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NIH SEED Small Business 101: Building Your Budget

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Great to see everybody joining us today for our second webinar session. I am Adam Sorkin, the Small Business Policy Manager for the NIH Small Business Education and Entrepreneurial Development Office, or SEED, as we like to call ourselves. Just taking care of a little bit of housekeeping at the top. We will be having a Q&A session at the end of today's presentation, so please use the Teams Q&A function to submit your questions as we move along. We will get to those questions once we wrap up the material.

Also, if you have an AI note-taker enabled, please disable it, as we're not allowed to accommodate those per NIH policy. All of the materials from this presentation, including the slides, recording, and transcript, will be made available to everyone who registered for this event, as well as posted on our website, roughly 7 to 10 business days from today. You'll be able to download the slides and review everything we've covered.

With that, we can jump right in.

Today, we're going to be talking about building your budget. Specifically, we'll cover what budgets are, where to find guidance and related resources, and what to think about when you're putting your budget together.

This is not going to be a detailed walkthrough of the nitty-gritty of the NIH budget forms, but we will try to hit the high points as they relate to the SBIR and STTR programs and how they're administered at NIH, helping you avoid some of the pitfalls that we commonly see applicants run into.

We'd also love to direct you to our website, where you can find additional resources and more information about the topics we're covering today. You can find us at **seed.nih.gov**. I also want to specifically call out our FAQ page at **seed.nih.gov/faqs**. There is a fairly detailed budget FAQ that gets into many of the topics we'll be discussing today.

While we are focusing primarily on NIH today, please note that several of our sister agencies also participate in the SBIR and STTR programs, most notably the FDA and CDC. They participate using the same parent solicitations that NIH uses, so most of the concepts we're covering today apply to their programs as well.

If you're familiar with SBIR and joined us last time, you're already aware of the flexibility around our programs and how they're set up. But just to review quickly, as with all SBIR programs, SBIR and STTR are phased programs.

Phase I involves demonstrating the feasibility of your technology and its commercial potential. Phase II focuses on full research and development, really taking your technology through those early stages of product development and enabling downstream R&D.

At NIH, we've got multiple ways to enter our program, and this does affect the way you think about your budget and how you put it together. We've got the standard Phase I application, the Fast-Track application, which combines both Phase I and Phase II, as well as the Direct-to-Phase II mechanism for companies that have already demonstrated feasibility using other funding sources and have no need to revisit that initial demonstration stage.

As a reminder, with the recent reauthorization, Direct-to-Phase II is available for both SBIR and STTR at NIH. Once you're in Phase II, we also have a number of great options to continue supporting commercialization. These include the Phase IIB Strategic Breakthrough Award and the Commercialization Readiness Pilot (CRP) Program. In general, their budgets work similarly, but we'll point out a few things to watch for where they differ.

At NIH and CDC, we also have flexibility regarding budget limits. We work with the Small Business Administration to maintain waivers that allow us to exceed the standard budget

guidelines for select topics. Each Institute and Center has its own specific guidance and budget levels for these situations and for applications addressing those topics.

As always, this is something you should discuss with your Program Officer as you prepare your application. I'll reiterate that several times throughout today's presentation, but it's important to keep in mind.

You can now find additional information for all participating Institutes and Centers on the Funding Considerations and Contacts page. We'll revisit that in just a couple of minutes, but we encourage you to take some time to become familiar with it, as it is new with the recent release of our current funding opportunities.

So, what are those funding opportunities, and where do you find them? Right here.

Our current parent Notices of Funding Opportunity (NOFOs) for SBIR and STTR, as well as their companion opportunities, are now open for the September 5 deadline. Specifically, you'll want to be looking for **PA-27-100** for SBIR and **PA-27-102** for STTR. If you've applied to SBIR in the past, you may notice that these opportunities are a little different than they used to be. We previously had separate opportunities for clinical trial and non-clinical trial proposals, but those have now been combined into single NOFOs that accommodate both options.

You'll also notice that the Phase IIB option has become the **Phase IIB Strategic Breakthrough Award**, and it is now offered as its own separate NOFO.

