NIH SBIR/STTR General Overview – Proposal Preparation

Grant Writing for Success

Presented by
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My Background

- 25+ years in the Federal Government
  - NIH: SBIR/STTR Program Manager; Researcher
    - Office of the Director
    - National Cancer Institute
  - FDA
  - USDA
  - Interagency policies/initiatives (DOD, NSF, DOE, NASA, DHS, etc.)
- 10+ years in non-profit and for-profit environments
  - Jackson Laboratory, Director of Sponsored Research
  - Small TX biotech company, VP Research
  - Small FL-based consulting company, Program Manager
- Scientific Background
  - Microbiology and immunology
  - Cancer genetics

Today's Objectives

- **SBIR/STTR Refresher**
- **NIH SBIR/STTR Program Review**
- **Key Forms G Items**
- **NIH SBIR/STTR Application Elements**
- **Review Process (in brief)**
- **Communicating with NIH**
- **Resources**
- **Answer Your Questions!**

Congressionally Mandated Programs

3.2%

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

~$3.2 billion annually across all Federal Agencies

0.45%

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

~$450 million annually across 5 Federal agencies

$1.2 Billion Dedicated SBIR-STTR Funding via Set-aside from NIH's R&D Budget

SBIR/STTR Program Goals

- Stimulate technological **innovation**
- Meet federal **research and development needs**
- Increase private-sector **commercialization** of innovation derived from federal research and development funding
- Foster and encourage **participation** in innovation and entrepreneurship by women and socially/economically disadvantaged individuals
- Foster **technology transfer** through cooperative R&D between small businesses and research institutions (STTR)

SBIR - STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award is *always* made to the small business

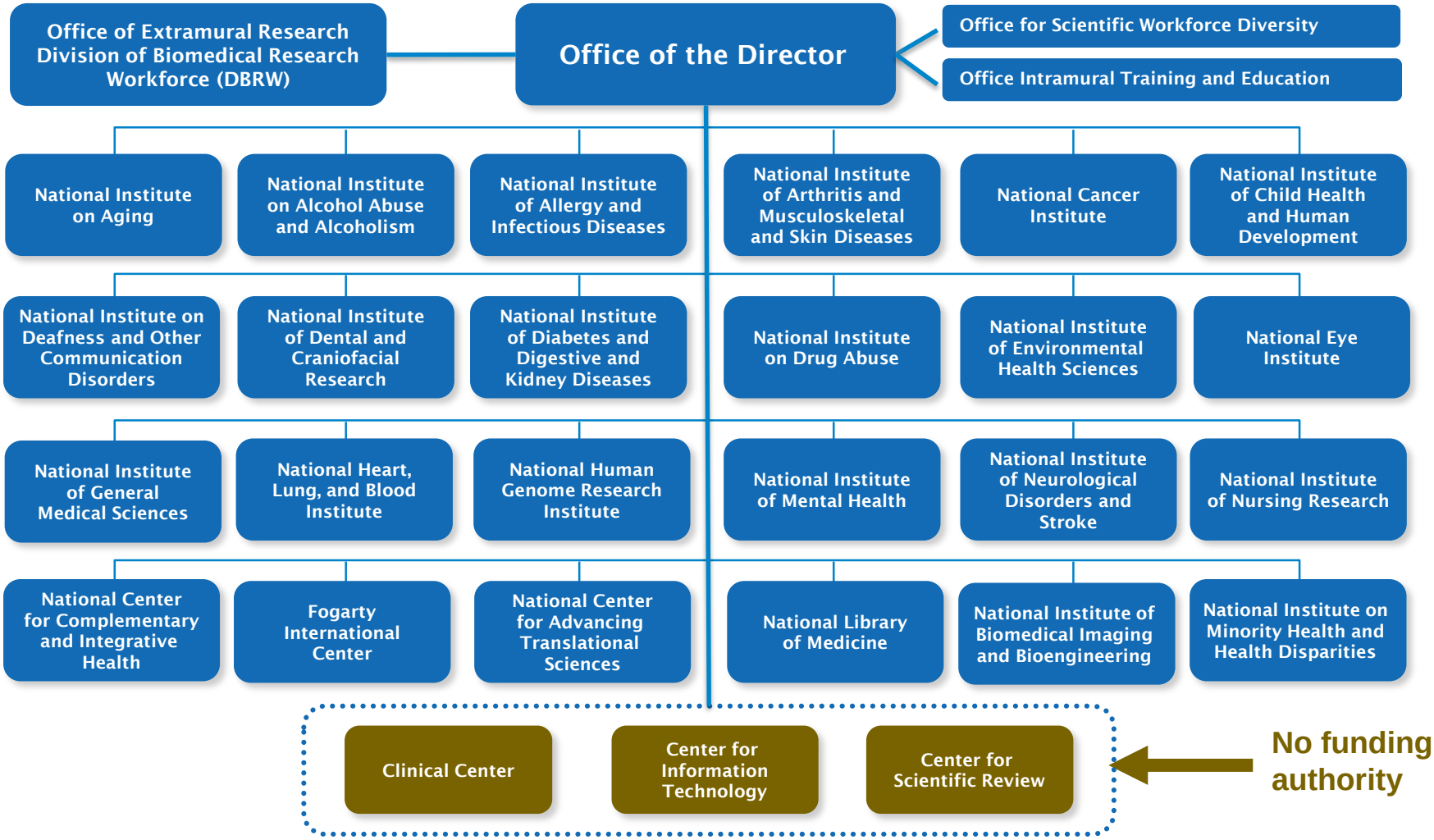
NIH Mission

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****.*

The Small Business Program helps NIH accelerate discoveries from bench to bedside

NIH National Institutes of Health
Turning Discovery Into Health

National Institutes of Health



ONE NIH, 27 Cultures

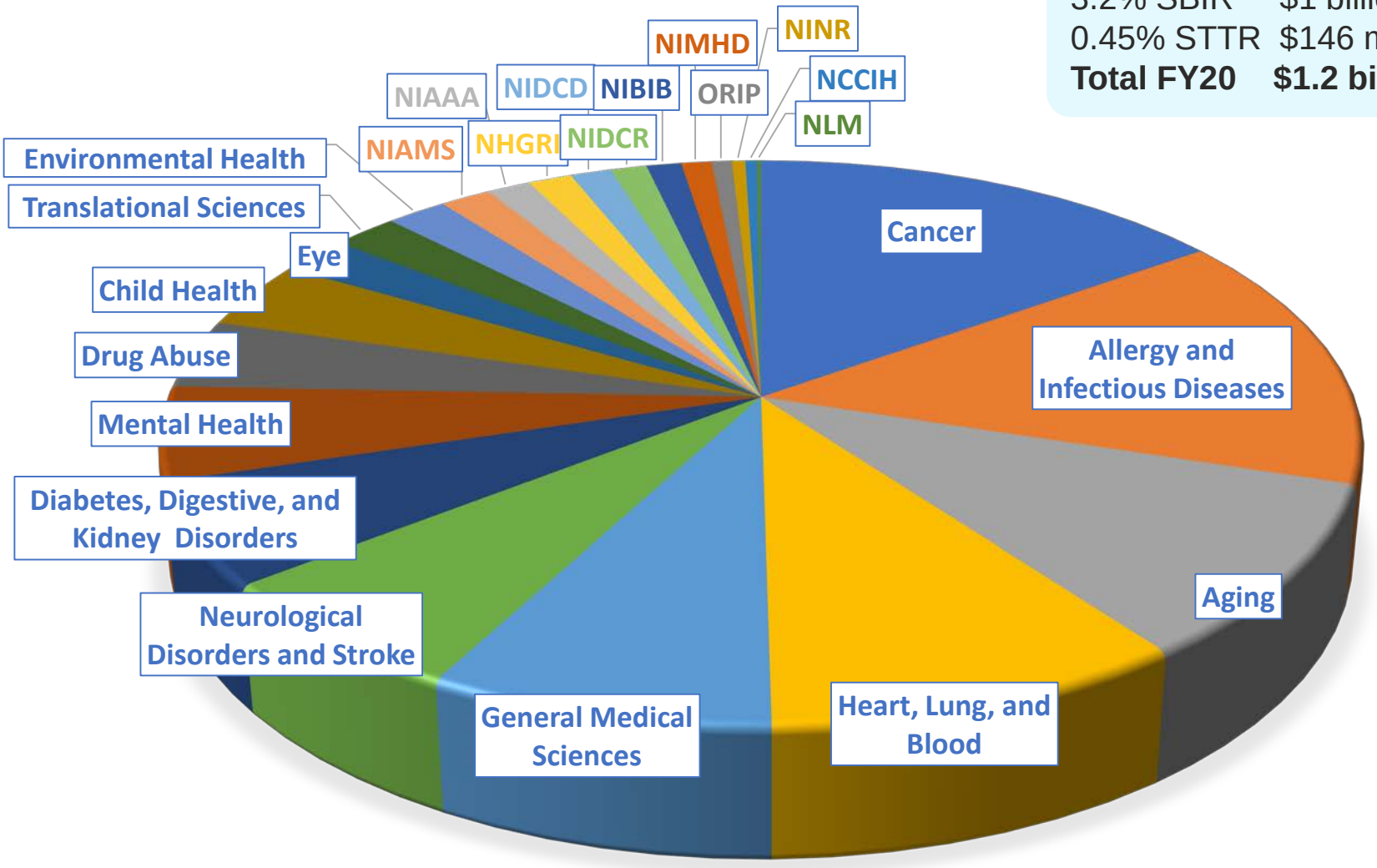
Each IC has its own

- **mission**
- **budget (and success rates)**
- **activities**
- **way of doing business**

You are in the right place to learn the myriad nuances!

