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Introduction to Career Development Awards and ESI/NI R01 Grants in Biomedical Informatics

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Extramural Programs

US National Library of Medicine

This document is available online at http://www.nlm.nih.gov/ep/NI_ESI.html

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Career Development Awards

NLM Career Development Support

- NLM offers early career development awards to help informatics researchers transition to a successful independent research career. Informatics as the intersection of computer, information, biomedical and behavioral sciences with application domains in health care delivery, basic biomedical research, public health, clinical and translational research
- NLM supports research career development in clinical/public health informatics, bioinformatics, translational informatics, and consumer health informatics.
- If you are graduating from your postdoctoral training fellowship at one of NLM's Biomedical Informatics Training Programs, and are ready to launch your research career, you may wish to consider applying for a career development award.

NLM Career Development Award for Biomedical Informatics (K01) (Par-13-284)

(<http://www.nlm.nih.gov/ep/GrantInformatics.html>)

- Provides support for promising junior investigators as they launch their careers in biomedical informatics research.

NIH Pathway to Independence Award (K99/R00)(PA-15-083)

(<http://www.nlm.nih.gov/ep/pathway.html>)

- Career transition assistance for biomedical informatics researchers moving from mentored research to their first independent research programs.

Mentored Career Development Award in Biomedical Big Data Science (K01) (RFA-HG-14-007) (<https://www.nlm.nih.gov/ep/BD2KGrants.html#MentoredCDA>)



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- Supports additional mentored training for scientists who will gain the knowledge and skills necessary to be independent researchers as well as to work in a team environment to develop new Big Data technologies, methods, and tools applicable to basic and clinical research.

Comparison of K99/R00 and K01 Programs	
K99/R00	K01
Eligibility	
To qualify, you must have a clinical or research doctoral degree with no more than four years of postdoctoral research training at the time of application, and have plans to apply for an assistant professorship at an academic institution (or equivalent institution). You do not have to be a U.S. citizen or permanent resident. However, you should have a visa that allows you to remain in this country long enough to: 1) move to an independent research career after the K99 phase, and 2) be productive on the research project for the duration of the R00 phase.	You must have a health professional or research doctoral degree. You must be in the first two years of your initial position, at an assistant professor level (or equivalent). U.S. citizen or permanent resident.
Funding Duration	
K99 phase: 1-2 years R00 phase: up to 3 years	Up to 3 years
What Do Career Development Awards Pay For?	
K99 Salary: Up to \$50,000/year plus fringe benefits Research expenses: Up to \$20,000/year Indirect costs: 8% R00 Total cost: \$249,000/year. Includes salary, fringe benefits, research support and applicable indirect costs Indirect costs: institution's indirect cost rate	K01 Salary: Up to \$85,000/year plus fringe benefits Research expenses: Up to \$50,000/year Indirect costs: 8%
What Minimum Effort Requirements Apply?	
K99 9 person-months (75% full-time professional effort) to career development and research experience	K01 9 person-months (75% full-time professional effort) on the award



Comparison of K99/R00 and K01 Programs

K99/R00	K01
<p>Remaining 3 months (25%) in teaching and/or clinical duties</p> <p>R00</p> <p>A total of 75% of full-time professional effort to research</p> <p>May devote effort to other research projects</p> <p>May reduce effort on the R00 award if additional independent research support is received. A reduction of effort by 25% or more will require NLM prior approval</p>	<p>Remaining 3 months can be divided among other research, clinical, and teaching activities</p>

Are K Awards Renewable?

- K99/R00 and K01 awards are not renewable.
- NLM expects K awardees to compete for independent research support, such as an R01.

Applying for a K99/R00 Award

- Your application must include a career development plan, a research plan with a description of the project you will pursue in the R00 phase, and at least three letters of reference.
- During the initial mentored (K99) phase, you must secure a tenure-track, full-time assistant professor position at an academic institution.
- To qualify for the independent (R00) phase, your department chair will need to submit a letter demonstrating the institution's commitment to you by providing protected research time, space, facilities, and support needed to conduct the proposed research.

Applying for a K01 Award

- Must have been in initial assistant professor (or equivalent) position for less than 2 years.
- Provide "protected time" for promising junior investigators as they launch their research careers.
- NLM supports research career development in clinical informatics, public health informatics, bioinformatics, translational informatics, and consumer health informatics.

