Executive Report:

R15 AREA Grants: How to Determine Your Eligibility & Write a Winning Proposal







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Dr. Sridhar Mani (Shri) served as co-author of this report. Dr. Sridhar Mani (Shri), is a Professor of Medicine and Genetics at the Albert Einstein College of Medicine, Bronx, NY. He was the Founding Director of the Phase I Experimental Therapeutics Program at the Montefiore/Einstein Cancer Center. He received his MD degree (1990) from the Mount Sinai School of Medicine, New York, NY followed by further postdoctoral training in Internal Medicine (Board Certified)(1990-1992) and Hematol-ogy/Oncology (Board Certified, Onc 1992-1995) at Yale-New Haven Hospital, Yale University School of Medicine, New Haven, CT. Subsequently, he was the program leader for gastrointestinal oncology at the University of Chicago, Chicago, IL. During his tenure as a medical student, he did summer work at Rockefeller and then as a postdoctoral fellow at Yale, he studied under Dr. Eric Fearon on the role of DCC in colon cancer. In 1998, he returned to NY (Albert Einstein College of Medicine) to develop a Phase I Program in Oncology and a laboratory effort on drug metabolism. He is the recipient of the Clinical Investigator Award from the Damon Runyon Foundation (New York) and presently is an NIH funded Investigator on the role of orphan nuclear receptors in metabolism. He is a permanent member of the Developmental Therapeutics Study Section of NCI and serves as an editorial board member for Cancer Research, Clinical Cancer Research, Clinical Cancer Research, Molecular Endocrinology, Molecular Endocrinology, Molecular Cancer Therapeutics, and Journal of Clinical Oncology.

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Best Regards,

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Introduction

The Academic Research Enhancement Award (AREA), also know as the R15, is a highly-competitive (but attainable) grant for supporting hands-on student involvement in research. For the R15, composing a winning proposal is only half the battle – you'll need to do some work upfront to determine your eligibility for the grant.

According to the NIH, the R15 grant program has three main goals:

- 1. To support meritorious research;
- 2. To strengthen the research environment of the institution; and
- 3. To expose students to research.

If your research is meritorious, it should be a renewable form of investigation and should have an impact on peer-reviewed contributions, according to Dr. Sridhar Mani, Professor of Medicine and Genetics at the Albert Einstein College of Medicine in the Bronx, New York.

The second goal of the AREA award program is enriching the institutional research environment. The NIH sees this grant as providing "seed money" to foster more long-term investigation that's sustainable, Dr. Mani explains.

And the third goal is to expose students to this research. You should provide evidence of the students performing the research and of a learning environment in your lab. Because the R15 is a renewable grant, the NIH wants to see the students co-authoring publications and presentations.

Like most other "R" grants, the AREA award is renewable with competing continuations. The grant also allows special supplements for qualifying students with disabilities and minority students.

The R15 grant has a \$300,000 maximum direct cost per project period of up to 3 years, plus your negotiated F&A (indirect cost) rate. If your direct cost is \$250,000 or less, you can opt for a modular budget in your proposal. So you would not have to provide a detailed budget in this case. If your direct cost is higher, however, you can't do a modular budget and would instead need to provide a detailed budget with a strong budget justification in your application.

NIH reviewers use the standard five criteria (Impact, Significance, Investigators, Environment and Approach) for evaluating R15 proposals, with a specific emphasis on AREA program goals. And you have 12 pages max for outlining your Research Strategy.

Your important R15 deadlines for electronic receipt dates are Feb. 25, June 25 and Oct. 25, with AIDS-related research proposals due Jan. 7, May 7 and Sept. 7.

But before you jump into composing your R15 proposal, you'll need to check your eligibility status and ensure that your research project meets all the special requirements that come with AREA awards.

Section I:

Check Your Eligibility & Prepare Before You Apply

The NIH has several different eligibility parameters for the R15 grant. First and foremost, your home institution must be a baccalaureate or advance degree granting institution.

Secondly, if your institution received \$6 million or less in research grants in four out of the last seven fiscal years, you can apply for the R15. This figure does not include "C," "S" and "G" grants. Check with your grants office to find out whether your institution qualifies for an R15, Dr. Mani advises.

