

Financial Services Update

AP & Procard Expense Verification Report
NIH Subaccount Transition Began 10/1/15

- As of October 1, 2015, NIH will only use subaccounts in the Payment Management System (PMS). Every grant that is awarded funding in FY 2016 will be transitioned into a subaccount.

- The transition of all NIH awards to PMS subaccounts will be complete by September 30, 2016.

- OSP will work with departments and Grant Accounting to close existing projects in PeopleSoft and establish new accounts and revise subawards once we start receiving conversion awards.

OMB Extension on Implementation of Procurement Standards

- A second year has been added to the grace period for implementation of the Procurement Standards, 200.317 through 200.326, of the Uniform Guidance (UG).

- Delay will allow non-federal entities to implement changes to their procurement policies and procedures in accordance with guidance on procurement standards.

- New standards require bid process for purchases over $3,000.

- Higher Ed community will continue working with OMB to try to change the $3k threshold during this time period.
Continuous Submission – Study Section status

For all Continuous Submission – Study Section members
Change the due date in Cayuse to the proposed submission deadline:

Proposal Summary

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Alert OSP to the Study Section status so that verification can be processed:

List of Reviewers Eligible for Continuous Submission

Individuals may determine their eligibility for the continuous submission option, by accessing the list below. Because of the potential for multiple reviewers to have the same name, please check your Commons profile to confirm your individual eligibility. The term of eligibility is shown after the name.

- List of Reviewers Eligible for Continuous Submission (Combined Regular and Recent Substantial Service) - (PDF - 661 KB) - 10/01/2015

PROPOSAL SUBMISSIONS TO OSP
September 2014 – September 2015

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## PROPOSALS

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## PROGRESS REPORT SUBMISSIONS TO OSP

**September 2014 – September 2015**

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NIH Operates Under a Continuing Resolution

Notice Number: NOT-OD-16-002

Key Dates
**Release Date:** October 2, 2015

Related Announcements
[NOT-OD-15-050](#)

Issued by
National Institutes of Health ([NIH](#))

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the Fiscal Year 2016 Continuing Appropriations Act, 2016 ([H.R. 719](#)) signed by President Obama on September 30, 2015. This Act (CR) continues government operations through December 11, 2015 at 99.7892 percent of the FY 2015 enacted level.

Continuing the procedures identified under [NOT-OD-15-050](#) and consistent with NIH practices during the CRs of [FY 2006 – 2015](#), the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2016 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2015 (see [NOT-OD-15-054](#) and [NOT-OD-15-048](#)) remain in effect under this CR, including the salary limitation set at Executive Level II of the Federal Pay Scale as described in [NOT-OD-15-049](#).

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)
Notice Number: NOT-OD-16-006

Key Dates
Release Date: October 13, 2015

Related Announcements
NOT-OD-16-004

Issued by
National Institutes of Health (NIH)

Purpose

This Notice is to inform potential applicants and offerors that the requirements of the Vertebrate Animals Section (VAS) of grant applications, cooperative agreements and contract proposals has changed. The changes have been made to remove redundancy with Institutional Animal Care and Use Committee review while meeting the requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Updated VAS Requirements
If live vertebrate animals are to be used, federal policy requires applicants to address the following criteria:

- Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the application or proposal. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
- Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

Anticipated Implementation
These requirements, as applicable, will take effect for all grant applications except Fellowship (F series) and Training (T series) grants for due dates on or after January 25, 2016, and will take effect for all applications for due dates on or after May 25, 2016. For contracts, see individual Requests for Proposals (RFPs) for details.

Summary of Changes
The VAS criteria are simplified by the following changes:

- A description of veterinary care is no longer required.
- Justification for the number of animals has been eliminated.
A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.

Application Review Criteria
As applicable for the project proposed, reviewers will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of procedures involving animals including species, strains, ages, sex and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for the euthanasia method if not consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals.

Resources
See the Vertebrate Animals Section webpage for more information on the VAS requirements. Here you will find a checklist, detailed instructions, plus links to worksheets.