As I mentioned before, there's also a link to the Funding Considerations and Contacts page, which specifies what your target Institute or Center (IC) would like you to know when you're preparing an application within its mission space.

When you look at each of these NOFOs, you'll notice they're organized in the same way. Learning how to navigate them is very helpful when you're looking for specific information. Since we're focusing on budgets today, I really want you to pay attention to two sections.

The first is **Section II, Award Information**. This section contains the broad budget guidance for each opportunity, including how much funding you can request and the maximum project period.

The second is **Section IV, Application and Submission Information**, which contains NOFO-specific instructions, including any NOFO-specific budget instructions. We don't use this section extensively for SBIR applications at the moment. In most cases, it simply directs applicants to follow the instructions in the application guide. However, it's important to keep an eye on this section because those instructions may change in the future.

When you go to **Section II**, this is what you'll want to look for regarding the budget. You'll see some general guidance at the top, including links to the current Small Business Administration Phase I and Phase II budget guidelines.

For each NOFO, you'll also find a table containing Institute- and Center-specific budget guidance. Each participating NIH Institute or Center, as well as our sister agencies, CDC and FDA, has its own specific guidance.

I do see some questions about the differences between the previous slide and the budget limits shown here. We'll discuss those differences, and how to access higher levels of funding, in just a moment.

I also want to point out that you'll see statutory project periods listed for each program. Please keep in mind that NIH offers some flexibility here, and I'll discuss that in a little more detail shortly.

You'll note that the current Phase I and Phase II guideline amounts are **\$323,000** for Phase I and **\$2,153,927** for Phase II. These amounts are established by law, and the Small Business Administration updates them annually to keep pace with inflation. These limits apply government-wide and are generally safe to use for NIH applications, although each participating Institute or Center has the discretion to establish lower limits if it chooses.

Keep in mind that the **Phase IIB Strategic Breakthrough Award** and the **Commercialization Readiness Pilot (CRP)** awards do not use these statutory guideline amounts. For those opportunities, you should always pay close attention to what's listed in the specific NOFO.

As I mentioned earlier, NIH recognizes that many types of biomedical research require funding above the standard SBA guidelines. Therefore, we work with the SBA to maintain waivers that allow us to exceed those limits for approved research topics.

Those are the waiver topics referenced in the tables you'll find within the NOFO.

Using the **Small Business Funding Considerations and Contacts** page, you can find a detailed list of all approved waiver topics, along with any additional Institute- or Center-specific budget guidance.

To access these higher funding levels, your application must address one of the approved waiver topics. You don't need to do anything special in your application other than request the higher budget amount. The determination is made on the back end by your Program Officer and Grants Management staff at the time of award.

You'll also notice the statutory guidance regarding project periods within each NOFO. This occasionally causes confusion because it doesn't always align perfectly with the guidance you'll find on our website.

You're encouraged to propose a project duration that is appropriate and reasonable for successfully completing the proposed work.

You'll find additional guidance regarding project duration both on our website and on the Funding Considerations and Contacts page. NIH does provide a reasonable amount of flexibility in this area.

When you visit the Funding Considerations and Contacts page, this is what you'll see at the top. You'll find links to NIH guidance, as well as guidance from the other participating agencies.

There are also links to general Institute and Center application information for all NIH grants, not just SBIR and STTR.

Most importantly, you'll find expandable sections for each participating Institute and Center. When you expand one of those sections, this is typically what you'll see. I've highlighted and bolded the elements that contain the most important budget guidance.

This information includes the **approved waiver topics**, which are required for any budget request that exceeds the SBA guidelines, as I mentioned earlier.

Again, you don't have to do anything special in your application to access those higher funding levels, although you're welcome to include a brief explanation in your budget justification identifying the waiver topic that best aligns with your research.

Some Institutes and Centers may also include **additional budget considerations**. Not every IC does this, but some provide specific guidance about how budgets are handled and the best way to approach budget development for applications submitted to that particular Institute or Center.

Some ICs may also have **set-aside funding** for particular research areas that were included in their appropriations. For example, the **National Institute on Aging (NIA)** has specific funding available for Alzheimer's disease research, which allows applicants in that area to request higher budget levels.