But then you should cross-check with the NIH on your institution's eligibility status. The NIH keeps an updated a list of institutions that are ineligible to apply for the R15 based on this criteria, which you can view online at http://grants.nih.gov/grants/funding/area_ineligible.xls. And remember that the majority of your work must be done at this home institution.

Additionally, your institution must fall within NIH's identified health professional schools and colleges that are eligible for the R15, which consist of:

- · School/college of medicine;
- · Veterinary medicine;
- Podiatry;
- Nutrition;
- Dentistry;
- Osteopathy;
- Pharmacy;
- Public Health;
- Optometry;
- Nursing;
- · Chiropractic medicine; and
- Allied health.

Finally, inline with the AREA program's three main goals, you must believe that you are doing "meritorious research" and foster a student learning environment that's tied to your research, Dr. Mani stresses. These two items go hand-in-hand. Your meritorious research should make an impact on your field, be publishable and be peer-recognized, while the students -- undergraduates and graduate students -- should have hands-on learning experiences with the research project.

Make Sure the Right Institute Accepts R15s

Also, keep in mind that not all NIH institutes and centers accept R15s. Mainly, the Fogarty International Center (FIC) and the National Institute on Minority Health and Health Disparities (NIMHD) are the ones that do not participate in the AREA grant program. The following institutes and centers do participate:

- National Center for Complementary and Alternative Medicine (NCCAM)
- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Human Genome Research Institute (NHGRI)
- National Heart, Lung, and Blood Institute (NHLBI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute on Drug Abuse (NIDA)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)

- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Library of Medicine (NLM)

Steps for Determining Eligibility

So here are your most important steps to determine whether you're eligible for the AREA program:

- 1. Review PA-12-006 (reissue of PA-10-070) carefully;
- 2. Contact your grants office for your institution's R15 eligibility status;
- 3. Cross-check the list of AREA eligible and ineligible institutions on the R15 home page;
- 4. Prepare a short summary (one page) of your research, resources and checklist components;
- 5. Present the summary to your Grants Officer; and
- 6. Present the summary to the program official at the NIH.

Before You Submit Your R15 Application...

After you determine that you are indeed eligible to apply for the R15, you'll need to take a few preparatory measures before you begin the application. Mainly, you'll need to garner institutional support and commitment -- which is a crucial part of winning AREA funding.

So before you even begin to think about putting an application together, identify a senior faculty member, business office administrator, or someone in the Deans Office who previously supported and submitted NIH grants, Dr. Mani advises. Sit down with this person and go through the R15:

- Guidelines;
- Checklist;
- Deadlines;
- · Submission & corrections process; and
- Review criteria

Your institution really needs to become involved in the R15 application process, particularly when you're drafting the resource page, equipment and student profiles -- all of which you must address to satisfy the Environment review criterion. Your institution should also encourage only selective submissions for the R15, because of the "two strikes" rule. Therefore, you should apply for the AREA grant only when you feel competitive and confident.

Rule of thumb: After one resubmission, don't attempt another try unless you have a 50-percent change in the grant proposal's content. You have only two resubmissions available to you for the R15.

You must demonstrate in your proposal that your institution provides and supports an environment that facilitates faculty success -- this is essential to nabbing a high score. For example, you can talk about in your proposal what your institution does regarding start-up packages, student environment, course work and credits, faculty promotions, tenure decisions based on independent and/or collaborative research, Dr. Mani says.

Draft a Cover Letter & Communicate with the Program Officer

Show this institutional commitment and support upfront in a cover letter to the NIH. You need to engage the program officer in reviewing your cover letter and discussing with you the best institute/center and study section for your particular research area, Dr. Mani says. Also discuss the study-section reviewers' areas of expertise and any potential conflicts with them reviewing your proposal. Bottom line: You don't want anything to stand in your way of getting a high score.

In your one-page cover letter, you must include a brief description of your research, so when the receipt & referrals (R&R) officer sees your application, he can make the appropriate assignment to a study section automatically.

