

NATIONAL INSTITUTES OF HEALTH

Module 1

<https://wisconsinctc.org/>



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Eligibility, Background and Registration

If you see this button



or yellow text

click on them to follow a link.



Eligibility

Registration

Product Fit

Application and Solicitation

Specific Aims

Checklist



Eligibility

SBIR

- Small business can work alone or with others
- Small Business has a larger R&D role. Partner may only perform up to 33% of the work in Phase I and up to 50% of the work in Phase II
- Primary investigator (PI) must be an >51% employee of the small business

STTR

- Small business must work with a nonprofit research institution
- Partner may only perform between 30-60% of the work in each Phase
- Primary investigator (PI) may be an employee of the small business OR the research institution

TIPS

- Ensure your company is U.S. owned and operated.
- If you have investors, double check VCOC eligibility.
- Begin SAM registration at least 2 months before submission, it takes time.
- STTR benefits researchers who don't want to leave university AND small companies without access to resources or facilities.

What suits you best
SBIR or STTR?



Watch eligibility video



Eligibility

APPLICANTS MUST BE COMPETITIVE

FAQs



TEAMS



A competitive team has more than just a P.I., it requires key personnel that fulfill all areas of need for small company.

Rolls that should be filled:

- Skilled in science and research in area of project focus
- Skilled in business/entrepreneurship
- Skilled in grant writing

COLLABORATORS



The rolls of your team's key personnel may be filled by contractors or consultants that work for a different company and complete research which you are unable to complete. Examples of these rolls include:

- Software coding
- Animal studies

FACILITIES



Applicants must have legitimate labs or facilities to house research. If an applicant doesn't have their own facility, it's important to note that SBIR/STTR funding doesn't pay for expensive equipment. Partnering with a nonprofit research institution that has an established lab may be the best option. STTRs must be partnered with a university and can use their facility.

SBIR VS STTR

- SBIR allows 1/3 of funding can go outside the company.
- STTR allows 30% of funding to go outside of the company and requires at least 30% to go to a university partner.
- All funding must remain in the U.S.

READ REQUIREMENTS

- U.S. Ownership & PI Eligibility
- Employee Count
- Eligible Venture Operating Company (VCOC)
- Establish Legal Business Entity

Homework

FILL IN YOUR INFORMATION BELOW

Provide a description of your current facility including it's capabilities and equipment. Include the location and estimated size of your facility.

List the equipment and lab capabilities that are required for your project.

List the gaps in your facilities capabilities and equipment and how you plan to make up for them. For example, if you don't have equipment where will you get it?

Homework

FILL IN YOUR INFORMATION BELOW

List your team members and key personnel. Include their role on the team, experience and area of expertise.

List your current collaborators, their areas of expertise and the roll and tasks they will complete.

List collaborator rolls in areas in which your team currently has gaps that will need to be filled.

Registration

Required to apply

Register ahead of time even if you don't have a topic yet. The registration process takes time and often prevents applicants from making deadlines.

SYSTEM FOR AWARD MANAGEMENT (SAM)

Required to do business with the U.S. government.

SAM will issue a 12-character unique entity identifier (UEI) used to complete your full SAM registration and which serves as the official organization identifier in other federal systems.
3-6 weeks



ERA COMMONS

Required to do business with NIH and some agency partners.

GRANTS.GOV

Required to submit grant applications through the federal-wide grant portal.

SMALL BUSINESS ADMINISTRATION (SBA) COMPANY REGISTRY

Required to participate in SBIR and STTR federal funding programs.



HOMework

FILL IN YOUR INFORMATION BELOW

UEI	
CAGE code	
Company ID	

What is your product?

IT'S IMPORTANT NOW TO THINK ABOUT YOUR PROJECT AS A PRODUCT

You need to know:

The client (who is going to pay for this product?)

The end user (who is going to ultimately use this product?)

The competition (If you haven't already, research and get an understanding of your competition and take note of the ways you are superior)



FEASIBILITY

What research do you need to do and what goals do you need to reach to show that your idea is feasible?



FOUR TOTAL OMNIBUS SOLICITATIONS

1 - SBIR, clinical trial required

2 - SBIR, clinical trial not allowed

3 - STTR, clinical trial required

4 - STTR, clinical trial not allowed

**Specific funding may have a clinical trial option*

Clinical trial is NOT the traditional FDA Phase I, Phase II, Phase III clinical trial.

- These are small studies with limited human subjects (Not large populations costing \$10s-\$100s of millions).
- It's essentially "Do you need to perform invasive research using humans."
- Not all institutes within NIH allow clinical trials.

Human subject's studies fall into the clinical trial categories add considerable complexity to your proposal.

- You need to develop a plan for number of people and why, as well as account for gender and racial diversity in subject recruitment
- Need to describe how you will de-identify and protect human subject's personal data.
- Need to describe and justify how invasive the work is.
- Need to get Institutional Review Board (IRB) approval.

Resources to determine "Clinical Trial" or not.