NIH SBIR/STTR Budget Allocations FY2020

3.2% SBIR $1 billion
0.45% STTR $146 million
Total FY20 $1.2 billion

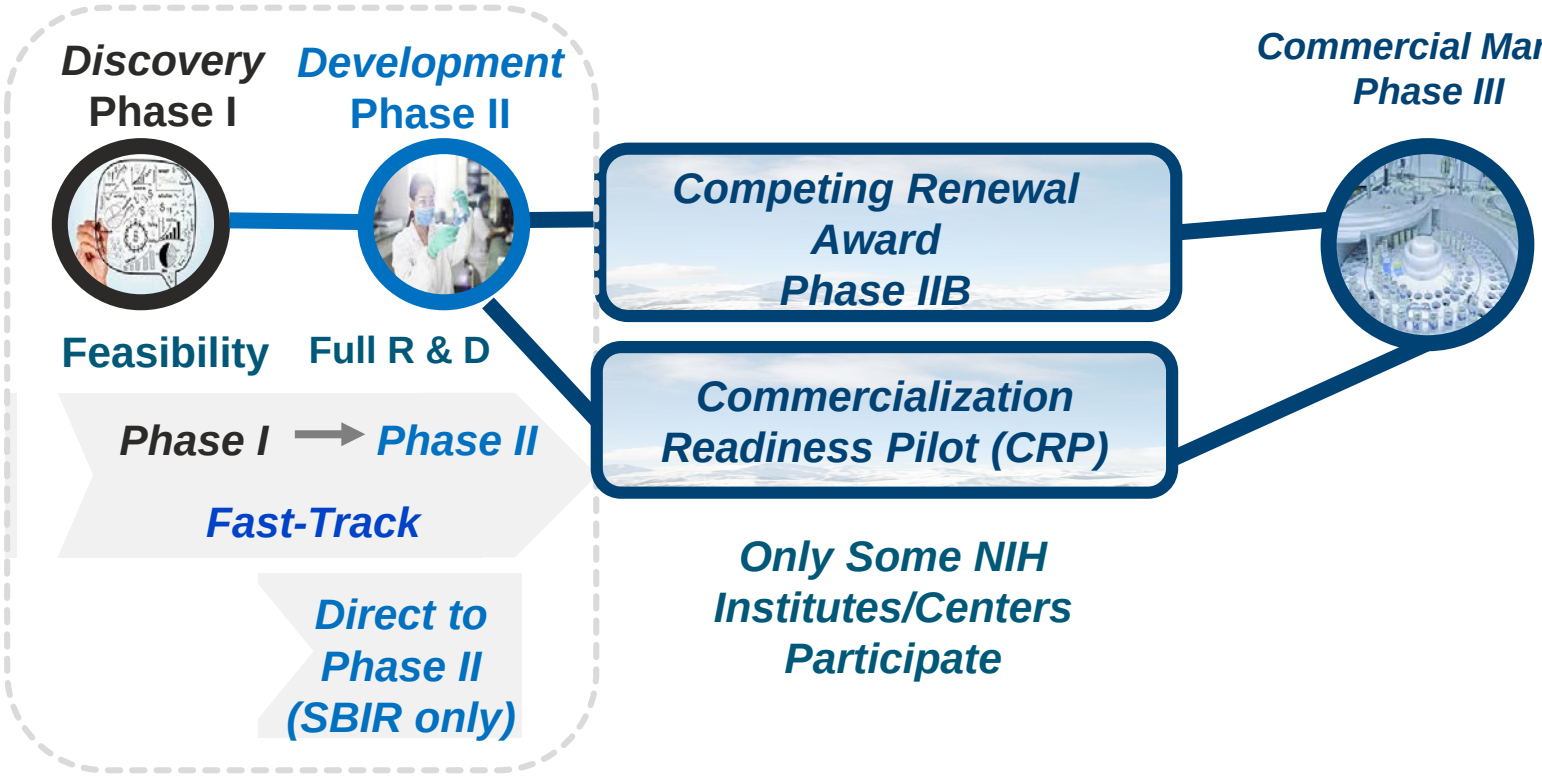


NIH-Wide SBIR/STTR Success Rates

*Excludes applications and awards issued using supplemental Coronavirus (COVID-19) appropriations.

Fiscal Year	SBIR/STTR	Phase[1]	Number of Applications Reviewed	Number of Applications Awarded	Success Rate[2]	Total Funding[3]
2020	SBIR	Phase I	3,620	450	12.4%	$122,375,161
2020	SBIR	Fast Track	637	108	17.0%	$45,233,516
2020	**SBIR**	**Total Phase II**	**1,260**	**324**	**25.7%**	**$302,763,267**
2020	SBIR	Regular Phase II	570	174	30.5%	$158,434,872
2020	SBIR	Direct Phase II	588	112	19.0%	$103,621,112
2020	SBIR	Phase IIB	102	38	37.3%	$40,707,283
2020	SBIR	CRP	53	6	11.3%	$4,057,444
2020	STTR	Phase I	1,066	186	17.4%	$52,804,650
2020	STTR	Fast Track	106	20	18.9%	$7,033,717
2020	**STTR**	**Total Phase II**	**99**	**27**	**27.3%**	**$23,102,158**
2020	STTR	Regular Phase II	95	26	27.4%	$22,102,158
2020	STTR	Phase IIB	4	1	25.0%	$1,000,000
2020	**FY TOTAL**		**6,841**	**1,121**	**16.4%**	**$557,369,913**

NIH SBIR/STTR Phases



Phase I: **$275,766**
1-2 years*
Phase II: **$1,838,436***
1-3 years

***NIH has a waiver from the Small Business Administration to exceed these budgets for most topics**

NIH Small Business Program Phases

Small Business Program Phases	Description
Phase I	A Phase I award helps you focus on the feasibility, technical merit, and commercial potential of your research project.
Phase II	A Phase II award lets you continue the research and development efforts initiated in Phase I. Once you've reached your Phase I milestones, you can apply for a Phase II award, even before the end of the Phase II award. You may submit your application for a Phase II award up to six receipt dates after your Phase I budget period expires.
Fast-Track	The fast-track process allows you to submit both Phase I and Phase II in one application for review. The Fast -Track mechanism can minimize the funding gap between phases but requires a fully developed Phase II application/plan at the time of submission.
Direct to Phase II (SBIR Only)	If your project has already demonstrated feasibility but you have not received a Phase I SBIR or STTR, you can apply for a Direct to Phase II award and bypass Phase I.
Phase IIB More info here	Some NIH Institutes and Centers offer Phase IIB awards for Phase II projects that require extraordinary time and effort beyond the standard Phase II period of 2 years. See the Phase IIB FAQs for more information.
Commercialization Readiness Pilot (CRP) Program More info here	The Commercialization Readiness Pilot (CRP) Program provides awarded Phase II and Phase IIB small businesses technical assistance and funding for late-stage development. Read more about the CRP program.

Technical Assistance and Entrepreneurial Training

Discovery
Phase I

Development
Phase II/IIB

Technical and Business Assistance (TABA) Programs

TABA Funding: Requested in the Application
Phase I- $6,500/year **Phase II- $50K**

Needs Assessment
Click here for details

Consulting Services
Click here for details

Additional Entrepreneurial Training and Assistance

NIH I-Corps™
Click here for details

NIH Concept to Clinic Commercializing Innovation (C3i): Medical Devices
Click here for details

Diversity Supplement
(PA-21-345)

https://sbir.nih.gov/tap

NIH SBIR/STTR Website

NEW LOOK!

SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Home / Small Business Funding

SMALL BUSINESS FUNDING

24 NIH Institutes and Centers along with CDC, FDA, and ACL fund scientists & entrepreneurs working to bring their **discoveries to patients.**

For a small business with a brilliant new idea in the life sciences, a funding infusion can do wonders to help translate that concept into reality. Did you know that the NIH small business programs are the largest source of early-stage capital for the life sciences in the U.S.? These programs set aside over $1.2 billion non-dilutive funds every year -- specifically to support small business research and development.

The road to bringing your discovery to patients begins here.

Small Business Program Basics

Learn about program basics, how to determine eligibility, and guidance on grants policy.