Another point to bring front-and-center for reviewers is your institution's ability to encourage mentorship, providing a solid platform for faculty interactions in research. Show that your institution allows and supports NIH workshop attendance, and encourages pre-submission discussions with NIH staff via email and submission of a specific aims page.

Prepare for Your Application: Additional Steps to Take

Finally, take some time to become familiar with the goals and specific focus of the NIH, applicable institute/ center and appropriate Center for Scientific Review (CSR) goals. Figure out whether your research fits with these goals and focuses, Dr. Mani advises. The best fit will weigh heavily on your ultimate score.

To perform this upfront analysis:

- Understand what the NIH defines as "any research" impacting "health" -- visit <u>http://www.nih.gov/about/mission.htm;</u>
- Look up specific research missions by institute -- on the NIH website's home page, click on "Institutes at NIH" to view descriptions of each institute and their missions;
- Look up the CSR's (<u>http://cms.csr.nih.gov/AboutCSR/</u>) Review Group Descriptions -- click on "Peer Review Meetings" in the right corner, and then on "Review Group Descriptions," which will give you all the study sections;
- Look for special AREA applications review sections and if your chosen study section has reviewed R15s before; and then
- Look at study sections with expertise that would cover your research area.

So in your cover letter, list all the institutes and CSR review groups that could potentially review your application and give you the most favorable response. You might choose one, two or three institutions and groups.

Next Step: Generate preliminary data that supports both your research and preferably the students, Dr. Mani says. And show that all tools and reagents are readily available, so that reviewers know not only that your aims and research goals are feasible, but also that you have the right tools for the job and you can achieve your goals in the one- to three-year timeframe.

Most of all, focus on student recruitment and training. Just like other grant proposals, you need to balance the enthusiasm and the commitment factor, Dr. Mani advises. ■

Section II:

Win the R15: Compose a Perfect Proposal

You've confirmed that you are indeed eligible to apply for the R15 grant and you've selected the right institute/ center and study section reviewers for your proposal. Now, you can finally begin to craft your R15 application. The NIH scores R15 proposals based on the basic five criteria, but two criteria are especially important to reviewers for this grant: Investigator(s) and Environment.

The following is a basic outline of what your R15 application should look like:

Specific Aims (1 page) Research Strategy (12 pages)	 Include an introductory paragraph with a hypothesis, and then the rationale for the aims and at least one sentence explaining what you'll do if you complete this grant project successfully. Significance (3/4 page max) Innovation (1/2 - 3/4 page max) Approach (10 pages max) For each Specific Aim: Introductory Paragraph Justification & Feasibility (cite review literature as a background and present your preliminary data) Research Designs Expected Outcomes (for you and for the students) Potential Pitfalls & Solutions (for you and for the students) Timetable (1/4 page) Future Directions (1/4 page optional but recommended) Progress Report (for renewal applications only) 	
Introduction (1 page max)	This is for revisions/resubmissions only. You should organize the introduc- tion according to review criterion, and be diplomatic yet factual and not combative.	
Biosketch	Include your Personal Statement, which should emphasize the AREA- specific goals, as well as why are you well-suited to be the PI, particularly in training students.	
Resources Page	Describe the environment to answer reviewers' questions about whether given the resources at your disposal you can feasibly complete the research, and whether the students will enhance their learning and con- tribute in that environment. Include your institutional commitment here as well.	

What R15 Reviewers Scrutinize the Most

Although some of the main review criteria (see <u>http://grants.nih.gov/grants/peer_review_process.htm#Criteria</u>) have clearly assigned areas in the proposal where you can address your important points. But some criteria have no designated areas in the proposal. Here are the main review criteria and where in the proposal you need to address each one:

- Significance: Research Strategy Significance subsection
- Investigator(s): Biographical Sketch Personal Statement
- Innovation: Research Strategy Innovation subsection
- Approach: Research Strategy Approach subsection
- Environment: Facilities & Other Resources Environment subsection

Illustrate Your Research's Significance

As you're describing your research project's significance, keep in mind that reviewers are looking for you to prove that your work is meritorious and appropriate for the students available. You'll also need to illustrate significance by proving that your project addresses an important problem or a critical barrier in the field, Dr. Mani says.

