

Introduction to ESI R01 and SBIR/STTRR Grants in Biomedical Informatics

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Extramural Programs

National Library of Medicine

NLM Informatics Training Conference
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This presentation is available online as a downloadable, printable document at http://www.nlm.nih.gov/ep/NI_ESI.html.



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Outline

NIH Pathway to Independence Award (K99/R00) (briefly)

Early Stage Investigator (ESI)

R01 Research Grants in Biomedical Informatics

SBIR/STTR Grant Programs

Questions and Answers

Note: Answers to Chat questions and additional support materials are added to the end of the presentation.



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What will NOT be covered

How to write a grant application.

Take advantage of training opportunities available in your current program.

Seek out opportunities to work on grant applications and research projects with your mentors and other trainees.

Participate in trainee available at your University, via NIH, and other organizations.



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What will NOT be covered

How to navigate the NIH grant application, review, and award processes

Take advantage of training opportunities available NIH and other organizations.

Participate in reviewing draft applications.

Collaborate with experienced researchers.

NIH Early Career Reviewer (ECR) Program

<https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/ECR>



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Learn to use NIH RePORT

NIH RePORT provides reports, access to data, analyses of NIH Research activities, and access to information about all funded research projects.

This tool can uncover funded projects and potential collaborators related to your work.

<http://report.nih.gov/index.aspx>



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NIH Pathway to Independence Award (K99/R00)

<https://grants.nih.gov/grants/guide/pa-files/PA-19-130.html>

Career transition support for postdoctoral fellows moving from mentored research to independent careers. The research career focus must be informatics or data science. Preference will be given to applicants who received their informatics and data science training at one of NLM's university-based training programs in Biomedical Informatics and Data Science.

<https://www.nlm.nih.gov/ep/pathway.html>



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NIH Pathway to Independence Award (K99/R00)

<https://grants.nih.gov/grants/guide/pa-files/PA-19-130.html>

Phased Program

K99: 1-2 years, mentored training and research experience

R00: up to 3 years, independent research

Eligibility

Clinical or research doctoral degree

<= 4 years of postdoc at time of application

Funding

K99 - \$50,000 salary \$20,000 research costs

R00 - \$249,000 total costs

<https://www.nlm.nih.gov/ep/pathway.html>



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NIH Early Stage Investigator (ESI) Policy?

In 2017 NIH announced a new policy designed to invest in the next generation of researchers. It is intended to provide opportunities for earlier research independence while enhancing workforce diversity and retain them as they become early established investigators.

Applies primarily to R01 and R01 like applications. R01 multi PI applications eligible as well.

<https://grants.nih.gov/policy/early-investigators/index.htm>



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NIH Early Stage Investigator Policy?

R01 Applications from ESI/NIs are given special consideration

Reviewers instructed to:

- focus more on the proposed approach than on the track record
- expect less preliminary data

NLM Funding Policy - R01 applications from ESIs, with Impact scores of 30 or better will be considered for funding, versus 23 for experienced investigator.

<https://www.nlm.nih.gov/ep/Payplan.html>



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Who are Early Stage Investigators?

You are!!! (Except for T15 faculty)



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What is an Early Stage Investigator (ESI)?

A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.



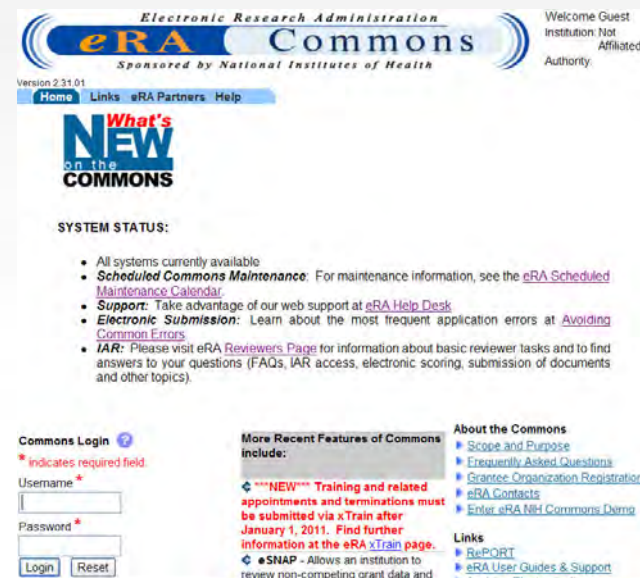
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Your eRA Commons Profile is Important!