LEARN MORE→

Find Funding

NIH has different funding mechanisms - find an active list of SBIR and STTR Grant FOAs, understand SBIR contracts, and learn about the specific research areas at each Institute and Center.

LEARN MORE→

How to Apply

Find step-by-step instructions on how to apply for SBIR and STTR grants, along with who to speak with for guidance at each step.

LEARN MORE→

Prepare Your Application

Ready to apply to an SBIR or STTR funding opportunity? Find guidance, resources for first-time applicants, and all the necessary forms in one convenient location.

LEARN MORE→

Frequently Asked Questions (FAQs)

Questions? Refer to our extensive FAQs that cover various components of the small business programs and more.

LEARN MORE→

NIH SEED
Helping Innovators Turn Discovery Into Health

NIH Staff | Contact & Help

Search

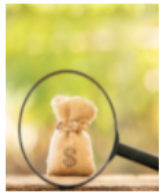
SMALL BUSINESS FUNDING | SUPPORT FOR SMALL BUSINESSES | PROGRAMS FOR ACADEMICS | PORTFOLIO | ABOUT SEED | APPLY

Home / Small Business Funding / Find Funding

SMALL BUSINESS FUNDING

FIND FUNDING

24 NIH Institutes and Centers fund scientists and entrepreneurs working to bring their discoveries to patients.



NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants and contracts provide different ways for life science entrepreneurs to obtain federal funding. Explore these options below.

Find the best small business funding opportunities for your innovation.

SBIR and STTR Grants (FOAs)

SBIR and STTR grant funding opportunities offer small business entrepreneurs a chance to obtain non-dilutive funding for early-stage research and development. Applications are accepted three times a year.

LEARN MORE → FOAs: Click Here

SBIR Contract Solicitations

SBIR contract solicitations are offered once a year and reflect specific research needs at various ICs across NIH. Learn more about these solicitations and how to submit a proposal.

LEARN MORE →

Navigate NIH's Research Areas

Did you know that 24 of the 27 NIH Institutes and Centers (ICs) provide funding to small businesses? Learn more about each IC and their therapeutic research areas of focus to find the best fit for your innovation.

LEARN MORE→

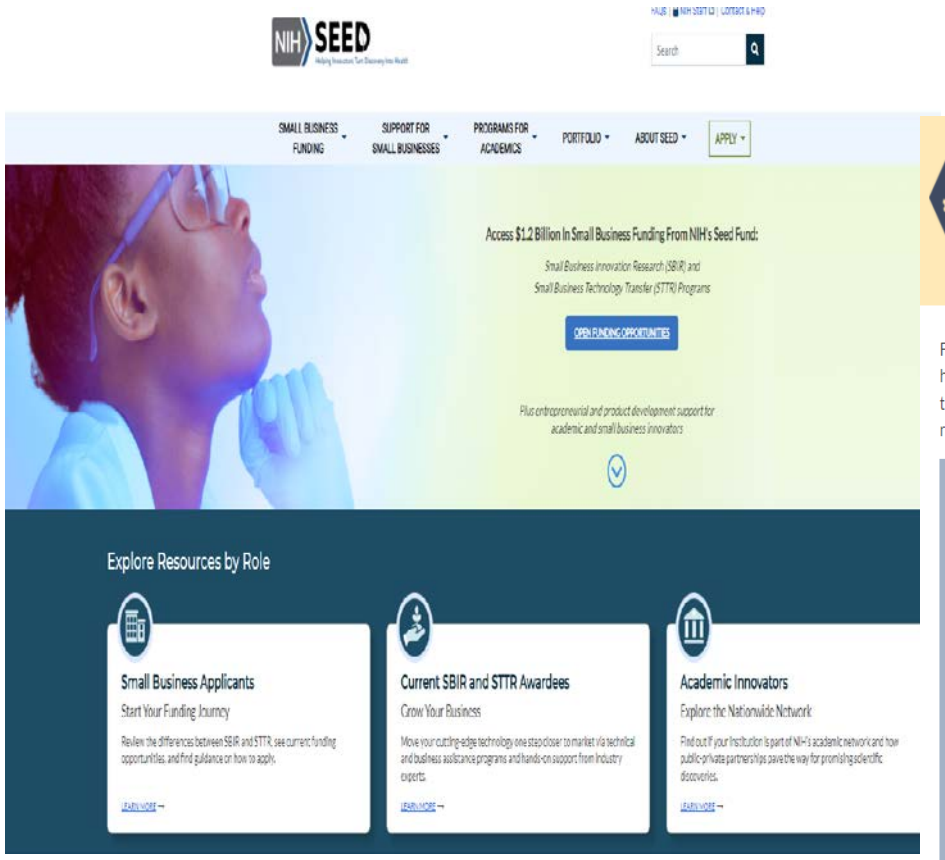
Frequently Asked Questions (FAQs)

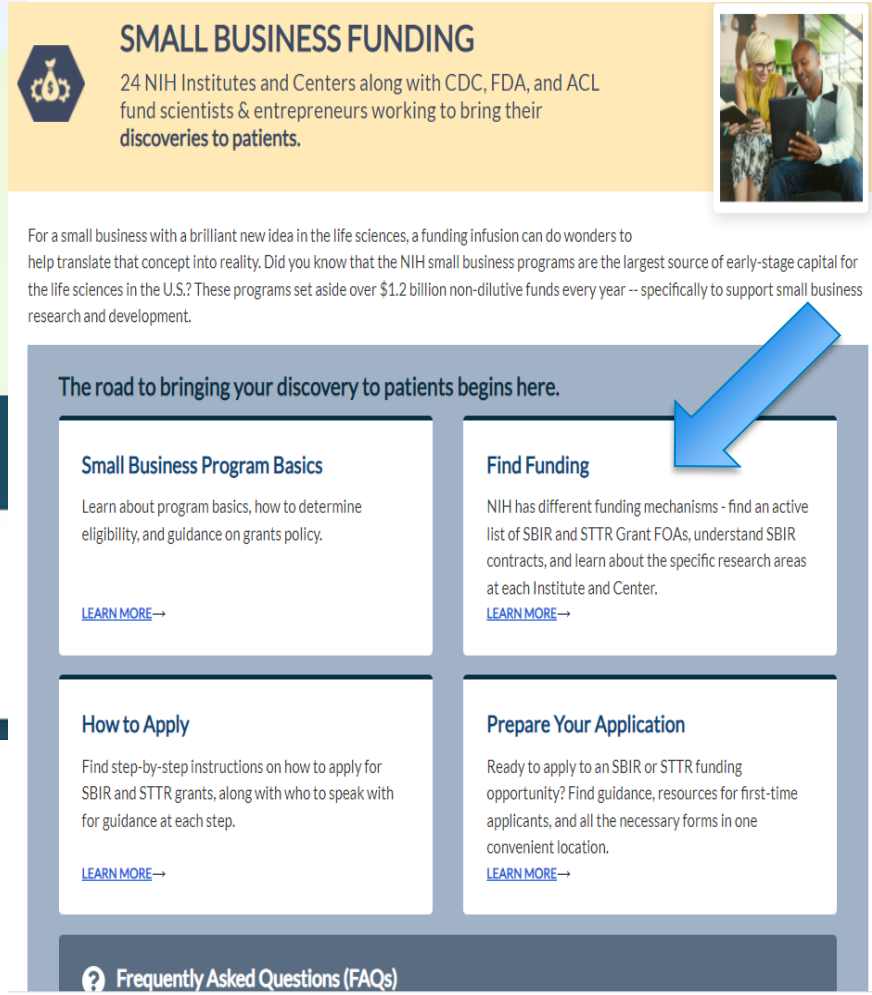
Questions? Refer to our extensive FAQs that cover various components of the small business programs and more.

LEARN MORE→

NIH SBIR/STTR Website

NEW LOOK!





