Fundamentals of the NIH Grant Process & Need to Know Resources

Sheri Cummins: NIH is the largest public funder of biomedical research in the world.

Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

In fiscal year 2019 NIH awarded over 55,000 extramural grants totaling more than $29.4 billion in funding. That funding supported research at 2,700 organizations throughout the U.S. and abroad.

All of us together have a shared responsibility for the appropriate stewardship of that tremendous investment.

I’m Sheri Cummins in the Office of Extramural Research. For the past 15 years I’ve helped countless applicants and grantees navigate the NIH grant process and our many resources.

If you are new to working with NIH, then chances are you’ve asked one, or maybe all, of these questions.

* Where do I start?
* Where’s the funding?
* Where do I turn when I need help or advice?
* What opportunities are available and how can I find them?
* What’s the application process & how long does it take?

These are precisely the questions we’ll cover and I’ll point out those need-to-know resources along the way.

Where do I start?

You’ll find all you need to know on the NIH Grants & Funding website.

Not familiar with an NIH term or acronym? Look it up in our Glossary.

Have a question? See if it’s answered in our FAQs.

You’ll also find our grant application instructions,

NIH Guide to Grants & Contracts

RePORTER and other tools to explore funded projects,

General grants process information, and

Policy and compliance pages.

We’ll talk more about many of these resources. For now, just be aware that it’s all there.

Where’s the funding?

To answer this question, you need to know a bit about how the National **Institutes** of Health is structured. NIH is made up of 27 different institutes and centers (or ICs) of which 24 offer funding opportunities and award grants. This is a very important point. NIH funding is made through these institutes and centers.

Each IC has its own mission, priorities, budget, and funding strategy which are stated on each IC’s website.

The vast majority of grant processes and polices apply across NIH. That said, you will find some variability from one IC to the next.

Do your homework. Identify which ICs might be interested in your area of science. Determine if your proposal fits within that ICs mission and priorities. Find out what’s already been funded? By law, NIH can’t support a project already funded or pay for research that’s already been done.

You need to know and be able to articulate what sets your proposal apart.

In 2019 our overall success rate for competing research grants was around 20%. This is a highly competitive process.

Let’s talk about finding that target IC. We have a great tool, called RePORTER at projectreporter.nih.gov, that can help identify ICs with potential interest in your area.

RePORTER allows you to explore decades of funded awards. If you’ve used RePORTER then you already have an idea of the wealth of information you can glean from it.

If you’ve never used it, I recommend starting with the Matchmaker tool.

You give Matchmaker up to 15,000 characters of text which you can pull from your abstract, specific aims, or other source that describes your proposed research and Matchmaker returns the awarded projects that most closely match that text.

The results include graphs along the top for the ICs, activity codes and study sections associated with those projects.

This example clearly has a strong match with NIAD - our National Institute of Allergy and Infectious Diseases. You can click on the NIAD bar in the graph and the results automatically filter to just those projects funded by that IC. You can drill down into each project and read the abstract and other details to get a feel for what’s been funded.

And at the top, you can even move from the Projects tab to the Program Officials tab to get a list of NIH scientific staff whose portfolios include the identified projects.

Using the RePORTER Matchmaker tool, with just a few queries and clicks, we identified both a potential funding institute and staff contacts. Pretty cool, huh?

Let’s take a moment to talk about reaching out to NIH and answer the question where do I turn when I need help or advice?

And notice I didn’t say “**if**” I said “**when** you need help or advice.”

There’s a lot to learn and know. Expectations are high. At some point, you’re gonna need help.

We just saw one way to identify potential Program Officials using Matchmaker. Program Officials are one of three players in the NIH Extramural Team. The other two are Scientific Review Officers and Grants Management Officers.

Each has a role in the application and award process.

I’ve solicited a little help from some colleagues to talk about these various roles. Let’s listen to what they have to say.

Mike Sesma: I'm Mike Sesma. I'm a program officer at the National Institute of General Medical Sciences. Like other program officers at the NIH, it's my job to interact with individuals like you who are interested in obtaining research or training support from the NIH. I should be one of the first people you contact when you begin to think about submitting an application. Before you put pen to paper or fingers to the keyboard, you should contact someone like me to understand what the process is all about. What the appropriate grant mechanism would be. How it's going to be reviewed. And then how long it will take once you submit the application to learn about the likelihood of funding. We can answer a lot of questions. We're very experienced with the process. Many of us have gone through it ourselves before we became staff members at NIH. So, it's important that you make that contact early. Give yourself enough time to develop the grant application. And then be ready with your questions. You can make contact with us by email or phone. Email is best. With some additional information in your email. Don't just write an email that says I'm interested in submitting a grant to your institute. Save a little time. Provide your biosketch and at least a one page summary of your research goals and objectives and what you wish to do with your research grant.