Inquiries
For questions or further information, contact:

Office of Laboratory Animal Welfare (OLAW)
Telephone: 301-496-7163
Email: olaw@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.
NIH & AHRQ Announce Transition to New Research Training Table Formats for 2016 and Upcoming Release of the xTRACT System

Notice Number: NOT-OD-16-007

Key Dates
**Release Date:** October 13, 2015

Related Announcements
NOT-OD-16-004
NOT-OD-16-005
NOT-OD-15-146
NOT-OD-15-112

Issued by
National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)

Purpose
This Notice serves to announce the availability of new research training data tables for use with FY 2016 institutional training grant applications and research performance progress reports (RPPRs). Table formats, instructions, and a completed set of tables with sample data may be found on the NIH website at: [http://grants.nih.gov/grants/funding/424/datatables.htm](http://grants.nih.gov/grants/funding/424/datatables.htm).

Where specified in the Funding Opportunity Announcement for a program, these tables may also be used in institutional career development and research education applications and RPPRs.

**Background and Related Information**

In keeping with the recommendations of NIH's Advisory Committee to the Director's Working Group on the Biomedical Research Workforce, we plan to introduce an electronic system, xTRACT, for creating research training data tables and storing the information reported in those tables. xTRACT is expected to be available for users to access via the [eRA Commons](https://era.nih.gov/era/index.htm) beginning October 16, 2015.

In conjunction with the development of xTRACT, and to implement related recommendations from the Working Group, we have revised existing research training data tables to:

- Reduce the number of tables from 12 to 8
- Minimize the reporting of individual-level information
- Extend the tracking of trainee outcomes from 10 to 15 years

Where possible, existing data will be used to pre-populate the xTRACT system, including trainee names and selected characteristics, institutions, grant numbers, and subsequent NIH, AHRQ and other HHS awards.

**Implementation**
For RPPRs due prior to December 1, 2015, and applications submitted for due dates prior to May 25, 2016, applicants are advised to continue to use previously issued training data table formats.

New training data table formats must be used for RPPRs due December 1, 2015, and after and applications submitted for due dates on or after May 25, 2016. Applicants may create tables for their applications and RPPRs either by using fillable tables in MS Word or via the xTRACT system.

The xTRACT system is being piloted as an option for creating data tables for T32, TL1, T90/R90, and T15 applications and RPPRs, and will not be required for FY 2016. Applicants for other predoctoral, postdoctoral, and career-level training, education, and career development activities that use training data tables (e.g., T35, R25, K12/KL2 awards) can also use xTRACT on a pilot basis, however, they may wish to wait for future editions of the system, which will include features tailored to their specific types of awards. Programs targeted to undergraduates (e.g., T34 awards) should not use the xTRACT system at all at this time, but should instead use the new, fillable tables designed for undergraduate programs available on the NIH website.

For institutions that wish to submit training-related data to the xTRACT system in batches, upload features are planned and are expected to be introduced gradually, beginning in late January 2016.

Inquiries

Please direct all inquiries to:

NIHTrain@mail.nih.gov

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files.
Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications

Notice Number: NOT-OD-16-012

Key Dates
**Release Date:** October 13, 2015

Related Announcements
[NOT-OD-16-011](#)
[NOT-OD-16-005](#)
[NOT-OD-16-004](#)
[NOT-OD-15-103](#)
[NOT-OD-15-102](#)

Issued by
National Institutes of Health ([NIH](#))
Agency for Healthcare Research and Quality ([AHRQ](#))

Purpose

This notice informs the biomedical research community of updates to application instructions and review language intended to enhance the reproducibility of research findings through increased scientific rigor and transparency. These updates will take effect for most* Career Development Award applications submitted for due dates on or after January 25, 2016. For research contracts, this policy will be effective for proposals received on/after January 25, 2016 and expected to result in contract awards in Fiscal Year 2017 and beyond.

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

The basic principles of rigor and transparency and the four areas of focus apply to the full spectrum of research, from basic to clinical. Investigators will need to consider how all four areas apply to their proposed research. Likewise, reviewers will assess whether these areas have been appropriately addressed by the applicant through revised language defining the peer review criteria.