Some ICs will also provide specific guidance regarding **project duration**, including recommended lengths for Phase I, Phase II, the Commercialization Readiness Pilot (CRP), and other funding opportunities.

As always, you'll also find contact information for the appropriate staff. You should use those contacts to discuss how well your project fits within the Institute's mission, make sure you're targeting the correct Institute or Center, and discuss any budget guidance or best practices.

Every IC manages its program a little differently, and those conversations can be extremely helpful in navigating those differences and making your application as competitive as possible.

When you're ready to begin preparing your budget, you'll find the budget forms in your application package. SBIR and STTR applications use NIH's standard **Research and Related (R&R) Budget Form**.

This is what the first page looks like. I'm not going to spend much time walking through the form itself, but you'll find it in every SBIR and STTR application package, regardless of where you access it.

If your project includes a **subaward**, you'll also find the corresponding subaward budget forms. Those forms are attached separately within the application package and are submitted as attachments to the appropriate section of the application.

Once you've located the forms and are ready to prepare your budget, it should go without saying—but I strongly encourage you to **read the instructions carefully**.

You'll find links to the detailed **Application Guide** in each NOFO, as well as on our website and within the slide deck.

In particular, you'll want to pay close attention to the **additional instructions for SBIR and STTR applications**.

I've included a small example here showing what that section of the Application Guide looks like.

This is where the guide gets into the nuts and bolts of completing the forms, specifically how to complete them for an SBIR or STTR application and everything we generally expect applicants to include in the budget.

We don't expect you to be perfect. A good-faith mistake isn't going to torpedo your application. In most cases, you'll have the opportunity to correct issues at the time of award if necessary.

However, carefully following the Application Guide and adhering to the instructions will generally make the process much smoother and help you avoid the unfortunate surprises that sometimes arise when expectations don't align with NIH funding policy.

As I mentioned earlier, you should also review **Section IV of the NOFO**. Any instructions contained within the NOFO supersede the Application Guide.

Currently, the **Commercialization Readiness Pilot (CRP) NOFO** is the only opportunity with budget-specific instructions, but that could certainly change in the future as additional funding opportunities are released.

I also want to point out the **annotated form set**, which is available to all applicants. It can be extremely helpful when you're troubleshooting problems or trying to understand exactly what a particular field on the form is asking for.

Usually, the forms are fairly straightforward—but not always—and the annotated version often helps clear up confusion.

Once you open the application package, this is what you'll see in the **R&R Budget Form**. The form includes all of your **direct costs**, beginning with **Senior/Key Personnel** and **Other Personnel**, followed by **Equipment, Travel, Participant/Trainee Support Costs**, and **Other Direct Costs**, which includes essentially everything else. I'll discuss each of these categories in more detail shortly.

The form also includes your **indirect costs**, which you may also see referred to as **Facilities and Administrative (F&A) costs**, your **SBIR fee**, and your **Budget Justification**.

I encourage you to make good use of the Budget Justification.

This is really your opportunity to provide reviewers with additional information about the scope of your team's contributions, explain any unusual costs included in your budget, and clearly

describe why the costs you're requesting are appropriate and how they'll enable your team to successfully complete the proposed project.

There are no special SBIR- or STTR-specific requirements for the Budget Justification, but it remains a very important component of your overall budget submission.

One of the first things you'll need to determine when building your budget is **how your budget periods will be structured**.

NIH grants and cooperative agreements—including SBIR and STTR awards—are funded in increments called **budget periods**.

Accordingly, you're encouraged to prepare your budget in **one-year increments**.

In some situations, your final budget period—or your only budget period—may be shorter. For example, many SBIR Phase I projects are only six months in duration. That's perfectly acceptable.

However, if your project extends beyond one year, NIH expects you to divide it into one-year budget periods.

This can occasionally become confusing for **Fast-Track applications**, so it's important to remember that **Phase I and Phase II should always be budgeted separately**.

For example, if you're proposing a Fast-Track project with a **six-month Phase I** followed by a **two-year Phase II**, you'll actually prepare **three budget periods**.