Alexander Politis: Hi. My name is Alexander Politis. I've served the NIH as a scientific review officer or SRO within the Center for Scientific Review of CSR for about 22 years and as an Integrated Review Group Chief for the Infectious Diseases and Microbiology review group for the past 18 years. The goal of every SRO is to generate a thorough and fair review of each grant application for which they have responsibility. The applications are clustered according to a particular area of biomedical science. SROs conduct an administrative review of the applications assigned to them as well as an assessment of the expertise needed for the review. They then recruit reviewers to form a study section. The SRO then trains the reviewers in the review procedures and they assign each grant application to a subset of reviewers. The SRO is the designated federal official who manages the study section meeting and guides the reviewers to ensure that NIH policies are implemented. They select a chairperson to partner with them to lead the discussions. The SRO does not offer any scientific opinion of any application and remains neutral to facilitate fair treatment of each application. After the meeting the SRO manages the release of priority scores assigned by the reviewers and generates summary statements. Those are the reports of the reviewer’s opinions including writing a resume and summary of discussion paragraph from the notes they took during the meeting to reflect the basis for the priority score assigned. When might you communicate with a SRO? The SRO that manages the review of your application is your NIH point of contact before the study section meeting and can answer procedural questions prior to the review. The SRO can also provide information about the study section guidelines, but in CSR the study section assignment authority rests with the IRG Chief who you may also contact. Note that the review staff are not in the position to advise you on how to revise your application or interpret reviewers comments on the summary statement they must remain objective so each application receives equal treatment.

Dede Rutburg: Hi. I'm Dede Rutburg the Chief Grants Management Officer for the National Institute of Dental and Craniofacial Research. It is in this role as grants management officer that I monitor grants compliance with fiscal and administrative procedures and laws federally and both from an NIH policy practice perspective. So, when would you reach out to me? Some examples would include knowing and wanting to verify and confirm allowable versus unallowable costs and expenses on a grant application. Also prior approval requests, this would include, but not limited to a carryover of unobligated balances as well as change in scope of aims and if your adding or human subjects or animal use. So, my bottom-lin recommendation is always reach out when in doubt.

Sheri Cummins: Thanks, everyone.

It’s important to know that reaching out is not only okay, it’s encouraged.

And it’s equally important to know, who to contact and when.

Now, let’s look at the available opportunities and how to find them.

We use funding opportunity announcements, or FOAs, to advertise our grant opportunities.

They contain all the information you need to successfully submit an application

FOAs include

* An opportunity description
* A list of participating institutes and centers
* Key dates like due dates and expiration date
* Award information like whether clinical trials are allowed and any project period or budget limitations.
* Eligibility information for both the applicant organization and the designated principal investigators. For my international friends out there, we clearly indicate in this section whether foreign institutions are eligible to apply and any citizenship requirements for the PD/PI.
* It includes an opportunity-specific submission requirements section
* Review criteria
* Award administration information
* And, scientific/research (think program), peer review, and financial/grants management contacts within the participating ICs.

You can find all NIH opportunities in the NIH Guide to Grants & Contracts and at Grants.gov which is the federal-wide portal for all grant making agencies.

You can also find subsets of our opportunities on our program specific pages like our small business page and on IC websites.

Both the NIH Guide and Grants.gov have robust search capabilities. I recommend searching both sites.

Since Grants.gov is federal-wide, you may find opportunities at other agencies you won’t find in the Guide.

In the Guide, in addition to the FOAs advertised in Grants.gov, you’ll also find notices, including

* + Notices of special interest
  + Policy updates
  + Changes to FOAs
  + Webinars and training events
  + And more

I recommend subscribing to our weekly emails that summarize the NIH Guide postings for the week. The links to subscribe to our listservs are under the News and Events tab on the grants site.

We post several types of FOAs

* Requests for Applications or RFAs,
* Parent Announcements, and
* Program Announcements or PAs.

We also use notices of special interest to highlight research areas of interest.

Requests for Applications have a narrowly defined scope and the participating IC or ICs set aside funds in their budgets to award applications submitted to that RFA. The award information section of the FOA indicates the number of expected awards and/or the amount of set-aside funding.

RFAs often have a single receipt date and may not be posted again. So, if you see one of interest its best not to wait.

Many ICs participate in our parent announcements which are used for investigator initiated or unsolicited research.