All New Investigators should update their eRA Commons profiles. This is the tool NIH uses for communication with Principal Investigators and the University.

To create an eRA Commons Profile contact your institution's office of research support or grant administration.

<https://commons.era.nih.gov/commons/>



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What are the NLM Biomedical Informatics Research R01 Programs?

NLM Express Research Grants in Biomedical Informatics and Bioinformatics (R01) (PAR 18-896)

Research Project Grant (NIH Parent R01) (PA-20-185)

Currently 21 FOAs NLM participating in
<https://www.nlm.nih.gov/ep/Grants.html>

Also see EP News for NLM funding program updates at <https://www.nlm.nih.gov/ep/index.html>



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NLM Express Research Grants in Biomedical Informatics (R01) (PAR-18-896)

- Focus on a well-defined research problem
- Propose a rigorous research design
- Base research on preliminary studies
- Produce innovations that advance what is known in the field of informatics and have the capacity to improve human health.

<http://www.nlm.nih.gov/ep/GrantResearch.html>



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NLM Express Research Grants in Biomedical Informatics (R01) (PAR-18-896)

NLM does not support infrastructure development or continued development of existing software tools or knowledge resources as an endpoint of research funded through this FOA, though such tools, data sets or other compilations of knowledge may be developed in order to test ideas and methods.

<http://www.nlm.nih.gov/ep/GrantResearch.html>



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NLM Express Research Grants in Biomedical Informatics (R01) (PAR-18-896)

NLM's research interests:

- Information & knowledge processing
- Advanced information retrieval, knowledge discovery in databases, discovery mining, and other techniques for in silico discovery
- Incorporation of machine intelligence into decision tools and resources for health care providers, scientists and consumers
- Information visualization and presentation approaches to enhance decisions, learning or understanding
- Innovative approaches for ensuring privacy and security of clinical and biomedical research data.



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NLM Express Research Grants in Biomedical Informatics (R01) (PAR-18-896)

NLM places a high priority on:

- innovation in the research it supports.
- well-defined research problem and rigorous research design based on preliminary studies.
- an evaluation plan to show potential impact of project outcomes.



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What are the NLM Express Research Grant Budget and Duration?

Limit of \$250,000 per year in direct costs.

Up to 4 years for the project period.



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Notice of Special Interest (NOSI)

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-107.html>

A Notice of Special Interest (NOSI) is a new format for NIH Institutes/Centers to share and update their research priorities. NOSIs are intended to replace Program Announcements (PAs) that do not have special review criteria or set aside funds.

Currently— NLM has 4 **PAR-18-896** NOSIs and participating in 5 NOSIs related to COVID – 19

<https://www.nlm.nih.gov/ep/Grants.html>



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Tips for working with NIH Staff

NLM staff are here to support the best research possible. That means helping researchers prepare, submit, and manage research.

- Be prepared – carefully review funding opportunity and discuss with your research team
- Be specific with your questions
- Start with email and follow up with a phone call – include your application/grant number in the email subject line if possible
- Prepare a specific aims page and email it to the program director



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Need Help with Your Proposal... Who Ya' Gonna' Call?

✓ **about the scientific and technical aspects of your application...**

Contact the Program Officer

- Clinical and Public Health Informatics
Dr. Hua-Chuan Sim, simh@mail.nih.gov
- Bioinformatics and Translational Informatics
Dr. Jane Ye, yej@mail.nih.gov
- Consumer Health Informatics and Data Science
Dr. Alan VanBiervliet, alan.vanbiervliet@nih.gov



**Program
Officer**



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Need Help with Your Proposal... Who Ya' Gonna' Call?

✓ for questions regarding the
review of the application ...

Contact the Scientific Review Officer

Dr. Zoe Huang, huangz@mail.nih.gov the
CSR scientific review officer will be listed on
the eRA Commons link to your submitted
proposal



**Program
Officer**

**Scientific
Review
Officer**



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Need Help with Your Proposal... Who Ya' Gonna' Call?

