2024 HHS Contract Solicitation Pre-proposal Conference (PHS-2025-1)

September 23, 2024, 2PM ET

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH

This presentation may include presenter's notes.

NIH SEED

Adam Sorkin, MEM, MSE, PE

Small Business Policy Manager
SEED (Small business Education & Entrepreneurial Development)

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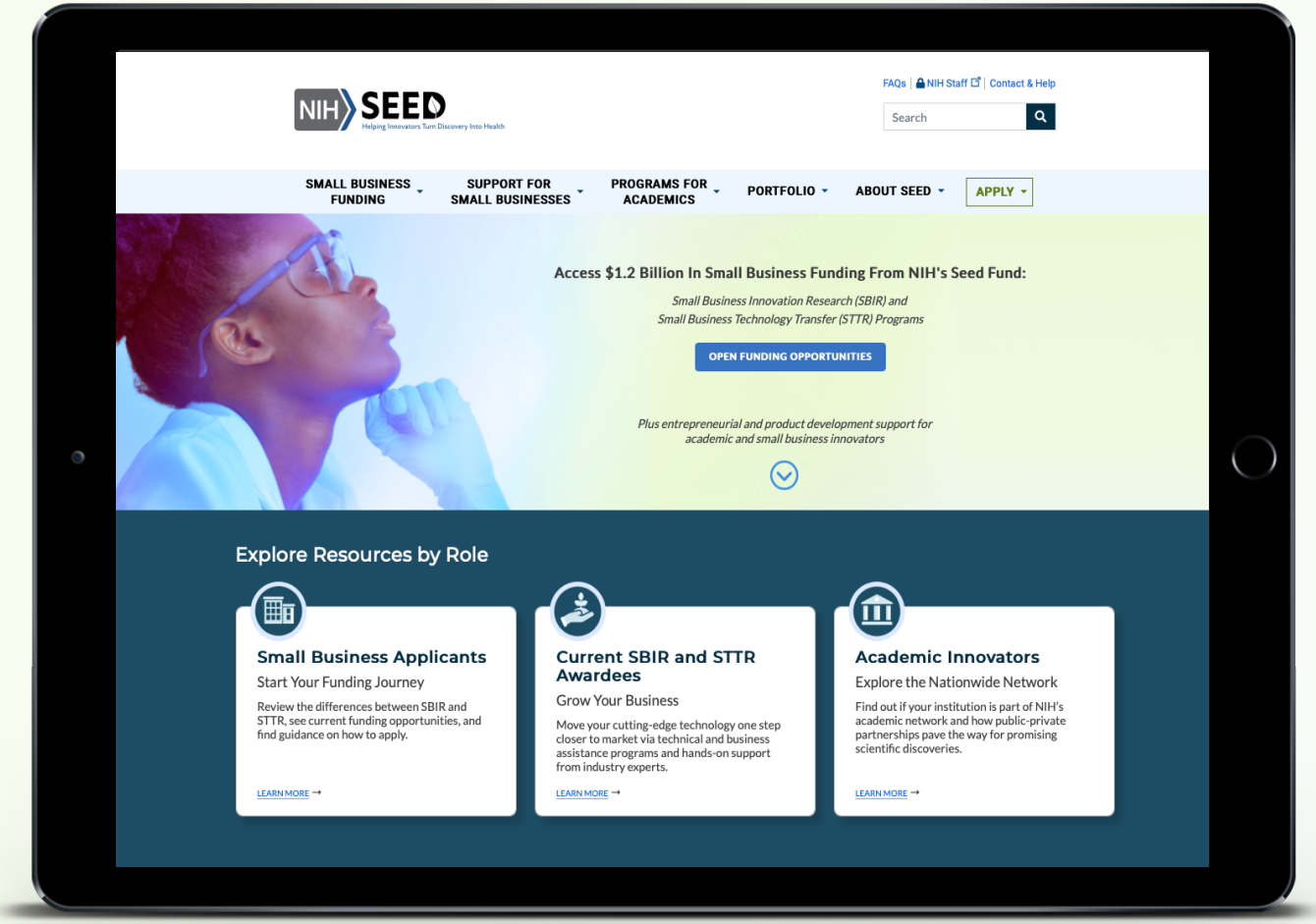
This presentation may include presenter's notes.

NIH SEED

Small Business Program Website



http://seed.nih.gov

HHS Mission and Divisions

National Institutes of Health
Turning Discovery Into Health

To enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health and social services.

National Institutes of Health
SBIR and STTR $1.4B

Centers for Disease Control and Prevention
SBIR $9 million

Advanced Research Projects Agency for Health
SBIR and STTR $38 million

SBIR $2 million

Administra nity Living
SBIR $3 million

ARPA-H, FDA and ACL do not participate

NIH Mission

National Institutes of Health
Turning Discovery Into Health




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

Congressionally Mandated Programs

$1.4 Billion Dedicated Funding via Set-aside from NIH's R&D Budget

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

$1.25 billion set-aside for small business concerns to engage in federal R&D -- with potential for commercialization