Parent announcements don’t specify a particular area of research. They simply provide the infrastructure and information needed to submit a research proposal that fits within the missions of the participating ICs.

They use a standard due date schedule that defines three submission, review, and award cycles per year. And, they are posted for up to 3 years and are then reissued.

We have parent announcements for research grants, fellowship, career development, administrative supplements and post-award administrative actions like a change of institution request. And, we have different parent FOAs depending on whether applications can propose clinical trials.

Unlike parent announcements, our program announcements or PAs highlight scientific areas of interest.

They are typically on-going programs posted in increments of up to 3 yrs.

They use the same standard due date schedule as parent announcements, unless they are identified as a PAR. A PAR is a program announcement with special receipt, referral or review considerations.

Applications to parent announcements and program announcements all compete for the same funding. They don’t have set-aside funds, unless they are identified as a PAS – which is a program announcement with set-aside funds.

Let’s pause for a second. As you work with NIH, you will hear the words “except”, “unless” and my personal favorite “it depends” **a lot.**

With so many funding organizations covering a broad range of topics, its not surprising that NIH processes are filled with nuances. Read the announcement carefully and reach out if you have questions.

It takes many months and lots of resources to get a full FOA approved and posted. With over 1200 opportunities posted at any given time some some of these opportunities get few or no responses at all.

A few years ago, we took a hard look at our program announcements and determined that much of their content is standard text repeated in each FOA.

We already have parent and other announcements that could be used to accept applications. All we needed was a way to provide the unique bits, the areas of scientific interest, that were buried in the PAs.

Some institutes were already successfully leveraging NIH Guide notices for that task. We can post a Guide notice in a matter of weeks, not months. So, we formalized that approach in the form of Notices of Special Interest, or NOSIs.

NOSIs provide the unique information for an initiative in a succinct document which is easier for applicants and they point to existing funding opportunity announcements for application submission which is more efficient for NIH. Win, win.

As I already hinted when talking about parent announcements, our FOAs cover a wide range of grant programs, including Research, Career development, Training, Fellowship, Program Project and Center grants, and Resource grants.

We identify these programs through the use of 3-character codes we call activity codes. For example, we use the R series for research grants and we have activity codes like R01, R03, R15,and many others.

K01 is an example of a career development activity code in our K series. T32 an example of training code. F30 an example of a fellowship code. And, P01 an example of a Program Project code.

You can learn about these activity codes on our Types of Grant Programs page. On the far right of the page there’s a link to a handy site that helps match programs and career stage from undergrad through to established investigator.

We’ve talked about identifying your target IC, available programs, and finding an FOA or NOSI that’s a good fit. Which brings us to our next question – What’s the application process and how long does it take?

You’ll find a Grants Process Overview on the grants.nih.gov site.

It takes you through the process from getting started, to applying for funding, to application referral & review, and finally the pre-award & award process.

You can click on each topic in the graphic to learn more about each step. But, I’ll walk you through the key points and help you get a feel for the timeline.

We’ll start with planning. At least 6 months prior to your target due date you should be well on your way to refining your research idea.

Reach out to NIH staff. Discuss your proposal. Make sure it fits within the IC mission and priorities.

We talked about the NIH team of program officials, grants management officers and scientific review officers. You’ll also need a team within your own organization and a plan to coordinate that team.

NIH awards grants to organizations, not to individual investigators. So, right of the bat, your team includes an Authorized Organization Representative or AORs (we refer to these folks as signing officials in eRA Commons). The AOR is responsible for submitting the application and it’s their electronic signature that is signing off on the terms and conditions of the grant on behalf of your organization.

Of course you’ll have one or more Project Director/Principal Investigators responsible for directing the supported project or program. You’ll hear them referred to as PD/PIs or PIs.

You may also have additional senior/key individuals, administrative staff, or collaborators. And, you’ll want to identify some colleagues to review your application and provide feedback. And, if they have grant or review experience, even better.

Once you have your team in place make sure everyone knows their role, the process that will be followed, and your timeline.

Establish that plan upfront.

You’re then ready to prepare to apply. If your organization has never submitted a grant application before, you’ll need to get started on multiple organization registrations, including the System for Award Management, Grants.gov and eRA Commons. It can take 6 or more weeks to complete the organization registrations, so don’t wait to get that started.

If your organization has submitted previously, make sure all registrations are current and active. The System for Award Management requires annual renewal. You can’t submit unless its active.