- See NIH's definition of Clinical Trial [HERE](#).
- Use this decision tool to help determine if you meet the definition of a clinical trial [HERE](#).
- Read the eight exemptions to NIH clinical trials [HERE](#).



HOMework

FILL IN YOUR INFORMATION BELOW

Describe your product.

What is the issue that your product solves and explain how it's currently resolved.

List measurable ways in which your product better than current competition.

Significance

WHY IS YOUR PRODUCT IMPORTANT?

Your SBIR proposal must communicate strong significance, but many proposals fall short in this area.

Your technology must solve a problem – Just studying or optimizing something is not interesting to NIH SBIR Reviewers unless it is solving a serious problem that someone, and preferably a lot of somebodies care about.

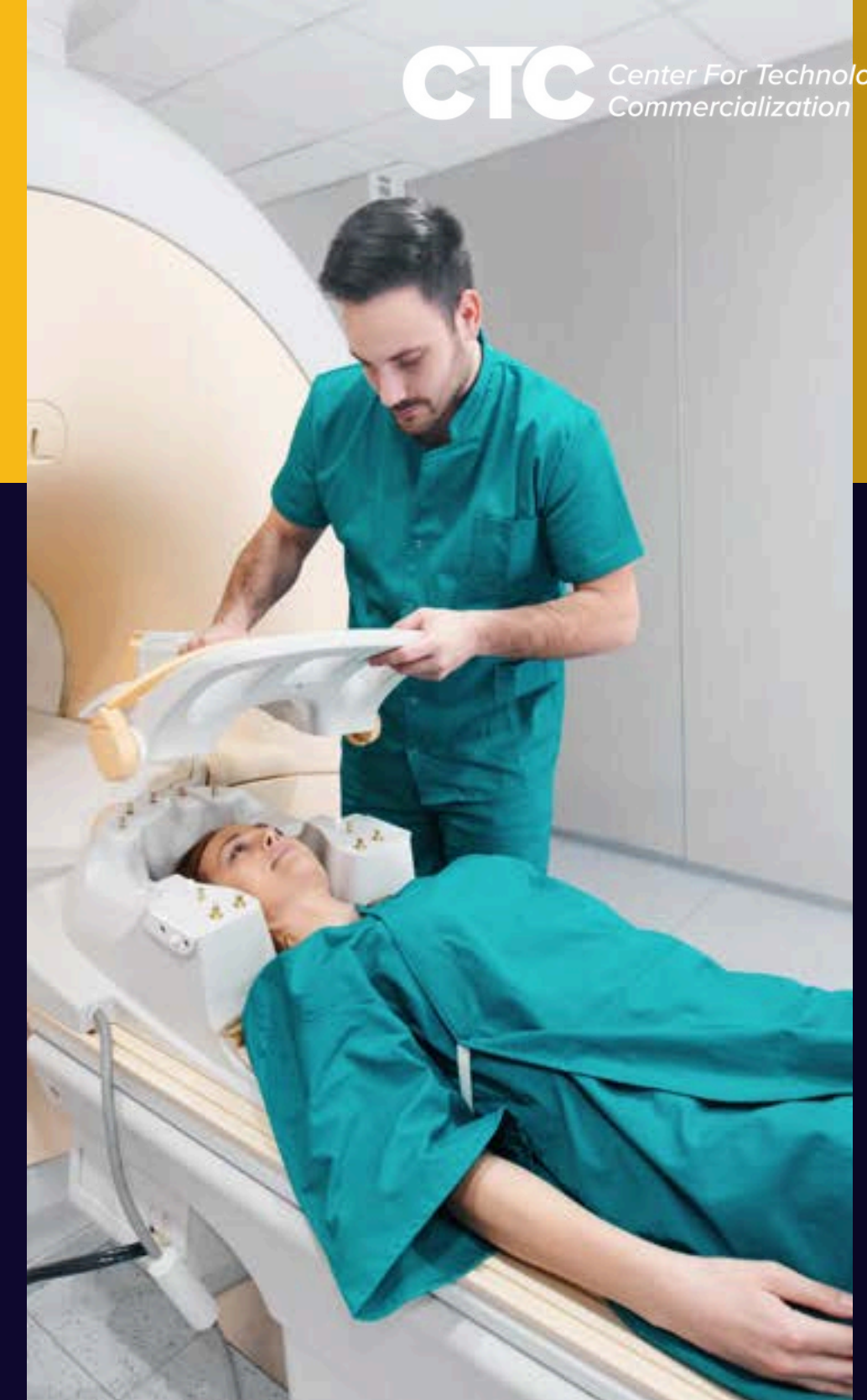
What problem does this solve, and who cares, and why?
SBIR projects may advance science but that is not the primary objective.

Demonstrate:

- Significant science
- Significant need in the market
- Avoid the golden hammer problem

Keep in mind:

The objective of the SBIR/STTR program is to solve a problem in a way that is commercially and societally significant.



Watch video



Market Gaps & Problems

A magazine is a periodical publication, which can either be printed or published electronically. It is issued regularly, usually every week or every month, and it contains a variety of content.