Writing a Career Development Award Application

- Before jumping in to write your application, carefully read the relevant FOA and follow the instructions in the [SF 424 Application Guide](#), including guidelines for page limits.
- Take a look at our website at <https://www.nlm.nih.gov/ep/GrantInformatics.html> and contact the Program Officer listed for your area of research interest.



- Your application will be peer reviewed by an NLM study section.

Take a Look at the Review Criteria

Read the relevant FOA for specific peer review criteria.

Candidate - Reviewers will assess your potential based on your CV (NIH biosketch), research and career plans, and reference letters. Make sure your CV highlights your past success.

Career Development Plan/Career Goals & Objectives - Make sure your research and career plans illustrate your commitment and potential for future contributions to the field.

Research Plan - Important considerations are significance, innovation, approach and human subjects protection, if applicable.

Mentor(s), Consultants(s), Collaborator(s) - For mentored positions, reviewers will assess your mentor's career and research supervision record, and whether his or her work and experience are relevant to your proposed Research Plan.

Environment and Institutional Commitment to the Candidate - Reviewers will evaluate the institution where the proposed research will be conducted. They'll consider whether your institution has suitable facilities and resources and is committed to your development as an investigator.

Align your career development plan to your professional goals

You need to show that you can establish a successful research career. Your career development plan is as important as your research plan. Be sure to:

- Justify your need for a K award and explain how it will be a vital step toward your ultimate career goal.
- Specify training and courses that you will participate in, how often you'll meet with mentor(s) and/or collaborator(s), and how all of this will help you reach your objectives.
- Stress your commitment to a career in biomedical informatics research.
- Read the relevant FOA for other elements you should include in the career development plan.

Design Your Research Plan Carefully

- Reviewers will look closely at your Research Plan. They will evaluate whether it is appropriate for and tailored to your experience level and if it allows you to develop the skills and knowledge needed for further career advancement.
- Reviewers will also consider whether the research question, design, and methodology are of significant scientific and technical merit.
- Make sure you relate the proposed research to your scientific career goals, and you are able to show that you'll achieve your objectives in the time you request.



Document Training on Responsible Conduct of Research

- Make sure you've included a plan for instruction in responsible conduct of research.
- Reviewers will evaluate your plan to see if it meets the FOA requirements, including format of instruction, selection of subject matter, and the role of the mentor/sponsor.

Recent Career Awards

Recently funded K awards are listed at:

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

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

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New and Early Stage Investigators

Who is a New Investigator?

A Program Director or Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a significant NIH independent research award. An independent research award is considered to be a R01 or equivalent award. R21s, R03s or K awards do not impact your New Investigator status. The involvement of New Investigators is considered essential to the vitality of health-related research and has been addressed by several important NIH programs and studies. In FY 2007, the NIH adopted a policy designed to reverse the steady decline in the number of New Investigators.

http://grants.nih.gov/grants/new_investigators/index.htm.

Who is an Early Stage Investigator (ESI)?

An ESI is a New Investigator within ten years of completing their terminal research degree or within ten years of completing their medical residency. You can request an extension to the 10 year period. Requests to extend the ESI period can include medical concerns, disability, family care responsibilities, extended periods of clinical training, natural disasters, and active duty military service. The majority of New Investigators supported by the NIH are expected to be ESIs.

What is the NIH ESI/NI Policy?

Applications from ESI/NIs will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. Their early career stage will be considered at the time of review and award.

The NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time funding from the NIH. The ESI/NI review considerations only apply to R01 grants. NIH research indicated a smaller proportion of individuals with initial R21 or R03 grant support subsequently apply for and obtain R01-equivalent funding. In addition, the initial success rate for R21 applications is often lower than for R01 applications.

NLM ESI/NI Policy - R01 applications from ESI/NIs, with Impact scores of 35 or better will be considered for funding. This is 5 points beyond the fundable level for experienced PIs.

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



What are the NLM R01 Biomedical Informatics Research Programs?

- NLM Express Research Grants in Biomedical Informatics and Bioinformatics (R01) (PAR 13-300)
- Research Project Grant (NIH Parent R01) (PA 13-302)
- NLM also participates in several trans NIH R01 programs such as in health literacy, health disparities and basic behavioral sciences.