FOAs: Click Here

Types of NIH Funding Opportunity Announcements (FOA)

Type of FOA	Description
Parent Announcements	• Broad FOAs allowing applicants to submit "investigator initiated" or "unsolicited" research ideas to a specific activity code (e.g., R01, R03) • Most applications to NIH = investigator initiated • Usually ongoing (3 years); standard receipt dates
Requests for Applications (RFA)	• Identifies specific scientific areas, amt of set-aside funds, anticipated # of awards • Usually, single receipt date • IC usually convenes review panel
Program Announcements (PA, PAR, PAS)	• Highlights specific, high-priority areas of interest • PAS: PA with set aside funds; PAR: has a special receipt, referral and/or review considerations • Usually ongoing (3 years) • Often use standard receipt dates • Most NIH ICs participate

NIH/CDC/FDA SBIR/STTR Solicitations and Due Dates

Standard Due Dates: Jan 5, April 5, Sept 5

- **PA-21-259 -- PHS 2021-2 Omnibus Solicitation of the NIH, CDC and FDA for SBIR Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed)**
- **PA-21-260 - PHS 2021-2 Omnibus Solicitation of the NIH and CDC for SBIR Grant Applications (Parent SBIR [R43/R44] Clinical Trial Required)**
- **PA-21-261 - PHS 2021-2 Omnibus Solicitation of the NIH for STTR Grant Applications (Parent STTR [R41/R42] Clinical Trial Required)**
- **PA-21-262 -PHS 2021-2 Omnibus Solicitation of the NIH for STTR Grant Applications (Parent STTR [R41/R42] Clinical Trial Not Allowed)**
- **SBIR Contract Solicitation (NIH, CDC)**
  Release: August November 2022 close date
- **NIH Guide for Grants and Contracts**
  Release: Weekly Receipt dates specified in each FOA
  (http://grants.nih.gov/grants/guide/index.html)

SBIR/STTR Topics

- **Search the Solicitation (e.g., digital health)**
  - **National Cancer Institute (NCI):** Major NCI SBIR/STTR Portfolio Areas:
    - Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, Cell-based Therapies)
    - In Vitro and In Vivo Diagnostics (e.g., Companion Diagnostics Prognostic Technologies)
    - Imaging Technologies (e.g., Agents, Devices, Image-Guided Interventions)
    - Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies, Hospital Devices)
    - Agents and Technologies for Cancer Prevention
    - Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
    - Tools for Cancer Biology Research
    - Digital Health Tools and Software Platform for Cancer Related Technologies

SBIR/STTR Topics

- **Search the Solicitation (e.g., digital health)**
  - **National Institute on Drug Abuse (NIDA) -** Topics of Special Interest
    - Biomarker Development for Substance Use Disorders (SUD)
    - Biomedical Robotic Cloud Labs
    - Substance Use Disorder (SUD) Drug Discovery and Development
    - Technologies for Safe and Controlled Methadone Dispensing for Use at Home
    - FDA-regulated Medical Devices for Substance Use Disorder (SUD)
    - Technological Approaches to Address Stigma Associated with Substance Use Disorders (SUD)
    - Digital Health Technologies to Address the Social Determinants of Health in context of Substance Use Disorders (SUD)
    - New technological approaches for the Investigation, Diagnosis, and Certification of Deaths Related to Drug Overdose

SBIR/STTR Topics

- **Search the Solicitation (e.g., natural products)**
  - **National Center for Complementary and Integrative Health (NCCIH)**

  Non-Clinical Trials Topics: Natural Products (including botanicals, herbs, probiotics, prebiotics, dietary supplements, special medicinal diets, and microbiome-/microbial-based therapeutics):
  - Development and validation of technologies for standardization and characterization of biologically active ingredients in natural products
  - Development and validation of technologies for taxonomic identification of botanical raw materials or detection of adulterants
  - Development and validation of technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products
  - Development and validation of methods for the sustainable production of low-yield natural products of commercial interest
  - Development of novel analytical tools and technologies to study the microbiome, including its composition, genetics, and bioactivity, that can help clarify associations between the human microbiome and brain function and health
  - Development of gut microbiome monitoring assays for validating safety and functional analysis of genomic and microbiota interactions
  - Development of complementary and integrative therapeutic approaches to modify and balance the gut microbiota in healthy populations and individuals with disrupted microbiota and related diseases

Electronic Submission

SBIR/STTR grant applications **and** SBIR contract proposals must be submitted **electronically**.

REQUIRED REGISTRATIONS

- DUNS Number / UEI (unique entity identifier)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

- Grants submit via ASSIST or Grants.gov Workspace
- For contracts, submit proposals with electronic Contract Proposal Submission (eCPS) website

NIH UEI Implementation

- For applications due on or after January 25, 2022, applicants **must** have a UEI at the time of application submission. UEI replaces DUNS on all FORMS-G application forms and packages.
- All entities currently registered in SAM have automatically been issued a UEI.
  - Note: DUNS still required for new registrants prior to April 2022. UEI will be issued as part of registration.
- Effective October 2021
  - eRA pulling UEI data for organizations in eRA Commons registered in SAM.gov. No action is required by the entity.
- Organizations will see their UEI in eRA Commons IPF early in January 2022.

Electronic Submission

- Be sure to use the correct Forms Set!
- NIH "FORMS-G" Grant Application Forms and Instructions must be used for Due Dates on or after January 25, 2022

Annotated Form Set for NIH Grant Applications

FORMS G Series

Key Changes in Forms G update

- Transition from DUNS to a unique entity identifier (UEI) issued by SAM.gov as the official identifier for doing business with the federal government (**NOT-OD-21-170**.) See ***Goodbye DUNS, Hello UEI.***
- Updated biosketch and other support format pages (**NOT-OD-21-110**.)
- Added question regarding Technical and Business Assistance (TABA) to the SBIR/STTR Information form (**NOT-OD-21-082**.)
- Updated country and state dropdown lists across all forms.
- Increased character limit to 100 characters for “Department” and “Division” fields.
- Expanded requirement for a Commons ID to all senior/key personnel (**NOT-OD-21-109**.)
- Increased number of “Other” direct cost budget lines from 3 to 10.

NIH Application Elements

- SF424 R&R Cover Page
- Performance Sites
- R&R Other Project Information
  - Project Summary
  - Project Narrative
  - Facilities/Other Resources
  - Other Attachments
    - SBC Registration (SBA)
- Senior/Key Personnel
- Budget
- SBIR/STTR Information
  - Commercialization Plan*
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
  - Specific Aims (1 page)
  - Research Strategy
  - Human Subjects*
  - Vertebrate Animals*

**as applicable*

NIH Application Elements (cont.)

- MPI Leadership Plan*
- Bibliography/References Cited
- Consortium/Contractual Arrangements*
- Letters of Support*
- Resource Sharing Plan
- Authentication of Key Biological and/or Chemical Resources

**as applicable*

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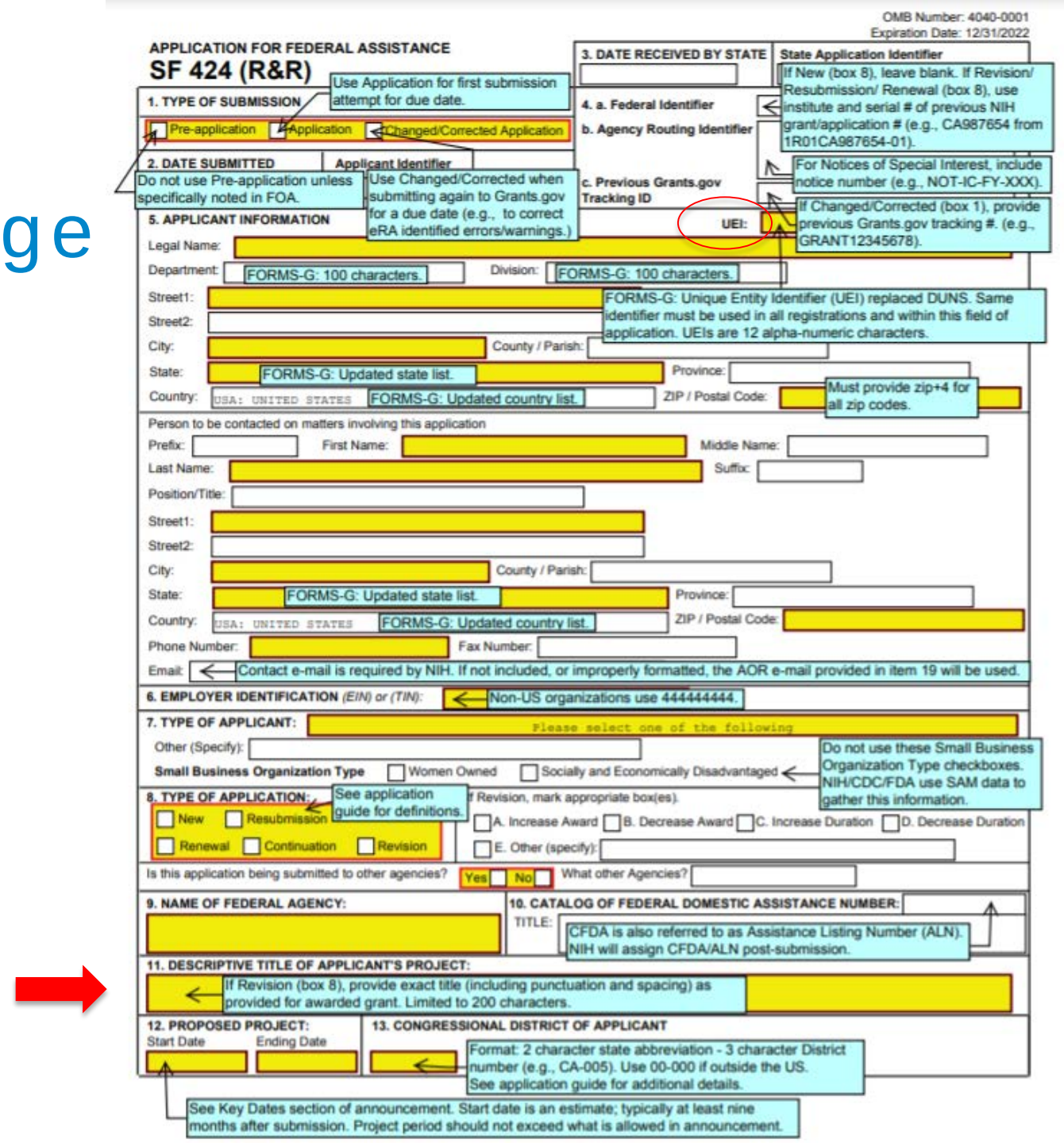
Cover Page