How is your research cutting-edge? What kind of impact will your research project have on your field? Reviewers will try to gauge the likelihood of you successfully meeting your project's goals.

Also explain in the significance subsection how achieving your project's aims will further drive scientific knowledge, technical capability and/or clinical practice, the NIH stresses. How will achieving the aims alter existing knowledge impacting your specific field?

Make the Investigator(s) Shine

R15 reviewers place a lot of emphasis on the investigators. You'll need to prove that the PDs/PIs, collaborators and key personnel involved are "well-suited" for the research project. Moreover, why are the investigator(s) well-suited for teaching and training students?

You must show evidence of the investigators' balance of both research and teaching experience, over the past five years. Also, you must present evidence of successful research mentoring over the past five years. These factors will weigh heavily on your scoring.

Additionally, if you have multiple PIs/PDs involved in the research project, you must show how their expertise are "complementary" and not the same. If you and the other investigator have the same expertise, this will reflect negatively in your scoring. And unlike R01s, R15s won't recognize Early Stage Investigators (ESIs) and New Investigators (NIs).

Show Your Work's Innovation

How will your research project change the current standards or paradigm in your field? The answer to this question is your "innovation." Reviewers are looking for something groundbreaking, and not just "new."

For innovation, you need to prove that your research will substantially refine or improve the existing methods in your field, which would change the direction of research. And you don't need to try to prove that your research is "vertically innovative," Dr. Mani says. Instead, you might want to prove that your project will move the field forward incrementally, through the project's necessary set of experiments that will impact your field.

Sell Your Approach

Above all, you must prove that your approach is well-reasoned, feasible and logical. Show reviewers that you can in fact complete the project goals given your resources. List out specific aims for your project, with each aim independent yet linked to the others. Avoid making each aim dependent upon the other, so that if one aim fails, the others will too.

Create sections for each aim dealing with "Expected Results" and "Potential Problems & Solutions." Show that if the project is early in development and there is a high risk but also a high reward, the strategy that you're using is feasible in your environment.

Also in your approach, you must include the "Protection of Human Subjects" and "Minorities/Gender/Children Inclusion" sections if you have a clinical project. Your institution can help you with these.

Focus on Your Environment to Nab a High Score

Because reviewers pay special attention to the environment criterion in R15s, you should spend some extra time on this area in your proposal. Show that you have the appropriate scientific environment, and reiterate the institutional support and commitment, particularly regarding teaching and research with students.

Provide a description of your university, including its mission, demographics and degree programs. You can provide URLs where applicable. Make this part approximately four to five paragraphs total. Additionally, describe the departmental environment, including student researchers, active student chapters, scholarships and grants for students, student presentations, available equipment, opportunities for inter-departmental or inter-university collaboration

Then, give the number of graduates enrolled in medical, dentistry, pharmacy, nursing or other health program or industry. Make this section one paragraph. Also provide a profile of the students that includes the percentage of students seeking a bachelor degree or post-baccalaureate degrees, over past 5 years.

Detail the unique features of your institution's environment that shows why you should get the R15 award. For example, say your dean allows you to forgo teaching for the first year in support of developing your project but still pays your salary. And describe how getting the grant will impact PI/PD development, as well as the research environment in your institution's academic sector.

Dr. Mani also recommends including:

- A description of the likely impact this award will have on enhancing the research environment and promoting successful research among your institution's student body;
- Your expectations for future growth (if applicable);
- A description of the university-level program for faculty/undergraduate research recognized by the highest office at your institution; and
- An example of new university-wide internal grants program to encourage interdisciplinary research by faculty who have primarily engaged in teaching. ■

Conclusion

The R15 award is very competitive, but for good reason. As you're going through the steps toward submitting an AREA application, always keep in mind that this is a research grant, not a teaching grant. The R15 is not for all projects -- or for all investigators. So be sure to double-check your eligibility for the R15 grant before you start laboring over the application process.

Through the AREA program, the NIH is looking to fund primarily promising investigators who have limited resources and whose institution has had limited research funding. The grant program aims to encourage talented investigators in sharing their knowledge and innovation with students through hands-on experiences.