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

NLM Express Research Grants in Biomedical Informatics (R01) (PAR 13-300)

This program supports research grants that advance the science of biomedical informatics. Informatics is concerned with the optimal organization, management, dissemination and use of information. Biomedical informatics can be defined as the intersection of computer and information sciences with an application domain such as health care, public health, basic biomedical research, or clinical translational research. In most instances, informatics projects of interest to NLM involve the application of computer and information sciences to information problems in a biomedical domain. <http://www.nlm.nih.gov/ep/GrantResearch.html>

The following basic informatics problem areas demonstrate the scope of NLM's research interests:

- Information & knowledge processing, including understanding, translation or summarization of natural language in real-time or near real-time, integration of information from heterogeneous sources.
- Advanced information retrieval, knowledge discovery in databases, discovery mining, and other techniques for in silico discovery and research including approaches for accelerating the linkage of phenomic and genomic information .
- 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.

Examples of application domains include, but are not limited to:

- Health Care, Public Health, Health Services Research, and Disaster Information Management;
- Basic Biological, Social and Behavioral Research;
- Multi-level computational models of biological and clinical processes;
- Translational Research that supports uses of data in electronic health records to support biomedical research, and the translation of biomedical research outcomes through application to problems in clinical care;



- Information Sciences; simulation, user customization, virtual environments, or innovative information techniques.

NLM places a high priority on innovation in the research it supports. While informatics research often involves software development and tool-building, a well-defined research problem and rigorous research design based on preliminary studies are essential elements of any application to NLM's research grant program. An evaluation plan to show potential impact of project outcomes is also highly encouraged. NLM does not support infrastructure development or continued development of existing software tools or knowledge resources.

What are the NLM Express Research Grant Budget and Duration?

- The NLM Express Research Grant has a limit of \$250,000 per year in direct costs
- Applicants may request up to 4 years for the project period.

Research Project Grant (NIH Parent R01) (PA 13-302)

- For investigators whose needs are not met by the NLM Express Research Grant Program, the NIH Parent R01 provides support for rigorous scientific research in biomedical informatics and bioinformatics.
- Since the parent R01 is used throughout the NIH, it is important to include an application cover letter requesting assignment to NLM. Staff at the NIH Receipt and Referral office will consider your request when determining the assignment of your application. This does not guarantee assignment to a particular institute but they try and honor your request.
- Refer to the NLM Express Research Grant information regarding NLM's research grant priorities and scope of interest. <http://www.nlm.nih.gov/ep/GrantResearchParent.html>

What are the R01 Deadlines?

- Deadlines for New Applications: February 5, June 5 and October 5 each year.
- Deadlines for Revised Applications: March 5, July 5 and November 5 each year
- **Important!!!** Deadlines and procedures can change, always check the NLM website and NIH resources for the most current information.

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

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NIH/NLM Grant Processes

What is the lifecycle of a NLM Grant Application?

Below is an illustration of the life cycle of a new NLM grant application. The application is submitted by the Feb 5 deadline through Grants.gov. It is best to submit well in advance of the deadline in case there is any problem with the application. The application will be reviewed by the Biomedical Library & Informatics Review Committee (BLIRC) in June. The BLIRC is NLM's standing study section. An impact or priority score will be available online via NIH Commons in 7 days and the complete Summary Statement is normally available in 4 weeks post BLIRC. A second level of review is conducted by the NLM Board of Regents in Sept or Oct. Final finding decisions are made in October and November. And finally a Notice of Award can be issued in November or December. Please note: Delays in the annual approval of a federal budget can extend the final stages of this process. <http://www.nlm.nih.gov/ep/Lifecycle.html>