OMB Number: 4040-0001
Expiration Date: 12/31/2022
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)
3. DATE RECEIVED BY STATE
State Application Identifier
1. TYPE OF SUBMISSION
Use Application for first submission attempt for due date.
Pre-application
Application
Changed/Corrected Application
4. a. Federal Identifier
b. Agency Routing Identifier
If New (box 8), leave blank. If Revision/ Resubmission/ Renewal (box 8), use institute and serial # of previous NIH grant/application # (e.g., CA987654 from 1R01CA987654-01).
2. DATE SUBMITTED
Applicant Identifier
Do not use Pre-application unless specifically noted in FOA.
Use Changed/Corrected when submitting again to Grants.gov for a due date (e.g., to correct eRA identified errors/warnings.)
c. Previous Grants.gov Tracking ID
For Notices of Special Interest, include notice number (e.g., NOT-IC-FY-XXX).
5. APPLICANT INFORMATION
UEI:
If Changed/Corrected (box 1), provide previous Grants.gov tracking #. (e.g., GRANT12345678).
Legal Name:
Department:
FORMS-G: 100 characters.
Division:
FORMS-G: 100 characters.
Street1:
Street2:
FORMS-G: Unique Entity Identifier (UEI) replaced DUNS. Same identifier must be used in all registrations and within this field of application. UEIs are 12 alpha-numeric characters.
City:
County / Parish:
State:
FORMS-G: Updated state list.
Province:
Country:
USA: UNITED STATES
FORMS-G: Updated country list.
ZIP / Postal Code:
Must provide zip+4 for all zip codes.
Person to be contacted on matters involving this application
Prefix:
First Name:
Middle Name:
Last Name:
Suffix:
Position/Title:
Street1:
Street2:
City:
County / Parish:
State:
FORMS-G: Updated state list.
Province:
Country:
USA: UNITED STATES
FORMS-G: Updated country list.
ZIP / Postal Code:
Phone Number:
Fax Number:
Email:
Contact e-mail is required by NIH. If not included, or improperly formatted, the AOR e-mail provided in item 19 will be used.
6. EMPLOYER IDENTIFICATION (EIN) or (TIN):
Non-US organizations use 444444444.
7. TYPE OF APPLICANT:
Please select one of the following
Other (Specify):
Small Business Organization Type
Women Owned
Socially and Economically Disadvantaged
Do not use these Small Business Organization Type checkboxes. NIH/CDC/FDA use SAM data to gather this information.
8. TYPE OF APPLICATION:
See application guide for definitions.
If Revision, mark appropriate box(es).
New
Resubmission
Renewal
Continuation
Revision
A. Increase Award
B. Decrease Award
C. Increase Duration
D. Decrease Duration
E. Other (specify):
Is this application being submitted to other agencies?
Yes
No
What other Agencies?
9. NAME OF FEDERAL AGENCY:
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:
CFDA is also referred to as Assistance Listing Number (ALN). NIH will assign CFDA/ALN post-submission.
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
If Revision (box 8), provide exact title (including punctuation and spacing) as provided for awarded grant. Limited to 200 characters.
12. PROPOSED PROJECT:
Start Date
Ending Date
13. CONGRESSIONAL DISTRICT OF APPLICANT
Format: 2 character state abbreviation - 3 character District number (e.g., CA-005). Use 00-000 if outside the US.
See application guide for additional details.
See Key Dates section of announcement. Start date is an estimate; typically at least nine months after submission. Project period should not exceed what is allowed in announcement.

NIH Application Elements

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  - Vertebrate Animals*

**as applicable*

Project Summary

- 30 lines of text or less
- Succinct, accurate description of proposed work
- Informative to others in the same field and understandable to a scientifically literate reader
- State project's broad, long-term objectives and specific aims
- Include description of research design/methods
- No proprietary or confidential information
- If application is funded, this becomes posted in NIH RePORTER

Problem	**What issue or question will be addressed?**
Background	**What is known or not known and why is the issue or question important?**
Hypothesis / Specific Aims	**What does the research expect to discover and what specific work will be accomplished?**
Methods / Approach	**What plans and methods will be used to accomplish the work?**
Anticipated Outcomes	**What are the intended outcomes and are they important?**
Significance	**If the project is successful, what will the scientific impact be?**

Project Summary - Example

Problem

Background

Significance

Methods/ Approach

Aims

Anticipated Outcomes

OncoPath: Intelligent Clinical Pathway Decision Support Tool for Pre-Authorization Documentation in Non-Small Cell Lung Cancer Treatment

Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
1R43CA261312-01A1	1R43CA261312-01	HENSLEY ALFORD, SHARON	VIZLITICS INC.

Description

Abstract Text

Project Abstract In a real-world clinical setting, busy oncologists lack the time for investigative case analysis across all feasible treatment options, frequently updated treatment guidelines and payor specific requirements. This results in sub- optimal decision making, incomplete pre-authorization (pre-auth) documentation, and problems with reimbursement. Overall, this increases medical costs and payment deficits within oncology. For example, pre- auth inefficiencies are estimated to add $83,000 a year per physician to healthcare costs, which is $1.1 billion annually in oncology alone. To devise a treatment plan, oncologists reference National Comprehensive Cancer Network Guidelines® (NCCN), other clinical society standards, and payor specific requirements in the context of a patient's medical history, tumor characteristics, and phase of treatment. One of the most used oncology treatment guidelines referenced by oncologists and adhered to by most payors is the National Comprehensive Cancer Network (NCCN) Guidelines®. These guidelines are presented as a schema that span 100s of pages. A technology driven clinical decision support (CDS) system could be employed to address the need to streamline treatment guideline analysis, payor rules review, and treatment decision documentation for reduced overall cost to oncology practices. This proposal focuses on developing an innovative and first-of- a-kind technology for CDS using non-small cell lung cancer (NSCLC) as the initial test case and incorporating NCCN Guidelines, general payor specific requirements and patient data overlaid to compute feasible treatment pathways. The team proposes the following Phase I Specific Aims: Aim 1: Develop a graph-based mathematical model and visual presentation of NSCLC NCCN treatment guidelines with generalized payor specific requirements. Develop a visually interactive graph-based representation of NCCN Guidelines®. Modeling guidelines as a visual graph (nodes and arcs) will enable oncologists to identify the optimal treatment pathway for their patients. Aim 2: Build an analytics engine that highlights the NCCN graph model with feasible treatment options given the patient's case details and common payor requirements. Use an opensource tool to create synthetic patient data and common payor constraints with an oncologist and health plan experts. Develop a library of graph traversal algorithms to overlay and visualize the patient data in a visual user interface. Aim 3: Execute, validate and test a proof-of-concept CDS workflow using OncoPath. Run the complete end-to-end CDS workflow with documentation of patient details, NCCN guideline, payor requirements and treatment decision using synthetic patient data and payor constraints generated in Aim 2. OncoPath will enable an efficient, oncologist-friendly approach to treatment decisions and documentation, subsequently benefitting the patient and decreasing oncology cost. Phase II will deploy a real-time instance of OncoPath in a single thoracic oncology practice for integrated workflow and time savings validation.

Project Narrative and Example

- 2-3 sentences
- Communicate public health relevance of the project
- Use plain language understandable by general audience
- Describe how the research would contribute to the fundamental knowledge about the nature and behavior of living systems, and/or the application of that knowledge to enhance health, lengthen life, and reduce illness/disability.
- If application is funded, this becomes posted in NIH RePORTER

Public Health Relevance Statement

Project Narrative In a real-world clinical setting, busy oncologists lack the time for investigative case analysis across all feasible treatment options, frequently updated treatment guidelines and payor specific requirements. This results in sub-optimal decision making, incomplete pre-authorization (pre-auth) documentation, and problems with reimbursement. Overall, this increases medical costs and payment deficits within oncology. To address this unmet need, this proposal aims to build OncoPath, a prototype tool in non-small cell lung cancer providing a first-of-a-kind visual representation of the NCCN Guidelines® with patient data overlaid to easily review, select, and document the patient information, treatment selection with NCCN supporting evidence, payor constraints, and any clinical narrative.

