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

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

Outline

Career Development Awards

NLM Career Development Support

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

NIH Pathway to Independence Award (K99/R00) (PA-18-398)
(https://www.nlm.nih.gov/ep/pathway.html)

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

NLM Career Development Award in Biomedical Informatics and Data Science (K01) (PAR-16-204) (https://www.nlm.nih.gov/ep/GrantInformatics.html**)**

- Provides support for promising junior investigators as they launch their careers in biomedical informatics 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. Junior investigators (i.e. early stage of faculty positions within 3 years of initial appointments at time of application submission or resubmission). Must have completed their research training. At the time of award, the institution must demonstrate that the applicant will have the academic title, space and other resources necessary to apply for research project grant (e.g., R01) level funding. 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 Support: 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 $100,000/year plus fringe benefits Research Support: 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. Remaining 3 person-months (25%) in teaching and/or clinical duties.	**K01** 9 person-months (75% full-time professional effort) on the award. Remaining 3 person-months can be divided among other duties.

Comparison of K99/R00 and K01 Programs	
K99/R00	**K01**
R00 A total of 75% of full-time professional effort to research. May devote effort to other research projects. 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	

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 (first) assistant professor (or equivalent) position for less than 3 years.
- Provide "protected time" for junior investigators as they launch their research careers.
- NLM supports research career development in clinical informatics, public health informatics, translational bioinformatics, consumer health informatics and data science.

Writing a Career Development Award Application

- Before starting to write your application, carefully read the relevant funding opportunity announcement (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/pathway.html or https://www.nlm.nih.gov/ep/GrantInformatics.html and contact the Program Officer listed for your area of research interest.
- Your application for K99/R00 and K01 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 NIH biosketch (CV), research and career plans, and reference letters. Make sure your biosketch 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 protection of human subjects, if applicable.

Mentor(s), Consultants(s), Collaborator(s) - 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 to launch your career or 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 can 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:
https://www.nlm.nih.gov/ep/awardspathway.html
https://www.nlm.nih.gov/ep/AwardsCareerDev.html

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ESI/NI Research Grants in Biomedical Informatics and Data Science

Who is a New Investigator (NI)?

A Program Director or Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously received substantial, independent funding from NIH. Substantial independent funding is considered to be a R01 or equivalent award. R21s, R03s or K awards do not impact the New Investigator status.

Who is an Early Stage Investigator (ESI)?

An ESI is a Program Director/Principal Investigator (PD/PI) who has completed their terminal research degree or 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. A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found here.

What is the NIH ESI/NI Policy?

Applications from ESIs/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 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 ESIs/NIs, with Impact scores of 32 or better will be considered for funding. This is 7 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 16-404)
- Research Project Grant (NIH Parent R01) (PA-18-484)
- NLM also participates in several trans NIH R01 programs such as in health disparities and basic behavioral sciences.

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

NLM Express Research Grants in Biomedical Informatics (R01) (PAR 16-404)

NLM offers support for innovative research in biomedical informatics and data science. The scope of NLM's interest in the research domain of informatics is broad and interdisciplinary, developing methods and approaches in biomedical computing, data science and related information fields for application domains of health and biomedicine, including health care delivery, basic biomedical research, clinical and translational research, precision medicine, public health, biosurveillance, health information management in disasters, and similar areas. NLM defines biomedical informatics as the science of optimal representation, organization, management, integration and presentation of information relevant to human health and biology, for purposes of learning, sharing and use. Informatics projects of interest to NLM involve the application of computer, data and information science concepts to research problems in a biomedical domain.

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, automated assignment of metadata
- Integration of very large data sets and/or heterogeneous data types to support discovery, learning and health care
- Advanced information retrieval, knowledge discovery in very large or heterogeneous data sets, discovery mining, and other techniques for in silico discovery and research including approaches for accelerating the linkage of phenotypic and genomic information
- Incorporation of machine intelligence into knowledge tools and resources for use by health care providers, scientists and consumers
- Models of complex data, simulations, information visualization and presentation approaches to enhance decisions, learning or understanding, particularly in large and heterogeneous data sets

- Innovative approaches for ensuring accuracy, privacy and security of clinical and biomedical research data
- Support for consumer and patient engagement in understanding, accessing, sharing, protecting and using their own health data

An application to NLM's research grant program should focus on a well-defined research problem and propose a rigorous research design, based on preliminary studies, which will result in innovations that advance what is known in the field of informatics and have the capacity to improve human health. NLM will 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 used to test ideas and methods.

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-18-484)

- 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 data science.
- Since the parent R01 is used throughout the NIH, it is important to include an Assignment Request Form 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 specific institute but they often 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/GrantResearch.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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Overview of 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 to the February 5 (R01) 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 Informatics, Library and Data Science Review Committee (BILDS) in June. The BILDS is NLM's standing study section. An impact score will be available online

via NIH Commons up to 7 days after the review meeting. The Summary Statement is normally available in 4 weeks post BILDS. A second level of review is conducted by the NLM Board of Regents in September. Final award decisions are made in October or November. Finally, a Notice of Award will be issued in November or December. Please note: Delays in the annual approval of a federal budget can delay the final stages of this process.
http://www.nlm.nih.gov/ep/Lifecycle.html