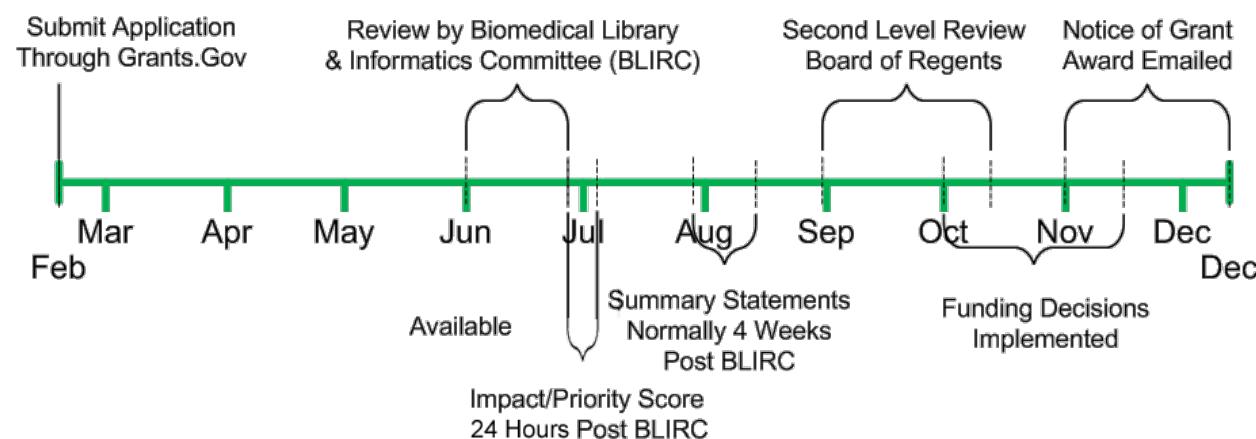


Figure 1. Illustration of the life cycle of an NLM grant application.

What is the NLM Funding Plan?

- **Funding Strategy:** NLM supports as many meritorious competing grant applications as possible, across the array of grant programs it offers. General funding guidelines are established each year based on the availability of funds. Final award decisions reflect considerations of program relevance, portfolio balance, recommendations of the NLM Board of Regents, and availability of funds. In keeping with NIH policy, budgets for awarded grants may receive programmatic or administrative adjustments. These adjustments take into consideration the overall scientific and technical merit of the grant application as well as the appropriateness of the requested budget. Although NLM's training authority is not part of the Ruth L. Kirschstein National Research Service Award (NRSA) programs, stipends and other details of NLM's training programs are modeled upon NRSA.
- **Fundable Range:** NLM uses the overall Impact Score as the primary basis for award decisions on all grant types, along with innovation and potential impact. For experienced investigators, applications with Impact scores 30 or better are the most likely to be funded. For Early Stage investigators and New Investigators seeking their first R01 research grant, applications with Impact scores of 35 or better will be considered for funding. All grant awards are subject to the availability of funds. <http://www.nlm.nih.gov/ep/Payplan.html>



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. You can also contact previous grantees regarding their work. <http://www.nlm.nih.gov/ep/funded.html>

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

For questions about the scientific and technical aspects of your application contact one of the NLM Program Officers.

- For Clinical and Public Health Informatics
Dr. Hua-Chuan Sim, simh@mail.nih.gov
- For Bioinformatics and Translational Informatics
Dr. Jane Ye, yej@mail.nih.gov
- For Consumer Health Informatics and Information Science
Dr. Alan VanBervliet, alan.vanbervliet@nih.gov

For questions regarding the application review process contact the Scientific Review Officers, Dr. Arthur Petrosian, petrosia@mail.nih.gov, or Dr. Zoe Huang, huangz@mail.nih.gov.

For help with the financial and business aspects of an application contact the NLM Chief Grants Management Officer, Dwight Mowery, mowery@mail.nih.gov

For information about specific grant programs NLM supports see the Grant Programs web page at <http://www.nlm.nih.gov/ep/Grants.html>

Tips for Working with NIH Staff

(adapted from Spires, MJ (2012). What to Say – and Not Say-to Program Officers. *The Chronicle of Higher Education*, March 28, 2012.)

The extramural staff (program, review and grants management) are there to help support the best research possible. They have a vested interest in helping researchers craft and implement the best possible research projects. The NIH staff are evaluated on the basis of the quality and success of funded research, not on the number of proposals submitted. NIH funding mechanisms are highly competitive. A brief e-mail to the right NIH staff member sometimes followed up with a phone call can save you from a great deal of time and improve the quality of your proposals.