The three main goals of the R15 grant (supporting meritorious research, exposing students to research and strengthening the institution's research environment) clearly endeavor to encourage students to continue their interests in biomedical research, subsequently becoming talented investigators themselves in the future.

Appendix A: NIH Key Contacts for R15s

NIH Institute/Center	Contacts
NCCAM	Dr. Partap S. Kalsa
	(301) 594-3462
http://www.nccam.nih.gov	khalsap@mail.nih.gov
	George Tucker
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Appendix B: R15 FAQs

- Q: On the R15 application, how do I determine the "start date?"
- A: The earliest project start date will depend on when you submit your R15 application. There are three cycles in each fiscal year and an earliest project start date for each cycle:
 - Cycle 1: September or December
 - Cycle 2: April
 - Cycle 3: July
- **Q:** In terms of the impact for R15s, is the impact on the field or the number of citations of your published works more important, or is the impact on student learning considered as well?
- A: Both the impact on your field and on student learning is important for R15s. In comparison to R01s where reviewers look at impact in terms of the number of high-level publications you have, in R15s both factors are important. You need to show impact on student learning, as well as some degree of peer-reviewed publications.

Keep in mind that reviewers tend to lean toward more importance on student learning. So there is a heavier emphasis on teaching and learning, and this is what you'd want to really maximize and show in your R15 proposal.

- Q: In my application, do I need to include detailed plans to train students?
- A: Your R15 application should not include training plans. Although one of the AREA program's main goals is to expose students to research, the grant is a research award, not a training or teaching award. Instead, focus on your plans to expose students to hands-on meritorious research.

- **Q:** How can I address impact in all five review areas significance, innovation, investigator, environment and approach?
- A: Under significance, you would need to present your research as not simply looking at something that's already been done and is known in the field. You would show that your research is adding to the field to show impact in innovation as well. You don't necessarily need to prove so much innovation that you've discovered a whole new paradigm, because the R15 isn't that type of grant.

For approach, you can show impact by detailing how feasible your work is, that you have the tools in place to achieve your research aims and that you have the preliminary data and students ongoing. Prove that the students will have a clear plan and will reach goals at the end of the grant. Also, show that you've explored the potential pitfalls and problems that you might encounter in your research. Under environment, show impact by offering letters of support to prove that you have institutional commitment, collaboration from your university and an environment for student learning.

- Q: What reports do I need to submit for the R15 grant?
- A: You must submit a Progress Report annually, on or before the anniversary of the project period start date for the award. You'll receive an email notification about two months before the report is due. See <u>http://grants.nih.gov/grants/policy/myf.htm</u> for more information.
- **Q:** When you're deciding which institute and study section is appropriate for your proposal, does one study section cover more than one institute? Or does one institute cover more than one study section?
- A: Typically, one institute covers one study section. In some cases, however, if you assign your proposal to a study section and to one institute, it might still get reviewed under that study section but under another institute.

For example, you have an R15 project that fits the missions of both the NIDDK and NCI, but from a study section point of view it's most applicable for Developmental Therapeutics (DT). If the project is slanted more toward cancer, the proposal would go to the NIDDK DT study section. If the research is slanted more toward the NIDDK's mission, the grant proposal is assigned primarily to the NIDDK and reviewed under a DT.

Really, you would need to discuss the details with your program official and SRO. Be sure to communicate your exact mission and the nature of your research in your cover letter.

- Q: Should I have a separate institutional profile and a PI lab profile of students?
- A: Yes, because this is helpful for the reviewer. Reviewers looking at an R15 application will want to know what the institution as a whole do with students and what the individual lab does with students. Also, the reviewers want to know that the institution supports the PI in furthering his goals with his students.
- Q: Can I transfer an R15 grant to another institution?
- A: You can transfer AREA grants to only other AREA-eligible institutions. There are many other factors involved in permitting an R15 grant transfer to another institution. You must contact your Program Officer as soon as you know that you're considering a transfer.

Also, keep in mind that if you have multiple PDs/PIs involved in the proposed R15 project, each PD/PI must have an appointment at an AREA-eligible institution and may not be the PD/PI of an active NIH grant at the time of the R15 award. ■



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