The first budget period covers only the six-month Phase I effort.

Then, when Phase II begins, you start with an entirely new budget period. The first year of Phase II becomes the second budget period, and the second year of Phase II becomes the third budget period.

Keep those budgets completely separate. Don't combine Phase I and Phase II costs into a single budget period.

This is an area where many applicants get tripped up. As a result, applicants are sometimes asked at the time of award to restructure budgets that don't follow this convention.

The first direct costs you'll work through are **Senior/Key Personnel**.

This category includes critical company employees—and **company employees only**—who are contributing effort directly to the research and development activities of the project, beginning with the SBIR Program Director/Principal Investigator (PD/PI). You'll want this information to be consistent with what you've entered on the **Senior/Key Person Profile** form.

Keep in mind that you should **not** include subaward personnel here. Those individuals belong in the corresponding sections of the **subaward budget**. For example, on an **STTR** project, if the Principal Investigator is employed by the partnering research institution rather than the small business, that individual should **not** appear in the company's budget. Instead, they should be included in the subaward budget submitted by the partnering institution.

In general, the information requested in this section is fairly straightforward. However, you do want to make sure that you're clearly communicating the amount of effort each individual is contributing during each budget period.

The next section is **Other Personnel**. This category includes all of the additional personnel or personnel roles you anticipate will contribute to the project. These individuals do not necessarily need to be identified by name, but you should clearly communicate to reviewers the level of staffing and effort you're committing across all project participants.

For SBIR and STTR applications in particular, it's also important to distinguish between **employees** and **outside contributors**. For the purposes of SBIR and STTR, an employee is considered any individual who works for the applicant small business on a full-time, part-time, or other basis, provided that individual works **at least 40 hours per month** for the applicant company.

NIH generally does **not** require a specific employment mechanism. While employees are often W-2 employees, there is flexibility to justify other employment arrangements within your

application. I encourage you to review the FAQ, which provides additional information about this flexibility and discusses how to approach situations where you're using a less conventional employment mechanism for senior/key personnel or other employees on the project.

Next, we move into the additional direct cost categories. I'm grouping **Equipment, Travel, and Participant/Trainee Support Costs** together because I don't plan to discuss them in great detail, but I do want to clear up a few common misconceptions.

First, **equipment and travel costs are allowable** under SBIR applications. We often hear confusion from applicants about whether equipment purchases are permitted, and the answer is yes. However, there are some important considerations. NIH specifically defines equipment as **tangible property with a useful life greater than one year and an acquisition cost greater than \$10,000**. Equipment purchases must be clearly justified, and we encourage you to discuss any significant equipment purchases with your Program Officer before submitting your application.

We want to ensure that your company is appropriately equipped to carry out the proposed work. At the same time, you also want reviewers to understand that your company already possesses the capabilities needed to successfully perform the project you're proposing. There is also helpful information regarding equipment purchases by for-profit organizations in the **NIH Grants Policy Statement**, and I encourage you to review those policies if you anticipate purchasing equipment as part of your project.

On the other hand, **Participant/Trainee Support Costs should not be used** unless they're specifically authorized in the Notice of Funding Opportunity. At present, **none of the SBIR or STTR NOFOs use Participant/Trainee Support Costs**, so you should generally leave that section blank.

The remaining direct costs are included under **Other Direct Costs**. This section covers a wide range of different expense categories, including **materials and supplies**, which encompasses all of the consumable supplies, laboratory materials, and other items necessary to complete your proposed work. Depending on the nature of your project, this category can represent a substantial portion of your budget.

You'll also see **publication costs, consultant services, and automatic data processing (ADP) and computer services**. I want to specifically highlight **consultant services**, because consultant costs are included when determining compliance with the SBIR and STTR work requirements, which I'll discuss in more detail shortly. When budgeting for consultants, you should include those costs in this section, and NIH also expects a **letter of support** describing the consultant's rate and explaining how that rate was calculated.

You'll also see a line item for **Subawards/Consortium/Contractual Costs**. This is an extremely important budget category. You should include **all subawards**, meaning your major subrecipient organizations, as well as any other subcontracted services associated with the project. If you're working with subrecipients, you should also prepare a detailed **subaward budget** that breaks down those costs and explains how the requested amount was determined. However, the **total amount of each subaward** should also be included on this top-level line within the **Other Direct Costs** section.