Following are a few general tips-

- **Be prepared** – Before contacting the NIH staff be sure to carefully study the relevant guidelines and application materials, also check the relevant NLM and NIH web sites for additional information. The federal guidelines can be confusing so talk with more experienced colleagues, mentors, and your institution's grant staff. Federal guidelines change, make sure you are working with the most current version. In general NIH grant awards are made to the institution, not the individual. Each institution has procedures that must be followed. Make friends with the staff in your grants and contracts office. They



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can help you avoid many mistakes and make the process less arduous. Also, participate in grantsmanship training that is available.

- **Be as specific with your questions as you can.** This will facilitate getting the answer to the right question.
- **It is often best to send your question initially in an email and then if needed follow-up with a phone call.** Emails will provide useful records that you can share with your team. Many questions can be quickly answered via an email. It also gives the NIH staff time to properly research an answer to your question. A phone conversation usually must be scheduled which can cause delays. For some issues, however, a phone conversation is needed for back and forth dialog.
- **When contacting scientific program staff regarding a project idea it is best to first thoroughly do your homework.** Review the literature, understand the resources you will need for your project, talk with your colleagues, and carefully review the NIH funding opportunities. Then draft a one page specific aims page that you can share with other researchers. Email this specific aims page to the program or scientific /research contact listed for the funding mechanism you have identified. In your email request a phone meeting. This way you can share your idea with the program staff, who also has a research background in the field, and a fruitful discussion can ensue. This also forces you to evaluate your idea and the resources you will need to successfully implement it.

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Grant Writing Tips

Where do I Find Information About Grants?

Funding Opportunity Announcements (FOA) are posted at

- NLM Extramural web site (<http://www.nlm.nih.gov/ep/index.html>)
- The NIH Guide (<http://grants.nih.gov/grants/guide/>) Tip – Subscribe for updates.
- Grants.gov (<http://www.grants.gov/>)
- Also subscribe to your institution's grant notification service

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 maintains a web page that contains a wide range of useful information for preparing an application and managing an award.
<http://www.nlm.nih.gov/ep/ForApplicants.html>
http://grants.nih.gov/grants/grants_process.htm
<http://www.niaid.nih.gov/researchfunding/grant/Pages/applying.aspx>
- Since NIH grant awards are made to eligible institutions and not to individuals, your institution will have procedures for preparing and submitting NIH grant applications. Become familiar with these procedures early in your planning period. Also participate in grant writing training at your institution or other organizations.



What Grants Have Been Funded by NIH in My Area?

- NIH RePORT provides reports, analyses of NIH Research activities, and access to information about all funded research projects. This tool can uncover funded projects related to your work. Tip- Use the Similar Projects and My Reporter features.

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

A screenshot of the NIH RePORT website. The header includes the NIH logo and the text "Research Portfolio Online Reporting Tools (RePORT)". Below the header is a navigation menu with links for QUICK LINKS, RESEARCH, ORGANIZATIONS, WORKFORCE, FUNDING, REPORTS, and LINKS. The main content area features a large magnifying glass over a globe, with the words "Patents", "Projects", "Publications", "Data", "Visualize", and "Map" overlaid. To the right of the magnifying glass is a section titled "The RePORT Expenditures and Results Tool (RePORTER)" with a brief description and a search bar. Below this are several icons representing different data categories: AWARDS BY LOCATION, NIH DATA BOOK, FUNDING FACTS, CATEGORICAL SPENDING, REPORT CATALOG, SPECIAL REPORTS, and ABOUT REPORT. At the bottom left is a "CLICK TO VIEW" button for the RePORTER tool. A footer note states: "In addition to carrying out its scientific mission, the NIH exemplifies and promotes the highest level of public service."

Figure 2. NIH's RePORT web page.

You can search RePORTer using many query strategies ranging from MESH terms to names of Investigators.