- ✓ for help with the financial and business aspects of an application

Contact the Grants Management Officer

■ Samantha Tempchin
samantha.tempchin@nih.gov



**Program
Officer**

**Scientific
Review
Officer**

**Grants
Management
Officer**



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NLM Offer Small Business Research & Development Support

Small Business Innovation Research (SBIR) program

Support U.S. small businesses that seek to undertake informatics and data science research and development leading to commercialization

Small Business Technology Transfer (STTR) program

Requires a small business to formally collaborate with a research institution

<https://www.nlm.nih.gov/ep/grantsbir.html>



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Phase I: Feasibility and Proof of Concept

The objective of Phase I is to establish the technical merit, feasibility, and commercial potential of the proposed R/R&D efforts and to determine the quality of performance of the small business awardee organization prior to providing further federal support in Phase II. Phase I awards normally do not exceed \$150,000 total costs for 6 months (SBIR) or 1 year (STTR).



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Phase II: Research/Research and Development

The objective of Phase II is to continue the R/R&D efforts initiated in Phase I. Funding is based on the results achieved in Phase I and the scientific and technical merit and commercial potential of the project proposed in Phase II. Only Phase I awardees are eligible for a Phase II award. SBIR/STTR Phase II awards normally do not exceed \$1,000,000 total costs for 2 years.



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Phase III: Commercialization

The objective of Phase III, where appropriate, is for the small business to pursue commercialization objectives resulting from the Phase I/II R/R&D activities. The NIH SBIR/STTR programs do not fund Phase III, and NIH does not generally provide any Phase III funding to small businesses.



SBIR and STTR Critical Differences

The SBIR and STTR programs have similar objectives, but differ in two major ways related to the Program Director (PD)/Principal Investigator (PI) and non-profit research partner.



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Project Director

Under SBIR, the PD/PI must be primarily employed with the small business concern at the time of award and for the duration of the project period, unless a waiver is granted by the NIH.

Under the STTR Program, primary employment is not stipulated so the PD/PI may be primarily employed* by either the small business concern or the collaborating non-profit research institution at the time of award and for the duration of the project period.



Non-Profit Research Partner

The SBIR program permits and encourages research partnerships. However, STTR requires that the small business concern formally collaborate with a non-profit research institution. Under SBIR, the research institution can complete up to 33 percent of the total effort for a Phase I, and up to 50 percent of the total effort for Phase II.

Under STTR, the small business must perform at least 40 percent of the work and the research institution must perform at least 30 percent. The remaining 30 percent may be with the small business concern, the collaborating non-profit research institution, or additional third party/parties.



NLM Current SBIR/STTR Programs

PHS 2019-02 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed) (PA-19-272)

<https://grants.nih.gov/grants/guide/pa-files/PA-19-272.html>

PHS 2019-02 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Not Allowed) (PA-19-270)

<https://grants.nih.gov/grants/guide/pa-files/PA-19-270.html>

NIH SBIR/STTR Helping to End Addiction Long-term (HEAL) Initiative (Clinical Trial Not Allowed)

[R41/R42 \(RFA-NS-20-009\)](#) and [R43/R44 \(RFA-NS-20-011\)](#)

An aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.



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Scope of NLM SBIR/STTR Grant Program

Use of formal and informal data sources to track disease outbreaks, pandemics

Approaches to help consumers and patients visualize their health data in the context of social and behavioral determinants

Tools for modeling the impact of behavior and social determinants of health on physiological systems

Tools and approaches for data integration of large disparate data resources

Technological approaches to protecting confidentiality while storing, sharing and using biomedical data

AI techniques for annotating, curating and managing biomedical data resources

Self-managing, self-documenting datasets

Tools to enhance security of biomedical data, including personal health data, for multi-party use (meaning, two or more users using the data at once)

New Technologies that facilitate real-time decisions in clinical practice and public health, using personal health data in electronic records or clinical trials

Tools for understanding and predicting climate and environmental effects on human health

AI techniques for characterizing and minimizing the impact of errors or incompleteness in a health data set



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Example Titles of Funded Project

Artificial intelligence-enabled, real-time communication software for optimizing clinical decision making during the allocation, procurement, and transplantation of donated organs

Improve medical decision making in emergency medicine via a new interface to visualize and understand relevant prior history for complex patients at the point-of care

Leveraging Advanced Clinical Phenotyping to Enhance Problem Lists and Support Value-based Healthcare

Associating Clinical Decision Support Use with Clinical Outcomes in a Visual Analytics Display



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Current NLM SBIR/STTR Funding Opportunity Announcement

SBIR/STTR Omnibus Parent Grant Applications SBIR [R43/R44] ([PA-19-272](#)) and STTR (R41/42) ([PA-19-270](#)) Clinical Trial Not Allowed

Support for small businesses that seek to undertake informatics research and development leading to commercialization.