Facilities and Other Resources

- Describe the scientific environment in which the research will be done.
- Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations
- Discuss how studies will employ useful collaborative arrangements.
- If there are multiple performance sites, describe the resources available at each site.

NIH Application Elements

- SF424 R&R Cover Page
- Performance Sites
- R&R Other Project Information
  - Project Summary
  - Project Narrative
  - Facilities/Other Resources
  - Other Attachments
    - SBC Registration (SBA)
- Senior/Key Personnel
- Budget
- SBIR/STTR Information
  - Commercialization Plan*
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
  - Specific Aims (1 page)
  - Research Strategy
  - Human Subjects*
  - Vertebrate Animals*

**as applicable*

Biographical Sketch

Create your biosketch here! SciENcv Science Experts Network Curriculum Vitae

Sample- See Here

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY

Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to (previously captured under Section D. Research Support).

A. Personal Statement

B. Positions, Scientific Appointments and Honors

C. Contributions to Science

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  - Vertebrate Animals*

**as applicable*

Commercialization Plan

- 12 pages:
  - Value of the SBIR / STTR Project, Expected Outcomes, and Impact
  - Company
  - Market, Customer, and Competition
  - Intellectual Property Protection
  - Finance Plan
  - Production and Marketing Plan
  - Revenue Stream

NIH Application Elements

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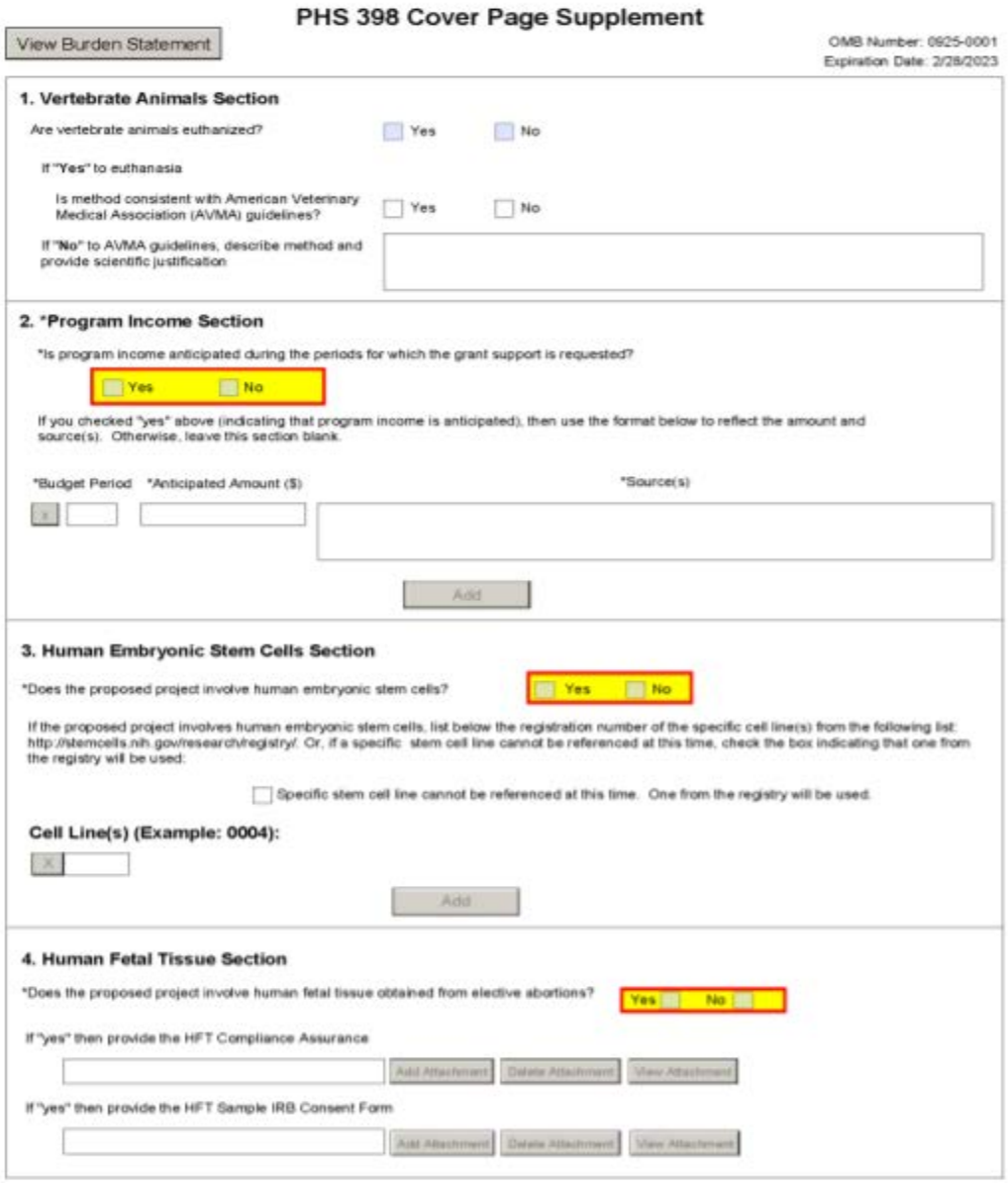
**as applicable*

PHS 398 Cover Page Supplement



PHS 398 Cover Page Supplement

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 2/28/2023

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☐ No

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

Add

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ☐ Yes ☐ No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

Add

4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions? ☐ Yes ☐ No

If "yes" then provide the HFT Compliance Assurance

Add Attachment | Delete Attachment | View Attachment

If "yes" then provide the HFT Sample IRB Consent Form

Add Attachment | Delete Attachment | View Attachment

NIH Application Elements

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  - Research Strategy
  - Human Subjects*
  - Vertebrate Animals*

**as applicable*

PHS 398 Research Plan

- **SPECIFIC AIMS**
  - 1 page – that's it!
  - State concisely the goals of the proposed research
  - Summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.
  - List succinctly the specific objectives of the research proposed

Note….

- Most important part of the application
- Reviewers have to like your idea by the time they finish reading this page.
- Persuade reviewers that
  - this project is important
  - you are the right person (or team) to do it, and
  - it will advance the state of the science.

More to come!
Attend the webinar on
January 18

PHS 398 Research Plan

RESEARCH STRATEGY

- 6 pages (Ph I) or 12 pages (Ph II, FT, Direct to Ph II)
- Major part of your Research Plan
- The nuts and bolts of your application
  - Rationale for your research and the experiments you will do to accomplish each aim.
- Three main sections
  - Significance
  - Innovation
  - Approach

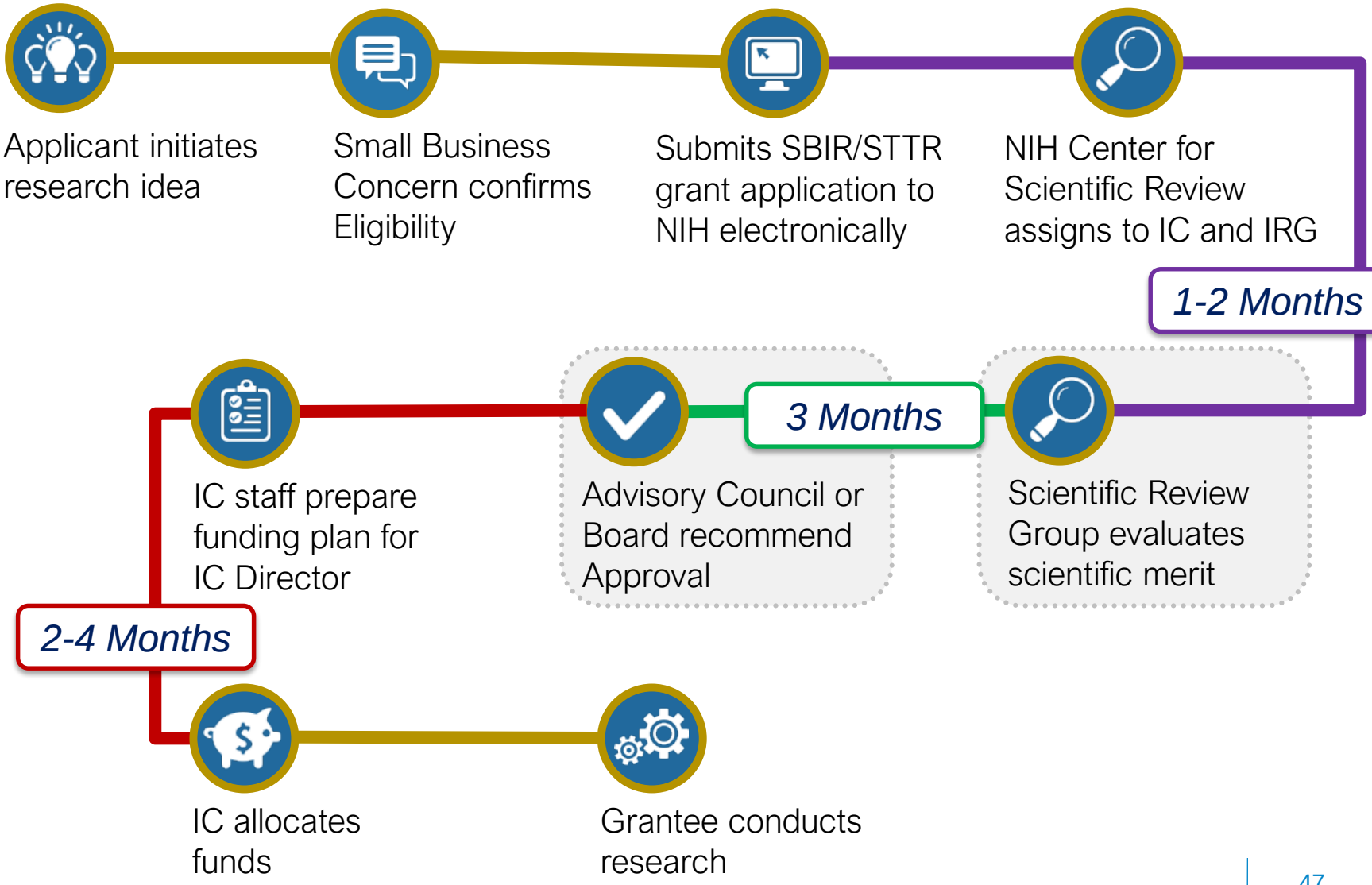
More to come!
Attend the webinar on
January 25