You'll also find categories for **equipment and facility rental or user fees, alterations and renovations**—which are less common for SBIR projects but are still allowable—and finally **Other**, followed by several blank lines. Those blank lines allow you to include direct costs that don't fit into the predefined categories.

One particularly important item belongs here: **Technical and Business Assistance (TAB A)**. If you're planning to request TAB A funding, this is where those costs should be included. It's a benefit we strongly encourage companies to take advantage of. Technical and Business Assistance (TAB A) has changed somewhat with the recent reauthorization, so we wanted to take a few minutes to revisit it. Briefly, TAB A funding allows companies to pay for different types of support that help identify and address product development needs that fall outside the scope of the project's specific aims. This could include resolving technical issues, manufacturing challenges, regulatory consulting, intellectual property services, and a variety of other commercialization-related activities.

We have a great deal of detailed information available on our website, and TABA is also discussed at length in the Application Guide. This is a section you should pay close attention to when preparing your budget request.

One important change is that TABA services can still be provided by an outside vendor, but under the recent reauthorization they may also be provided by a new or existing employee of your company or by someone who is already working with your organization. This gives applicants much more flexibility regarding who performs these technical and business assistance activities.

For **Phase I**, you may request up to **\$6,500** for the entire project.

For **Phase II**, and again for the **Phase IIB Strategic Breakthrough Award**, you may request up to **\$50,000** to support TABA activities.

We strongly encourage you to follow the instructions carefully. Doing so can save you a significant amount of work later in the award process.

Be sure to label the requested cost as **Technical and Business Assistance** on one of the blank **Other Direct Costs** lines. Specifically, this should be entered on **lines 8 through 17** of the Other Direct Costs section.

Then, in your **Budget Justification**, make sure you describe:

- The work that will be performed under TABA.
- The name of the vendor or staff member who will provide the services.
- The expected benefits and anticipated outcomes of those activities.

This information is important because NIH needs it to approve the TABA request, and it is also reported to the Small Business Administration. If the information is incomplete, we will need to work with you to resolve those issues before an award can be made.

After completing your direct costs, you'll move on to the **Indirect Costs** section.

Indirect costs are expenses that cannot be directly attributed to a specific research activity or project task. Generally, these are administrative and overhead expenses—or, put another way, the general costs of doing business that support the conduct of your research project.

If your organization already has a negotiated indirect cost rate agreement with NIH or another federal agency, you should use that negotiated rate when developing your budget.

If you do **not** have a negotiated indirect cost rate—and that's not unusual—SBIR and STTR work somewhat differently from many other NIH funding mechanisms, particularly if you've previously submitted NIH research project grant applications.

If you do not have a negotiated indirect cost rate, you may estimate your actual indirect costs at **up to 40 percent of total direct costs**. Note that this calculation is based on **total direct costs**, not modified total direct costs. In other words, you simply use the total amount shown at the end of your direct cost section.

For **Phase I**, NIH generally will not negotiate an indirect cost rate agreement and will instead use the rate you propose.

For **Phase II**, NIH generally will not request additional documentation for proposed indirect cost rates of **40 percent or less**. However, if you're proposing a rate greater than 40 percent, NIH may negotiate that rate through the **Division of Financial Advisory Services (DFAS)**. In those situations, you may be asked to provide additional supporting documentation before the rate is approved.

Keep in mind that the indirect, or Facilities and Administrative (F&A), costs charged to your award should reflect the **actual costs incurred** during the performance of the project and may not exceed the approved award rate.

For example, if you request a 40 percent indirect cost rate but your actual indirect costs are only 35 percent, you cannot simply spend the remaining five percent on other activities without first rebudgeting those funds.

We recognize that estimating indirect costs can sometimes be challenging, but it's important that your proposed rate be as accurate as possible.

I also want to encourage you to take advantage of the **SBIR and STTR fee**. All SBIR and STTR applicants may request a **reasonable fee of up to 7 percent of total costs**. This fee may be used by the small business for essentially any purpose, including commercialization activities.