Notice of Special Interest: Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Applications Directed at the Adoption of the Fast Healthcare Interoperability Resources (FHIR®) Standard

Support for innovative health IT solutions, implementing the FHIR standard, to enable more effective patient-centered care coordination, population health management, and data science research support.

NIH SBIR/STTR Helping to End Addiction Long-term (HEAL) Initiative (Clinical Trial Not Allowed) [R41/R42 \(RFA-NS-20-009\)](#) and [R43/R44 \(RFA-NS-20-011\)](#)

An aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis



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NLM SBIR/STTR Contacts

Program Contact

Dr. Jane Ye

301-594-4882

yej@mail.nih.gov

Grant Management Contact

Ms. Samantha Tempchin

301-496-4221

samantha.tempchin@nih.gov



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Any questions

End Of session.

Chat Responses and Additional Information follows.



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Session Chat and Responses Pt 1

Chat June 22, 2020

1:24 PM from Melissa Glueck to everyone: Could the speaker please confirm that trainees who have been on T15 are given preference in K99/R00s? **Yes this is stated at <https://www.nlm.nih.gov/ep/pathway.html>**

1:25 PM from Mirza Khan to everyone: Does this preference also extend to VA trainees? **Not at this time.**

June 22, 2020 1:25 PM from Adam Rule to everyone: Does NLM have any additional specific funding priorities for Early State Investigators aside from the general NIH criteria? **"NLM supports research career development in biomedical informatics and bioinformatics. We define informatics as the intersection of computer, information, biomedical and behavioral sciences with one or more application domains. Application domains of interest include health care delivery, basic biomedical research, clinical and translational research, public health and others. Whatever the application domain, the research career focus must be informatics. Preference will be given to applicants who received their informatics training at one of NLM's university-based training programs in Biomedical Informatics."** <https://www.nlm.nih.gov/ep/pathway.html>

June 22, 2020 1:28 PM from Ray to everyone: When does the 4 year clock for the K99/R00 start? After doctoral degree or most recent degree received? Or is it after the T15 ends? **From the start of postdoctoral research experience.** <https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html>

June 22, 2020 1:45 PM from Malec, Scott Alexander to everyone: Is it permissible to apply for an R21 while on a K99 mechanism as long as one's time is < 100%? **Yes, generally during the R00 phase but applications could be made during the K99 period that would begin during the R00 period. Many Researchers in the R00 stage serve as co-investigators w=etc. on other research projects as well.** https://grants.nih.gov/grants/forms/change_institution_request.htm



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Session Chat and Responses Pt 2

June 22, 2020 1:50 PM from Ray to everyone: How portable are these various funding mechanisms (SBIR/STTR, K99, R01) in terms of the PI switching roles or institutions? **Switching positions is common particularly early in the career. The R00 phase typically occurs at a different organization than the K99 phase. There are formal mechanisms for transferring grants from one University or research organization to another. Both institutions have paperwork which is submitted to NIH for approval. Normally the process works smoothly. The receiving organization needs to show they have the necessary resources to support the research project.**
https://grants.nih.gov/grants/forms/change_institution_request.htm Transferring SBIR/STTR can be more difficult since it is commercial/business related so other factors need to be considered.