Confirm your funding opportunity. NIH posts opportunities 30-60 days prior to the first due date. You may find a newly published opportunity that is even better fit than the one you originally chose. You’ll also want to check the Related Notices section of the opportunity for any late breaking changes or corrections.

And you must identify the submission method you will use to prepare and submit your application.

Grant application forms **must** be prepared and submitted using NIH’s ASSIST, Grants.gov’s Workspace, or your institution may have its own system-to-system solution. Your office of sponsored research can help identify the best option for your situation.

Honestly, it doesn’t matter which option you choose.

Your application will flow through the Grants.gov federal portal and then on to eRA Commons. eRA Commons is our system to exchange information electronically with our applicants and grantees.

Since all applications follow that same flow, they’re all subject to the same

* Registrations
* Business rule validations
* And, are assembled into a consistent format for funding consideration.

By the time the applications are seen by NIH staff we can’t tell which system was used to submit them.

You’ll login to your submission option, provide the funding opportunity number, and you’ll be presented with the exact set of forms needed to write your application.

Much of the really good stuff in your application - your abstract, specific aims, research strategy, biosketches will be in attachments which are uploaded in pdf format into specific form fields. All of these critical pieces of your proposal can be started well in advance of pulling together the application forms.

Write a strong proposal that addresses the review criteria in the opportunity.

And most importantly, *read* and *follow* all instructions.

Our How to Apply – Application Guide, which is easily found on our grants page and linked within every opportunity, contains your general application instructions.

On the How to Apply – Application Guide page you’ll find sections for Prepare to Apply, Write Application, and Submit. Here’s a few highlights.

In the Prepare to Apply section you’ll find details on the organization and individual registrations needed to apply. Understand Funding Opportunities talks about the different types of announcements – RFAs, PAs, parent announcements and NOSIs. Types of Applications explains the difference between new, revision, renewal, and resubmission applications. And, you can learn about ASSIST, Workspace and system-to-system solutions under Submission Options.

Write Application includes some great information on developing your budget. Remember I said much of your proposal is in pdf attachments. The Format Attachments page describes our rules for fonts, margins, filenames, images, links and more. Many of the attachments have strict page limits all applicants must follow for fairness. There is a link to our standard page limits table and any exceptions would be noted in your FOA or NOSI.

Under Submit we explain the process for submitting and tracking your application and how we validate your application using a combination of system and manual checks. There’s a link to our standard due dates table that we talked about earlier. A link to Submission Policies that explain what happens if your due date falls on a weekend or holiday or when Washington area government offices are closed, or your institution is closed due to weather or natural disaster. And finally what to do if a problem with a government system impacts your ability to submit your application on time.

We have videos, FAQs, resources, and most importantly form-by-form, field-by-field instructions for completing your application forms.

You must read and follow **all** instructions.

The application guide provides general instructions and the FOA provides opportunity-specific instructions that augment or may even differ from the application guide. So, when completing your application forms you’ll follow the application guide unless the FOA tells you to do something different.

Many of our opportunities are active for up to 3 years. We can change a lot of policies in 3 years. And, from time to time, we make mistakes and need to post corrective notices for an opportunity. NIH Guide Notices win over both the FOA and general application guide instructions.

You’ve followed all the guidance and written a strong proposal. You’re checking off items in your internal plan. You’ve reviewed the application internally and it’s in the hands of your Authorized Organization Representative ready to submit.

Applications are due at 5pm local time of the submitting organization on the date specified in the opportunity.

After you submit your application it flows through Grants.gov and then on to NIH’s eRA Commons. Track your application. If errors are identified at Grants.gov or eRA Commons, your application will not complete the submission process. NIH staff will not see it. If free of system-identified errors, however, the system will assemble all your forms and application attachments into a consolidated document in a consistent format with headers, footers, a table of contents and bookmarks and place it in eRA Commons. From this point forward, you will continue to use eRA Commons from checking status of your application to closeout of an awarded grant.

Submit early! When we say “early” we mean days, not hours or minutes ahead of the deadline. This gives you time to address unforeseen issues and thoroughly check that final assembled application image in eRA Commons. That assembled eApplication is the same document that will be used by reviewers and staff for funding consideration. It’s your responsibility to check it in eRA Commons and notify us of any assembly issues within the 2 days following the submission.

After the 2-business day viewing window, your application automatically moves on to our receipt and referral staff.

NIH referral staff conduct additional application checks, then assign an application number, a potential funding institute, and an Integrated Review Group or IRG.  An IRG is a cluster of scientifically related study sections. An IRG chief then assigns the applications to specific study sections for review.  Assignment details show in eRA Commons in about 2 weeks after that due date.