PHS 398 Research Plan

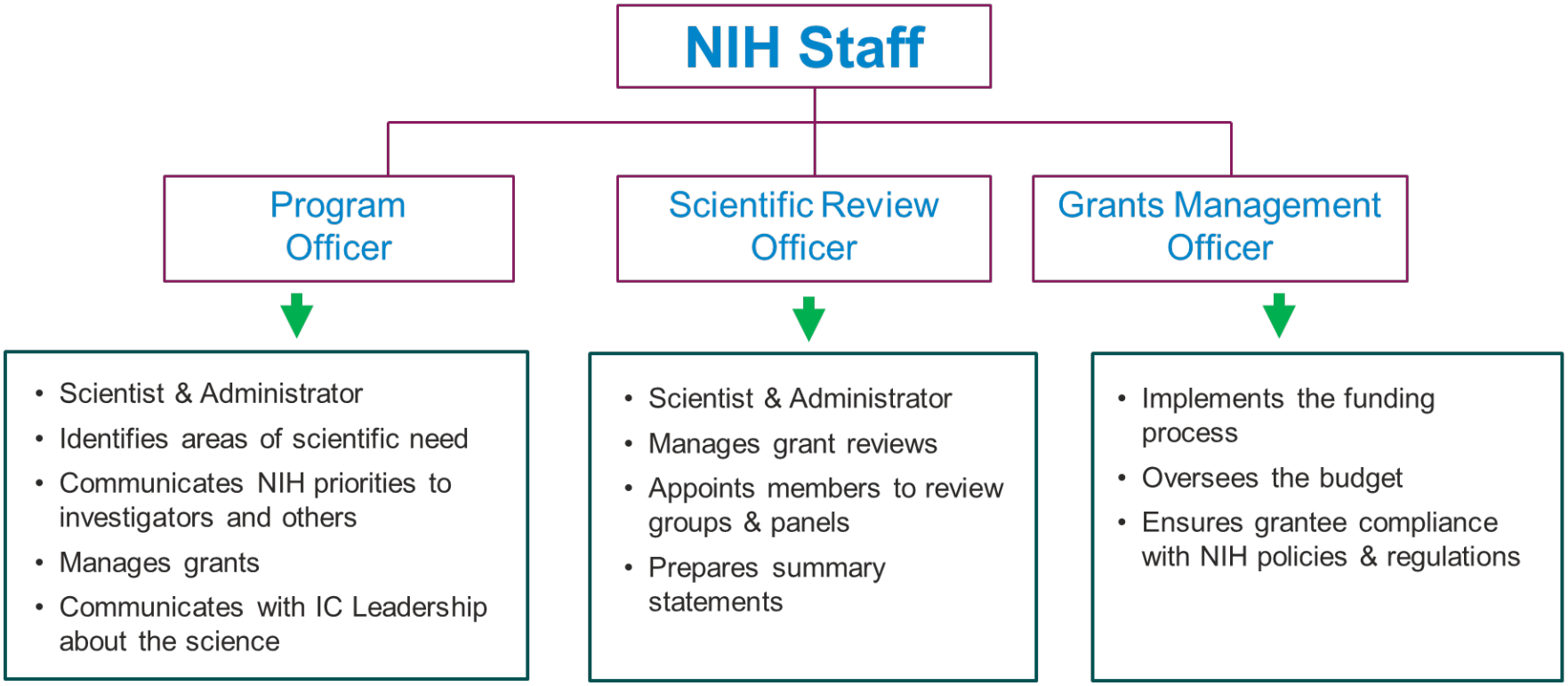
HUMAN SUBJECTS AND VERTEBRATE ANIMALS

- Human Subjects
  - Exempt or non-exempt research? Decision trees to help guide you
  - Non-exempt: 4 key areas:
    1. Risks to Human Subjects
    2. Adequacy of Protection Against Risks
    3. Potential Benefits of the Proposed Research to Research Participants and Others
    4. Importance of the Knowledge to be Gained
  - Plus more so be sure you have expertise in completing this information
- Vertebrate Animals
  - Description of Procedures
  - Justification (that the species are appropriate for the proposed research.)
  - Minimization of Pain and Distress
  - Identify all project performance/collaborating) sites and describe the research activities with vertebrate animals that will be conducted at those sites.
  - Explain when and how animals are expected to be used if plans for the use of animals have not been finalized

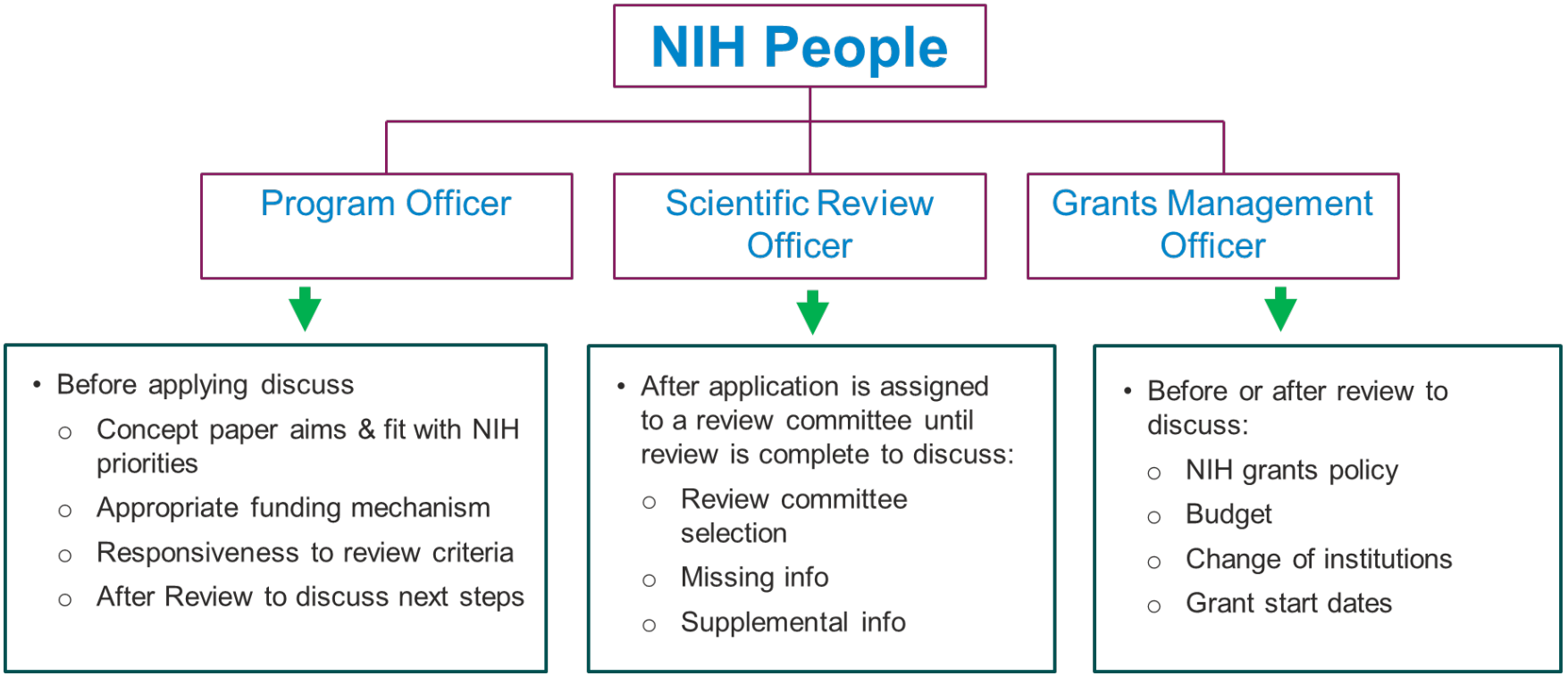
NIH Application - Review Process



Communicating with NIH is Key

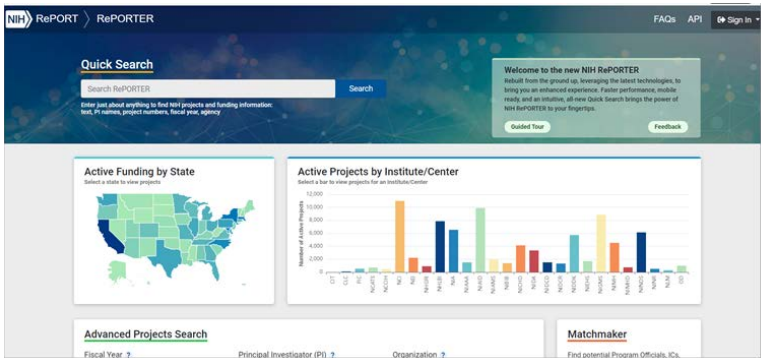


Who Should I talk to? When? And About What?