June 22, 2020 1:51 PM from Rupali Mankar to everyone: Can postdocs apply for SBIR/STTR? **Yes, it would require either the business or the institution approval. Virtually all NIH grants are submitted by and awarded to organizations not individuals.**

June 22, 2020 1:59 PM What is the protocol for providing productivity updates prior to application review by the assigned study review group? **NLM allows the PIs to submit supplemental or additional materials (including corrections, letters, or publication being accepted, et al), in an email, as long as 30 days before the review meeting. We will accept it and put it in the grant folder of this application. Reviewers can see the new information and consider the additional information at the time of the review. First step is to contact the Scientific Review Officer (SRO) assigned to the application.**

June 22, 2020 1:45 PM from Malec, Scott Alexander to everyone: Is it permissible to apply for an R21 while on a K99 mechanism as long as one's time is < 100%? **Yes, generally during the R00 phase but applications could be made during the K99 period that would begin during the R00 period. Many Researchers in the R00 stage serve as co-investigators etc. on other research projects as well.**
https://grants.nih.gov/grants/forms/change_institution_request.htm



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Following is additional information about preparing grant applications for the National Library of Medicine



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Excellent Grant Preparation Tips

Adapted from Dr. Jason Moore, University of Pennsylvania

- 1) Articulate an important and timely informatics question.
- 2) Propose *new* and *novel* informatics methods.
- 3) Avoid purely applied software engineering projects.
- 4) Compare your algorithm or method to the state of the art in field.
- 5) Describe a solid plan for how you will *evaluate* your novel informatics method.



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Excellent Grant Preparation Tips

Adapted from Dr. Jason Moore, University of Pennsylvania

- 6) Apply your methodology to real data when possible.
- 7) Provide as many details as possible about your novel informatics algorithm or method.
- 8) Significance, innovation and approach have the biggest impact on your final score.
- 9) Make sure you have good collaborators with real effort budgeted to cover project needs.
- 10) Be productive! Publications, related research projects, relevant work experiences.



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A few extra Grant Preparation Tips

- 1) Take advantage of training in grant writing: courses and practical experience.
- 2) Do your homework – conduct a thorough analysis of the literature.
- 3) Have colleagues critically review the application throughout its development stages.



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Good Grants Get Considered, **Outstanding** Grants Get Funded



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Where do I Find Information about Grants?

Funding Opportunity Announcements (FOA)
posted at:

- NLM Extramural Programs web site
<http://www.nlm.nih.gov/ep/index.html>
- the NIH Guide
<http://grants.nih.gov/grants/guide/>
- Grants.gov <http://www.grants.gov/>
- Subscribe to your institution's grant notification service



Learn about the NIH Grants and Peer Review Processes

Learn about the NIH grant process

http://grants.nih.gov/grants/grants_process.htm

Learn how your application will be reviewed and write with your audience, the reviewers, in mind.

http://grants.nih.gov/grants/peer_review_process.htm

<http://public.csr.nih.gov/ApplicantResources/Pages/default.aspx>

NIH National Institutes of Health
Office of Extramural Research

HOME ABOUT GRANTS FUNDING FORMS & DEADLINES GRANTS POLICY eRA NEWS & EVENTS ABOUT OER

Grants & Funding

Grants Process

- Grants Process Overview
- Planning Your Application
- Writing Your Application
- Submitting Your Application
- Receipt and Referral
- Peer Review Process**
- Award Management
- Post Award Management

Types of Grant Programs

- How to Apply
- Peer Review Process
- Award Management
- Foreign Grants Information
- NIH Financial Operations

Peer Review Process

"To maintain our edge . . . we've got to protect our rigorous peer review system and ensure that we only fund proposals that promise the biggest bang for taxpayer dollars . . . that's what's going to maintain our standards of scientific excellence for years to come."

Remarks by President Barack Obama on the 150th Anniversary of the National Academy of Sciences, April 28, 2013

On This Page:

- Overview
- First Level of Review - Scientific Review Groups
 - Peer Review Roles and Meeting Overview
 - Peer Review Criteria and Considerations

Related Resources

- Peer Review Policies & Practices**
- Guides, Tips, and Tutorials:**
 - Sample Summary Statements
 - Application Planning Tips
 - Application Writing Tips
 - Paylines, Percentiles and Success Rates (blog post)
 - Correlating Overall Impact and Criterion Scores (blog post)
 - Information for New Grantees
 - NIH Guide for Grants



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Where can I find help for writing a grant application?

NLM and other NIH Institutes and Centers provide a wide range of help for applicants. NLM grant writing help

<http://www.nlm.nih.gov/ep/ForApplicants.html>

NIH Grant process

http://grants.nih.gov/grants/grants_process.htm

<http://grants.nih.gov/reproducibility/index.htm>

NIH grant awards are made to eligible institutions and not to individuals. There will be procedures established by your institution regarding preparing and submitting NIH grant applications.