Think about:

- Size of the Problem
- Size of the Opportunity
 - how much of the Problem can your technology impact?
- Advantages of your approach
 - how you overcome the shortfalls of the alternatives
 - benefits to the users of your technology
- Not just the features that you think make it special
- Aggregate impact
 - To economy, public health, society, etc.
- Commercial Merit
 - Show a reasonable path to commercialization

Questions to consider:

- Current market solutions: What existing products are in market? Who sells them? Why are those not meeting the need?
- Stating that there is no competition is not realistic.
- Current 'Good Enough' solutions: Customers may use their own 'duct tape' solutions or do nothing. What are these approaches? Why are existing approaches poor?
- Investment and Research: What emerging solutions via startups and research attempt to address need? Why might yours be better?

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BRAINSTORM MARKET GAPS (SBIR PROBLEM) AND CURRENT SOLUTIONS

Current market solutions: What existing products are in market? Who sells them? Why are those not meeting the need?	
Current ‘Good Enough’ solutions: Customers may use their own ‘duct tape’ solutions or do nothing. What are these approaches? Why are existing approaches poor?	
Investment and Research: What emerging solutions via startups and research attempt to address need? Why might yours be better?	

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FILL IN YOUR INFORMATION BELOW

Problem to be solved	
Gap in current solutions	
Prelim studies	

Move on to work on your Specific Aims

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FILL IN YOUR INFORMATION BELOW

How important is your problem?	
How many people are concerned or affected by this problem?	
What is the current cost of the problem?	
What are the barriers to addressing this problem?	

Include evidence for each answer in the form of links or pdfs

Strategies for finding a topic

Find an internal Institute of NIH that fits your product or research [HERE](#)
 Identify a target components likely interested in your future solution

- Which health conditions will your product address?
- Which institutes (CDC, FDA, etc.) ALSO care about those health conditions?
- Note special budget limits, clinical trial preference, and allowance of TABA (Technical and Business Assistance)

OR

Search by keyword [HERE](#)

Copy key words/phrases from Institute that indicates your solution addresses one of their chief concerns.

If your product is unique and doesn't fit current topics, search past topics [HERE](#) to indicate if NIH has ever had an interest.



Finding your agency and topic



Review Omnibus



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FILL IN YOUR INFORMATION BELOW

List the Institutes that may be interested in your product.	
List the program manager of that institution and their contact information.	
How does your project advance the Institute’s mission/goals? List exact website phrases that confirm your approach.	
List the specific topics or omnibus solicitation related to your project.	

Include evidence for each answer in the form of links or pdfs

NIH SBIR/STTR Application

Read ALL of the solicitation and write down the requirements.
If an application is missing something it will be declined.

Don't wait until the last minute, there are always challenges

PAGE LIMITS

- Specific Aims page: 1 Page
- Phase I: 6 Pages
- Phase II: 12 Pages
- Roughly half of the 6 or 12 pages should relate to the technical research.

Note the three headings in the guidelines:

- Phase 2: Significance, Innovation, Approach, Results
- Phase 1: Significance, Innovation, Approach,

SAMPLE APPLICATION

Review sample applications and take note of:

- No Commercialization plan required for Phase 1 SBIR/STTR

NIH APPLICATION TUTORIALS

- Prepare to apply
- Write application
- Submit

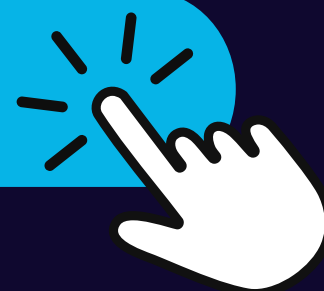
NIH SBIR/STTR INSTRUCTIONS

- Review SF424 Application Form (B), Version H
- Preview all required sections especially animal and human research.
- Be sure to use proper headings

Preview Solicitation

Follow the link below to find and review the four omnibus solicitations as well as specific funding opportunities.

Solicitations



Prepare Specific Aims Approach

Put together the information that you found researching institutes and funded topics to begin thinking about possible specific aims. Be sure that your specific aims have measurable outcomes and milestones.



Specific aims video



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**PREPARE 2-3 SPECIFIC AND MEASURABLE AIMS.
INCLUDE EVIDENCE OF PAST OR CURRENT FUNDING FROM AGENCY.**

Include evidence for each answer in the form of links or pdfs

CHECKLIST

At the end of module two you should have to following checklist completed. Don't move on to session two until this checklist is complete.

- **Online registrations**
- **Select institute with shared focus and evidence of funding**
- **Eligibility confirmed including PI and collaborators**
- **2-3 specific aims ideas**
- **Decide on STTR or SBIR strategy**

HAVE QUESTIONS?

Reach out to the CTC with questions or concerns [here](#).

FINISHED WITH SESSION ONE?

It's time to reach out and check in with your CTC consultant to discuss the overview summary.

Todd Strother



Rob Baranowski