Use These Resources to Find the Right IC and PO

- Talk to mentors and colleagues
- Search NIH RePORTER for funded projects
- Search NIH MATCHMAKER for similar projects and their POs
- Review IC missions, strategic plans, & research priorities
- Review IC division or program webpages



Example: NIH RePORTER Search

- Search NIH RePORTER for funded projects

  “Digital Health” SBIR/STTR
  https://reporter.nih.gov/search/YVpKaWVWnE-qjE3QrA0M1g/projects?shared=true

T	Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
Mouse Home Cage Health Monitoring Using Virtual Cage Inspection and a Digital Health Biomarker										
1		R43OD030200-01A1			WRIGHT, ZACHARY	WRIGHT WOLD SCIENTIFIC, LLC	2021	OD	OD	$223,898
Digital health for medication adherence among African Americans with hypertension										
1		R43MD015969-01A1			WEITZMAN, PATRICIA FLYNN	ENVIRONMENT AND HEALTH GROUP, INC.	2021	NIMHD	NIMHD	$256,460
Remote Digital Health Intervention to Improve Balance and Reduce Fall Risk										
1		R43AG074833-01			VANVLEET, THOMAS	POSIT SCIENCE CORPORATION	2021	NIA	NIA	$254,947
Limbix Spark: a CBT-based mobile intervention for adolescent depression										
1		R44MH125636-01			LAKE, JESSICA COMPTON, SCOTT N PERAKSLIS, ERIC D	LIMBIX HEALTH, INC.	2021	NIMH	NIMH	$449,928
Demonstration of a Digital Care Program for Methamphetamine Use Disorder										
1		R43DA055394-01			MUHLNER, KRISTIN	AFFECT THERAPEUTICS, INC.	2021	NIDA	NIDA	$309,360
SurvivorCare: A digital health solution to support long-term cancer survivorship using patient navigation										
2		R44CA265301-02			HO, Y. XIAN JACKSON, JONATHAN LEE	DIMAGI, INC.	2021	NCI	NCI	$764,805
A Mightier healthcare system: Introducing a game-based pediatric mental health intervention into payor-sponsored care to evaluate financial and clinical outcomes										
5		R44MH124574-02			KAHN, JASON	NEUROMOTION, INC.	2021	NIMH	NIMH	$733,178
HEAL - Development and implementation of a provider prescribed, behavioral digital therapeutic designed to support, educate, screen and remotely monitor patients with chronic pain										
1		R44AT011593-01			MASTERSON, JO WATERS, DEANNA	2MORROW, INC	2021	NCCIH	NCCIH	$251,986
Development of a Digital Cognitive Screening Test to detect Mild Cognitive Impairment and Dementia in Clinical Settings.										
1		R41AG074835-01			MANKODIYA, KUNAL	ECHOWEAR LLC	2021	NIA	NIA	$300,234
A Chatbot Utilizing Machine Learning and Natural Language Processing to Implement the Brief Negotiation Interview to Improve Engagement in Buprenorphine Treatment among Justice-Involved Individuals										
3		R43DA051267-01A1S1			PANTALON, MARIANNE S PANTALON, MICHAEL V	CENTER FOR PROGRESSIVE RECOVERY, LLC	2021	NIDA	NIDA	$55,000
Automated Seizure Detection for Home Seizure Monitoring with Epilog Sensors										
1		U44NS121562-01			LEHMKUHLE, MARK J.	EPITEL, INC.	2021	NINDS	NINDS	$999,853
A MULTIFACETED DIGITAL HEALTH PLATFORM TO ADVANCE ALZHEIMER'S DISEASE PATIENT MONITORING, SAFETY, CARE, AND RESEARCH.										
1		R43AG072981-01A1			CORKEY, JON ANDREW	AMISSA, INC.	2021	NIA	NIA	$495,787

Example: NIH RePORTER Search

- Search NIH RePORTER for funded projects

  “Natural Products” AND SBIR/STTR
  https://reporter.nih.gov/search/qdaWcgV6lUW4H_R-VZRFWA/projects?shared=true

T	Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
Cellular membrane affinity chromatography kit for drug discovery										
3	R41	AT011716	-01S1		CIESLA, LUKASZ MICHAL	REGIS TECHNOLOGIES INC	2022	NCCIH	NCCIH	$26,807
Development of Natural Product Inspired Adjuvants to Treat Tolerant Infections										
5	R41	AI152873	-02		PIERCE, JOSHUA G.	SYNOXA SCIENCES, INC	2021	NIAID	NIAID	$283,828
Development of Single Agent Antibiofilm Antibiotics										
5	R41	AI155280	-02		PIERCE, JOSHUA G.	SYNOXA SCIENCES, INC	2021	NIAID	NIAID	$289,153
Discovery of Small Molecules as Antimalarial Agents										
1	R43	AI164621	-01		ZHU, SHUREN	CASCADE THERAPEUTICS, INC.	2021	NIAID	NIAID	$256,500
A new class of broad-spectrum antibacterials for treating MDR infections										
5	R44	AI152665	-02		TESTA, CHARLES	CURZA GLOBAL, LLC	2021	NIAID	NIAID	$1,000,000
Microbiome-Balancing Wraps for Managing Eczema										
1	R43	AT011486	-01A1		PARITALA, HANUMANTHARAO	CFD RESEARCH CORPORATION	2021	NCCIH	NCCIH	$253,024
Ultrahigh Throughput Microscale Mass Spectrometry for Pharmaceutical Prenylation Enzyme Engineering										
1	R41	GM143989	-01		PRINCE, ROBIN ABATE, ADAM R.	FLUID DISCOVERY INC	2021	NIGMS	NIGMS	$253,795
Gas Chromatography-Molecular Rotational Resonance Spectrometer										
5	R44	GM139446	-02		NEILL, JUSTIN LINDSAY	BRIGHTSPEC, INC.	2021	NIGMS	NIGMS	$604,022
Oleocanthal functional food products for breast cancer recurrence control										
3	R41	CA247025	-01A1S1		EL SAYED, KHALID A	OLEOLIVE, LLC	2021	NCI	NCI	$54,756
Rapid discovery of thousands of intact biosynthetic gene pathways for bioactive natural product compounds from un-sequenced filamentous fungi using a novel FAC-NGS tool										
5	R44	AI140943	-03		WU, CHENGCANG CHARLES BOK, JIN WOO CROFTS, TERENCE SPENCER	INTACT GENOMICS, INC.	2021	NIAID	NCCIH NIAID	$662,270 $337,730
Cellular membrane affinity chromatography kit for drug discovery										
1	R41	AT011716	-01		CIESLA, LUKASZ MICHAL	REGIS TECHNOLOGIES INC	2021	NCCIH	NCCIH	$223,895
Efficacy of an Electrophile Scavenger in the Prevention of Gastrointestinal Inflammatory Carcinogenesis										
1	R41	CA257262	-01A1		RATHMACHER, JOHN A WILSON, KEITH T.	MTI BIOTECH, INC.	2021	NCI	NCI	$400,000

Resources

- NIH SBIR/STTR Website: https://seed.nih.gov/
- NIH RePORTER (Abstracts of funded projects): https://reporter.nih.gov/
- Sample applications (NIAID): https://www.niaid.nih.gov/grants-contracts/sample-applications
- NIH Peer Review Process: https://grants.nih.gov/grants/peer-review.htm
- Your TAP Team!

More Webinars in 2022!

- **January 18:** Writing the Specific Aims Page for NIH SBIR/STTR Applications
- **January 25:** Understanding the NIH SBIR/STTR Peer Review Process

Thank You!

Jo Anne Goodnight

joanne.goodnight@gmail.com