A screenshot of the NIH RePORTER search interface. On the left, there is a sidebar with a yellow background containing a list of search strategies: "Search by" followed by "MESH terms", "Key words", "Organizations", "States", "Investigators", "Mechanisms", "Solicitations", and "Institutes". The main search interface includes fields for "Project Number", "Principal Investigator (Last Name, First Name)", "Organization", "DUNS Number", "Department", and "Additional Institution Types". There are also dropdown menus for "Funding Type", "Agency Ref.", "Award Type", "Award Year", "Exclude", "Study End", "MAP", "Funding Type is P-A", and "Public Health Reference". On the right, the search results are displayed under the heading "NIH RePORTER Version: 6.4.0". The results are filtered by "QUERY" and "BROWSE NIH". A "MATCHMAKER BETA" tab is also present. Below the search results, there is a section titled "Use Matchmaker to find similar projects" with instructions: "Enter abstracts or other scientific text and Matchmaker will return a list of 100 similar project submitted text. Up to 15,000 characters are permitted." A text input field labeled "Enter your Text:" is shown.

Figure 3. Can search NIH Reporter for funded projects with similarities to your project using multiple strategies.

You can also search NIH RePORTER for similar projects with similarities to your concept/proposal by using the MatchMaker tool. Enter abstracts or other scientific text and Matchmaker will return a list of 100 similar projects from RePORTER. These matches are based on the terms and concepts used in the submitted text.



How does NIH review a grant?

When writing an application you need to understand how it will be reviewed and write with your audience, the reviewers, in mind. NIH provides many excellent resources to learn about the review process.

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

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

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

Your eRA Commons Profile is Important!

eRA Commons is the primary tool NIH uses to communicate with applicants, awardees, university grants officials, and reviewers. This is where you will track your application from submission to award. It is also where you will obtain the impact score and summary statement following a review. All New Investigators should update their eRA Commons profiles to ensure that you are given appropriate consideration on R01 applications. Your ESI/NI status is automatically determined by the information in eRA Commons. To create an eRA Commons Profile contact your institution's office of research support or grant administration.

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

Writing Grants That Get Funded

The Research Plan should answer 6 essential questions, these are:

- What important problem is being addressed?
- What do you intend to do to address the problem?
- What has already been done?
- Is the work feasible yet novel?
- How will you do it?
- Do you have the team and the resources to do it?

Successful applications typically are:

- Impactful!
- Well-focused and explicitly written with milestones, metrics, contingencies
- Not overly ambitious
- Understandable by a non-expert, intelligent reader
- Well justified (for people, time, budget)

Tips for Preparing NLM Research Applications - Adapted from Dr. Jason Moore, Dartmouth Univ., Dr. Moore is a successful NIH/NLM grantee and was a member of the NLM Biomedical Library & Informatics Review Committee. <http://compgen.blogspot.com/search?q=grant>

- **Articulate an important and timely informatics question.** Be forward-thinking. Make sure that answering your particular scientific question will have an impact on biomedical research or clinical practice.
- **Propose new and novel informatics methods.** Innovation is very important. Know the literature and where your new method fits in.
- **Avoid purely applied software engineering projects.** Don't focus your grant only on building a database, web server or software package. The majority of the grant must be



focused on new and novel algorithms or methods. NLM is looking for new informatics methods.

- **A solid plan for how you will evaluate your novel informatics method is critical.** Don't just propose a new algorithm or method. How do you know that your novel method is working better than what people are currently using? What significance criteria will you use? Don't forget the details of how you will actually do the analysis.
- **Application to real data is important.** Simulation studies can be very important for a project. However, it is typically important to also systematically test your strategy/algorithm with real biomedical data.
- **Provide as many details as possible about your new and novel informatics algorithm or method given space constraints.**
- **Be productive!** Your reviewers need to be convinced that if you are awarded a grant that you will actually make a contribution to the professional literature.
- **Significance, innovation and approach have the biggest impact on your final score.**
- **Make sure you have good collaborators with real effort budgeted to cover your weaknesses.** Generally a significant collaborator might have 5-10% effort or more based on the project tasks. Minimal effort by important project collaborators may raise concerns among the peer reviewers.

A few additional Grant preparation Tips

- **Take advantage of training in grant writing: both courses and practical experience.** Obtain a sample of a successful or highly scored application from your mentors, these are very useful when you are writing your own applications.
- **Do your homework – conduct a thorough analysis of the literature.** It is often valuable to involve a skilled medical or reference librarian in the process.
- **Have colleagues critically review the application throughout its development stages.**

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Good Grants Get Considered, Outstanding Grants Get Funded

Questions and Answers from the webinar are available at

http://www.nlm.nih.gov/ep/NI_ESI.html.