*Notes & Exceptions:
• Career Development Award activity codes excluded from this policy include K02, K05, and K24, as candidates for these awards are expected to have independent, peer reviewed research support at the time the career award is made.
• Refer to NOT-OD-16-011 for updates to Research grant application instructions and review language.
• Fellowship and Training grant applications submitted for the May 25, 2016 due date and beyond will include new instructions and review criteria to address this policy. Details on these changes will be available by December 2015.

Implementation

Updates to Research Strategy Guidance

By November 25, 2015 application guide instructions will be updated to include the following additional guidance for the Significance and Approach sections of the Research Strategy, in addition to the existing instructions.

Significance
Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

Approach
Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

New Authentication of Key Biological and/or Chemical Resources Attachment

Award applications for the activity codes covered by the policy must include a new PDF attachment related to the authentication of key biological and/or chemical resources.

Authentication of Key Biological and/or Chemical Resources
Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

Key biological and/or chemical resources may or may not be generated with NIH funds and:
1) may differ from laboratory to laboratory or over time;
2) may have qualities and/or qualifications that could influence the research data; and
3) are integral to the proposed research.

These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095).

Applications submitted for due dates between January 25, 2016 and May 24, 2016 will use the FORMS-C forms and application guide. The general application guide will be updated by November 25, 2015 with instructions for this new attachment and guidance to upload your PDF document (titled "Authentication of Key Resources Plan") in the "Other Attachments" section of the "Other Project Information" form.

Applications submitted for due dates on or after May 25, 2016, will use updated FORMS-D forms. The PHS 398 Research Plan form will include a new "Authentication of Key Biological and/or Chemical Resources" attachment field. FORMS-D application forms and instructions will be available for all active funding opportunity announcements at least 60 days prior to due dates that fall on or after May 25, 2016.

Application Review Information

Unless stated otherwise in the Funding Opportunity Announcement, reviewers will be asked to consider additional review questions in order to assess rigor and transparency in Career Development Award applications. By November 25, 2015, all active Funding Opportunity Announcements will be updated to reference these additional review questions.

Scored Review Criteria

Research Plan

- Is there a strong scientific premise for the project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Additional Review Considerations

Authentication of Key Biological and/or Chemical Resources
For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

The review criteria stated in the Funding Opportunity Announcement always prevail in the evaluation of applications submitted under that announcement.

Research Performance Progress Reports

Research Performance Progress Reports (RPPR) submitted January 25, 2016 or later will be expected to emphasize rigorous approaches taken to ensure robust and unbiased results. Rigor should be
addressed in the RPPR for any grant that funds research or training in research; grants that support other activities do not need to address rigor. This includes non-competing continuation reports (Type 5) for grants reviewed and awarded before implementation of the policy. The RPPR instructions will be updated by January 25, 2016. Reporting on rigor in RPPR will help NIH implement and evaluate the policy for both current and new awards, as well as prepare non-competing renewals for the next competitive renewal.

Resources

- Website describing reproducibility efforts for NIH applicants and grantees
- Frequently Asked Questions

Background

NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. Key to the successful application of that knowledge toward health outcomes is scientific rigor in conducting biomedical research. One of NIH’s four stated goals is to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science (see http://www.nih.gov/about/mission.htm).

These rigor and transparency updates:

- clarify long-standing expectations to ensure that NIH is funding the best and most rigorous science,
- highlight the need for applicants to describe details that may have been previously overlooked,
- highlight the need for reviewers to consider such details in their reviews through updated review language, and
- minimize additional burden.

These are not new expectations, but NIH is formalizing these expectations in grant applications and reviews. Some investigators already address some of the four areas of rigor in their applications, while other investigators are doing so in their research but not providing details in applications and/or publications. All biomedical science will benefit from increased attention to rigor and transparency in research grant applications and reviews.