It can support project-related expenses that might not otherwise be allowable under an SBIR or STTR award, giving your company additional flexibility. Generally, the fee becomes available proportionally as the remainder of the award funds are drawn down throughout the life of the project.

That covers the major components of the budget request itself. However, when putting your budget together, it's also important to keep in mind the specific **SBIR and STTR program requirements**.

I want to briefly review the key differences between the two programs. The award is **always made to the small business**. The company is always the primary recipient, and the company's budget is always the primary budget. For **STTR** awards, the partnering research institution is always the **subrecipient**, as are any additional collaborating organizations. That required research partnership is one of the major distinctions between the SBIR and STTR programs, and it's reflected in the budget as well.

As I mentioned earlier, the **STTR Principal Investigator** should appear either in the primary company budget or in the subaward budget, depending on where that individual is employed. If the Principal Investigator is employed by the partnering research institution, that individual belongs in the **subaward budget**.

For **SBIR** applications, however, the Principal Investigator should always appear in the **company's primary budget** and should never be included in a subaward budget.

You're also going to want to pay close attention to the **work requirement calculations**, because the required distribution of effort is based on the budget. For the STTR program in particular, remember that a **single partnering research institution** must satisfy the required minimum research effort, even if you include additional research institutions as collaborators.

This is another area where applicants frequently encounter problems. Budgets are often returned for revision because they don't satisfy the required work distribution percentages. Accordingly, it's something you should review carefully.

Be sure that you're attributing **fee-for-service costs** appropriately. These costs should always be reflected as part of the **company's effort**. For example, if you're using a contractor or service provider to perform a routine service that is commercially available—meaning there are multiple providers offering the same type of service in a competitive marketplace—and that provider is **not** making a unique or significant intellectual contribution to your project, those costs are generally considered **fee-for-service**. Because those services are commercially available and are provided to many different customers, they are typically treated as fee-for-service costs. As a result, they count toward the **company's effort** and are **not** considered outsourced research for purposes of calculating the SBIR or STTR work requirements.

For **Fast-Track applications**, remember that the work requirements apply **separately** to the Phase I and Phase II budget periods. In particular, make sure that both the Phase I and Phase II portions of an SBIR Fast-Track application independently satisfy the applicable work requirements, since those requirements differ between the two phases.

You'll also notice that our Notices of Funding Opportunity discuss **deviations** from the work requirements. Please keep in mind that deviations are considered only in **rare circumstances**. They are not common and are reviewed on a case-by-case basis by the awarding Institute or Center. For **STTR** projects, deviations are **not permitted**. If a proposed budget does not meet the required STTR work allocation, it will need to be revised to bring it into compliance before an award can be made.

After an award has been issued, you will generally have opportunities to make certain budget changes. I'm not going to spend much time on post-award budgeting today, but I do want to take this opportunity to highlight our upcoming webinar on **July 28, Managing Your SBIR and STTR Award Effectively**, which will cover many of these post-award budget issues, as well as a variety of other award management topics.

We're looking forward to that session, and we hope you'll join us.

Lastly, I wanted to point you toward several helpful application resources. These include the **Application Guide** and instructions that I mentioned earlier, the **annotated forms**, and **sample applications**, which include the budget proposals that were submitted along with the rest of the application. Do keep in mind, however, that some sensitive budget information may be redacted from those sample applications.

I also want to highlight the resources that may be available through your state's **SBA FAST Program** affiliate. These organizations often have experts who can help you work through your budget and your application to ensure that it is well-developed and a good fit for NIH.

Finally, I wanted to mention a few **new electronic submission requirements**. Although these are not budget-specific, they are important.

Be sure that you have an **ORCID iD** and that you're prepared to submit the new **NIH Biographical Sketch** format, which will be required for all NIH applications, including SBIR and STTR applications, going forward.

And finally, one last reminder: **talk to your Program Officer**, ideally **at least one month before the application deadline**.

We always recommend reaching out early and now is an excellent time to begin making those connections.

A question and answer session followed this portion of the webinar.