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How can I find NIH grants similar to my project?

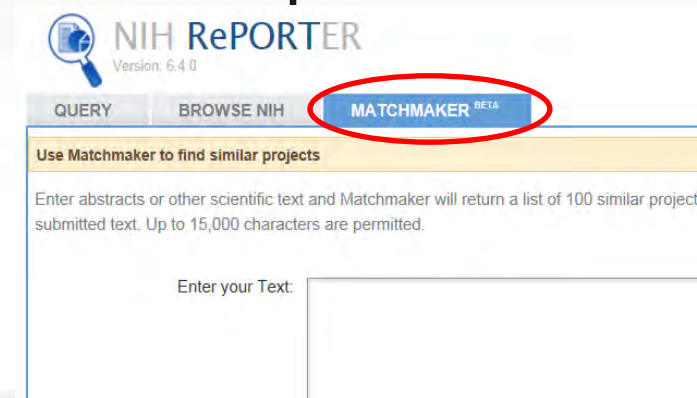
Use the query feature to search

<http://projectreporter.nih.gov/reporter.cfm>



Use the MATCHMAKER function to find similarities based on an abstract or project description.

<http://projectreporter.nih.gov/reporter.cfm>



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Related Notices **ARE** Important!

Department of Health and Human Services

Part 1. Overview Information

Participating Organization (s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Library of Medicine (NLM)
Funding Opportunity Title	NLM Express Research Grants in Biomedical Informatics (R01)
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PAR-11-208
Related Notices	<ul style="list-style-type: none">• May 5, 2016 - Notice of Clarification of Language in PAR 13-300. See Notice NOT-LM-16-004.• NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015)• NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015)• NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015)• June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same.• August 21, 2013: Removed reference to ASSIST in section IV.3, since ASSIST is currently only available for multi-project applications.
Funding Opportunity Announcement (FOA)	PAR-13-300



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Two Level System for Application Review

1st Level

Scientific Review (SRG)

Independent outside reviewers
Evaluate scientific merit & significance
Recommend length and level of funding



2nd Level

NLM Board of Regents

Assess quality of SRG Review
Make recommendation to Institute staff on funding
Evaluate program priorities
Advise on policy

NLM Funding Plan - <http://www.nlm.nih.gov/ep/Payplan.html>

Funding Strategy: Final award decisions reflect considerations of

- Peer review scores
- Program relevance
- Portfolio balance
- Recommendations of the NLM Board of Regents, and
- Availability of funds

Fundable Range:

- Experienced investigators - impact scores 30 or better
- ESI/NI R01 - impact scores of 33 or better
- K99/R00 and K01 - impact scores of 30 or better
- F30/F31 NRSA Fellowship – impact score of 30 or better



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What Grants have NLM Funded?

NLM maintains links to information about all funded projects. Knowing what research has been funded in the past can help your planning.

<http://www.nlm.nih.gov/ep/funded.html>



The screenshot displays the NIH U.S. National Library of Medicine website. The header includes the NIH logo and the text "U.S. National Library of Medicine". A search bar is located in the top right corner. Below the header, there are navigation tabs: "Databases", "Find, Read, Learn", "Explore NLM", "Research at NLM", and "NLM for You". A "Contact NLM" link is also present. The main content area is titled "Grants and Funding: Extramural Programs (EP)". Below this title, there is a breadcrumb trail: "Home > Grants and Funding". The section is titled "Extramural Programs Awards" and includes a paragraph stating: "Each link below takes you to a list of awards made since 1997 in NLM's active grant programs. Inactive grant programs are included in the year-by-year listings." Below this paragraph, there is a section titled "Research Support" with a list of links: "American Recovery and Reinvestment Act Awards", "Research Grants-R01", "Exploratory/Developmental Awards-R21", "NIH Director's Pioneer Awards", "High Priority Short Term Project Awards", "Informatics for Disaster Management Grants", "BISTI Grants", "IAIMS Grants", "Small Project Grants-R03", and "Conference Awards-R13". On the right side of the page, there is a sidebar with the heading "NLM Award News" and a link to "ARRA Investment Reports".



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