Inquiries

Please direct all inquiries to:

reproducibility@nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
Process to transition awards to new PMS Subaccounts

NIH is transitioning to Payment Management System (PMS) subaccounts in response to a HHS directive to Agencies intended to enhance financial data integrity and financial closeout for all awards. The subaccount system will give Agencies more timely data on the spending activity for each Federal grant award.

New awards issued after 10/1/2014 were issued in the new PMS subaccount system (P subaccount) and setup in Peoplesoft accordingly.

For continuing awards issued before 10/1/2014, NIH will begin transitioning to the PMS subaccounts between October 1, 2015 and September 30, 2016. Once the next budget year is issued, the award will effectively be separated into two mini “competitive segments.”

- the first segment begins at the budget period start date of the current competitive segment and ends at budget period end date of the FY15 award and
- the second segment begins with the budget period start date of the FY16 award and ends with the project period end date on that award.
- See attached spreadsheet for an example on how the transition will separate the budget years

For the subaccount transition, NIH is using type 4s as a technical solution to separately track obligations and payments for awards that are transitioning to PMS subaccounts.

UMMS will create a new award number in Peoplesoft for the type 4s awards. The new award number will use the same number as the first segment of funds, but will add “WPM” to the prefix. (e.g. 00000001424 will become WPM00001424) This will let users know the funds are related to the same contract, but have been separated into 2 segments due to the PMS subaccount change. The new award number will be created by Grant Accounting in advance of the start date and emailed to the Dept Admin 120 days prior so they can use the same closeout process/checklist currently in place.

Awards in a no cost extension status in FY2016 will not require a new award number since NIH will allow these to remain in the prior PMS system until expiration.

UMMS will be required to submit a final FFR for the first segment of funds 90 days after the end date which indicate the balance of unobligated funds to be added to the second segment. The carryover terms specified in the notice of award will dictate if a prior approval request is required.

- Automatic carryover authority – Office of Financial Management (OFM) will automatically authorize the carryover in the PMS subaccount equal to the amount of unobligated balance reported on the FFR (subject to the existing policy relating to unobligated balances in excess of 25% of the total authorized amount).
- Prior approval of carryover – OFM will automatically transfer the unobligated balance reported on the FFR to the subaccount but the grantee is still required to submit a prior approval request to use carryover funds.

A revised NOA reflecting the approved carryover amount will be issued.
<table>
<thead>
<tr>
<th>ACRONYM/TERM</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>AVMA</td>
<td>American Veterinary Medical Association</td>
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<tr>
<td>Continuing Resolution</td>
<td>A type of appropriations legislation that sets aside for money to specific federal government departments, agencies, and programs. The money provides funding for operations, personnel, equipment, and activities.</td>
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<tr>
<td>Continuous Submission</td>
<td>Policy that allows appointed members of NIH review and Advisory Groups, and peer reviewers with recent substantial service (six times in 18 months), to submit their research grant applications (R01, R21, or R34) on a continuous basis.</td>
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<tr>
<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
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<td>K02</td>
<td>Research Scientist Development Award - Research</td>
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<td>K05</td>
<td>Research Scientist Award</td>
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<tr>
<td>K24</td>
<td>Midcareer Investigator Award in Patient-Oriented Research</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>OSP</td>
<td>Office of Sponsored Programs (formerly Research Funding Services)</td>
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<tr>
<td>PMS</td>
<td>US Department of Health &amp; Human Services Payment Management System</td>
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<tr>
<td>R90</td>
<td>Interdisciplinary Regular Research Training Award</td>
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<tr>
<td>RPPR</td>
<td>Research Performance Progress Report. Progress reports are required annually to document grantee accomplishments and compliance with terms of award. They describe scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year. See <a href="http://grants.nih.gov/grants/rrpr/">http://grants.nih.gov/grants/rrpr/</a></td>
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<tr>
<td>SUMMIT</td>
<td>SUMMIT is the UMass Medical School's web based reporting tool.</td>
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<td>T15</td>
<td>Continuing Education Training Grants</td>
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<td>Institutional National Research Service Award</td>
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<td>Interdisciplinary Research Training Award</td>
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<td>Linked Training Award</td>
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