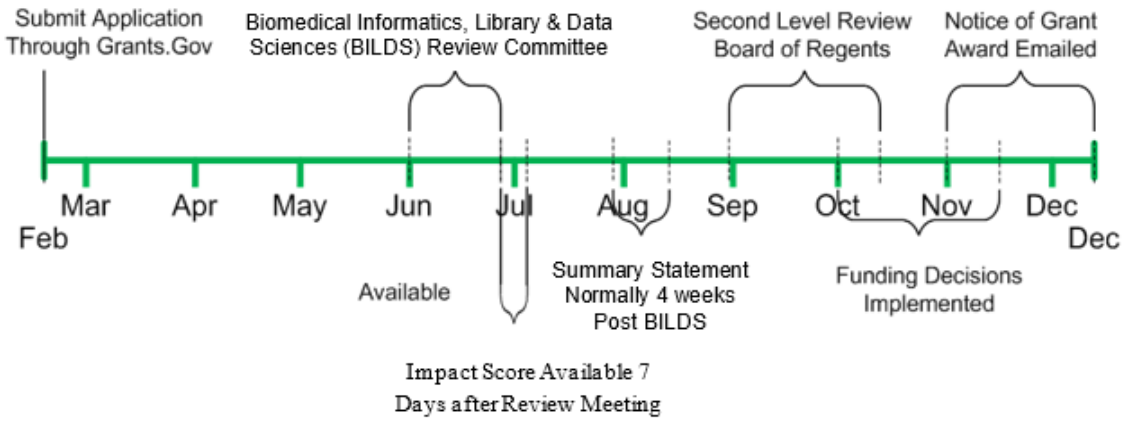

Figure 1. Illustration of the life cycle of an NLM grant application.

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, with priority on research and training. General funding guidelines are established each year based on available appropriated 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 of proposed research. For experienced investigators, applications with Impact scores 25 or better are the most likely to be considered for funding. For Early Stage investigators and New investigators seeking their first R01 research grants, applications with Impact scores of 32 or better will be considered for funding. For career transition awards and fellowships, applications with Impacts scores of 28 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 Application… Who Should You 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 VanBiervliet, alan.vanbiervliet@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 program staff (program, review and grants management) are here to help support the best research possible. They have a vested interest in helping researchers craft and implement the best possible research projects. 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 a great deal of time and improve the quality of your proposals.

Following are a few general tips-

- **Be prepared** – Before contacting 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 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 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 right 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 description of your specific aims that you can share with other researchers. Email this specific aims page to the program or scientific/research contact listed for the funding opportunity announcement 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.
  http://www.nlm.nih.gov/ep/ForApplicants.html
  http://grants.nih.gov/grants/grants_process.htm
  https://www.niaid.nih.gov/grants-contracts/apply-grant

- 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 "Matchmaker" to find similar projects.
  http://report.nih.gov/index.aspx

Figure 2. NIH's RePORT web page.

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

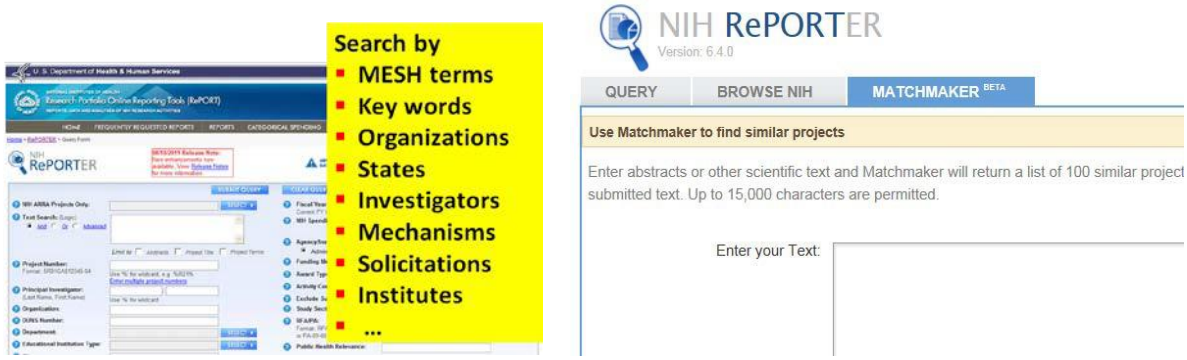

Figure 3. Search NIH RePORTER for funded projects with similarities to your project.

You can also search NIH RePORTER for 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 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 Early Stage Investigators or 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, and 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, University of Pennsylvania. Dr. Moore is a successful NLM/NIH grantee and a former member of the NLM Biomedical Informatics, Library and Data Science Review Committee**.**

- **Articulate an important and timely informatics question.** Be forward-thinking. Know what is hot and what is going to be hot. 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. Most of the grant must be focused on new and novel algorithms or methods. NLM is looking for new informatics methods.
- **Compare your algorithm or method to state of the art in field.** Don't just propose a new algorithm or method. You need to have a baseline approach to compare it to. How do you know that your novel method is going to work better that what people are currently using?
- **A solid plan for how you will *evaluate* your novel informatics method is critical.** How will you know whether your approach is truly working better than the state of the art in

the field? Be very specific about how you will evaluate your approach and what the criteria are for concluding it is indeed working.

- **Application to real data is important.** Simulation studies are necessary but not sufficient. Describe the biomedical data you will analyze and how you will improve your method based on results. Don't forget the details of how you will actually do the analysis. What significance criteria will you use?

- **Provide as many details as possible about your new and novel informatics algorithm or method given space constraints.** Reviewers are unlikely to give you the benefit of the doubt, especially if you are a junior investigator with a poor track record. Tell the reviewers exactly how you are going to develop, extend, modify, apply and evaluate your informatics approach.

- **Be productive!** Reviewers want to see a good paper trail from your previous faculty, postdoc and graduate student research. Reviewers need to be convinced that if you are awarded a grant, you will actually make a contribution to the literature. It is well worth those extra evenings and weekends to get your papers submitted.

- **Innovation and approach have the biggest impact on your final score.** The NLM did a factor analysis of scores for significance, innovation, approach, investigator and environment and their relationship with overall impact score. Innovation and approach had the highest correlation with the overall 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 health science 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