During the Peer Review stage the Scientific Review Officer is your key contact and will be listed on the application’s eRA Commons status page. The SRO manages the initial peer review. Reviewers are selected. Applications assigned for review. The study section meets and assesses the applications against the review criteria in the FOAs. And approximately 2-3 days after the meeting the priority scores and percentile rankings will be available in eRA Commons. It takes a bit longer for the SRO to prepare the Summary Statements which document the official outcome of the review, but many are available in eRA Commons within about a month.

Now, that’s clearly an oversimplification of the peer review process. You’ll find lots more information including full videos on the grants.nih.gov and Center for Scientific Review websites.

Once the Summary Statement is released, the Program Official becomes your key contact. They can help clarify points made in the summary statement though they can’t discuss details of the review beyond what’s covered in the summary statement. If your application didn’t receive a favorable score, they can provide advice on next steps.

During the pre-award and award process and on through the life-cycle of a grant, the program officer and the grants management officer work together much like the administrators and researchers do in your own organization. The PO handles scientific and programmatic aspects of the project and the grants management officer or specialist handles the business and administrative aspects of the award.

If you receive a score that is broadly in the competitive range, you may be asked to submit additional information through the just-in-time function in eRA Commons. This would be stuff like other support and additional human subjects and animal welfare information. The just-in-time request is not an indicator of award, but the information requested would need to be in place prior to making an award if chosen for funding. So, it behooves you to submit the information when requested.

NIH uses a 2-level peer review process. Level 1 is that initial scientific review. Level 2 is what we call Council. Council procedures can vary across ICs, but each IC Director chairs a National Advisory Council for their IC. The Council recommends applications for funding, but it’sthe IC Director makes final funding decisions.

If your application is selected for award, you will receive a Notice of Award or NoA which is viewable in eRA Commons. It takes about 9 months from the submission due date to receiving that notice of award.

The NoA is a legally binding document. It includes award data, payment information, and the terms and conditions of the award. When the grantee organization draws down funds, it is considered an acceptance of the award and associated terms and conditions.

Those terms and conditions are documented in the NIH Grants Policy Statement or GPS. The Grants Policy Statement is updated each fall and details the rules, responsibilities and expectations for appropriate stewardship of a grant throughout its life cycle.

Grantees are responsible for managing the day-to-day operations of their grant. NIH monitors grants very carefully. Active monitoring includes reports and correspondence from the grantee, audit reports, and site visits.

Let’s do a quick review of the questions and answers we covered.

Where do I start?

Grants.nih.gov. From that site, you’ll find all the other need-to-know resources we talked about.

Where’s the funding?

The funding is done through the NIH institutes and centers and we saw how Matchmaker can help identify ICs and program officials in your scientific area.

Where do I turn when I need help or advice?

We talked about the 3 players in the NIH Extramural team – the program official, scientific review officer, and the grants management officer.

You can also find additional contacts, including the eRA Commons Support Desk on the grants.nih.gov help page and in the contact section of all FOAs.

What opportunities are available and how can I find them?

We discussed the different types of FOAs – RFAs, parent announcements, PAs, and NOSIs. And, the programs we offer – research, career development, training , fellowship, project center and resource. All of these opportunities can be found in the NIH Guide and Grants.gov.

What’s the application process & how long does it take?

We discussed how it takes a lot of time and planning to apply for funding. At least 6 months ahead of the due date you should be reaching out to NIH and building your internal team and plan.

You must complete or confirm your registrations and choose a submission option before you can pull together your application.

When writing your application, you must follow all application instructions in the application guide the FOA-specific instructions and any relevant Guide notices. And be sure to address the FOA review criteria in your proposals.

And, you’ll submit days ahead of the due date to make sure you have time to address any unforeseen issues.

About 2 weeks after you submit, your referral and review assignment will be available in eRA Commons status.

The peer review meeting will take place on the day indicated in eRA Commons. Two-three days after the meeting, the priority score & percentile information will be added to the status. And the summary statement will follow about 1 month after review.

Peer review was our first level of review. The second level was council where funding recommendations are made. Following council the IC director makes final funding decisions.

If selected for funding you’ll receive the notice of award which will be approximately 9 months after your application due date.

Post-award monitoring and reporting are carried out through the duration of the award. And that is the life-cycle of your application or grant.

One final thought before we close out this formal presentation.

I encourage you to check out the News & Events section of our website. It has links to our “Open Mike” blog, NIH Extramural Nexus newsletter, listservs, YouTube channel, podcasts, and social media.

You can always count on change. It’s important to keep informed.