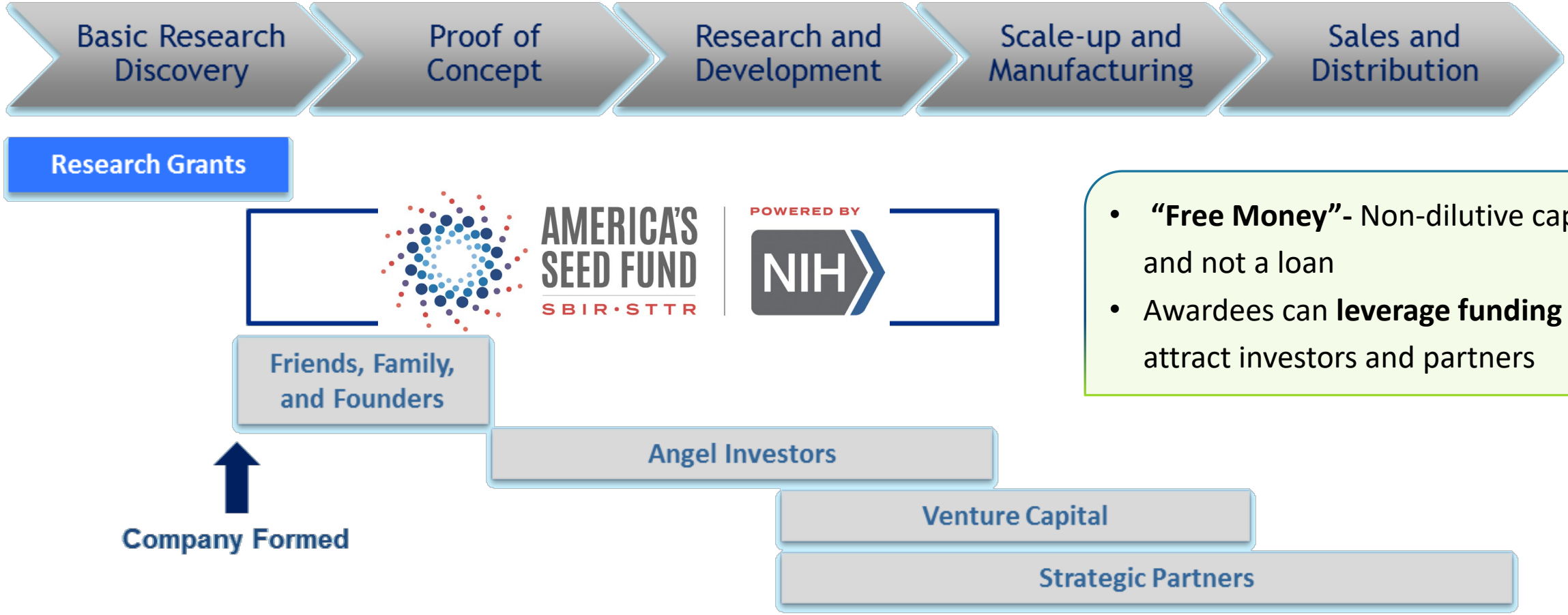
L BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

$17 lion Set-aside to facilitate cooperative R&D between small business conce d US research institutions -- with potential for commercialization

THERE ARE NO STTR CONTRACTS

Benefits of NIH Funding

The largest sources of early-stage capital for life sciences in the US

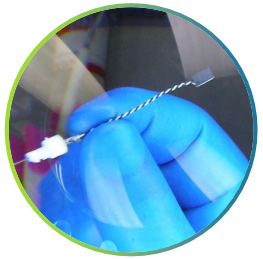


- **"Free Money"-** Non-dilutive capital and not a loan
- Awardees can **leverage funding** to attract investors and partners

Small Business Success Stories

seed.nih.gov/portfolio/stories

PINNACLE TECHNOLOGY INC

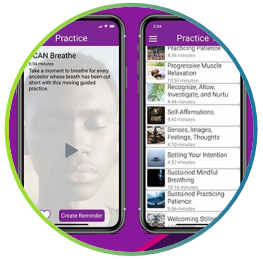


Biomedical company advances Brain Disorder Research

FHC
Neural microTargeting™ Worldwide

Rural company goes deep in the brain to treat movement disorders

trifoia®



Digital learning company supports parents, teachers, underserved communities

Eligibility Criteria

Determined at the time of award

- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
  - Greater than 50% US-owned by individuals (citizens or permanent residents) and independently operated <OR>
  - Greater than 50% owned and controlled by other business concerns that are greater than 50% US-owned and controlled by one or more individuals, an Indian tribe, ANC or NHO (or a wholly owned business entity of such tribe, ANC or NHO) <OR>
  - **SBIR ONLY**: Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

WOSB and SDB Definitions

What is a Women-Owned Small Business (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women

What is a Socially and Economically Disadvantaged Business (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged

Self-certify by registering your business in the System for Award Management (sam.gov)

Phased Programs

Phase I → Phase II
Fast-Track

Direct to Phase II
(SBIR only)

Competing Renewal Award
Phase IIB

Commercialization Readiness Pilot (CRP)

Only Some NIH Institutes/Centers Participate

Phase I: $306,872/1-2 years*
Phase II: $2,045,816/1-3 years*

***NIH, CDC, ARPA-H have a waiver from the Small Business Administration to exceed these budgets for selected topics**

SBIR and STTR Critical Differences

Award is always made to the small business

	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

THERE ARE NO STTR CONTRACTS

Open Funding Opportunities

General Grant Omnibus Solicitations

Clinical Trials Not Allowed:
SBIR (PA-24-245) and STTR (PA-24-247)

Clinical Trials Required:
SBIR (PA-24-246) and STTR (PA-24-248)

Read the "Program Descriptions and Research Topics" Section in the Solicitation

Targeted Solicitations

Specific Grant Solicitations:
https://seed.nih.gov/small-business-funding/

NOT-OD-24-079
Women's Health Research

SBIR NIH/CDC Contract Solicitation

SBIR Contract Solicitations:
https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

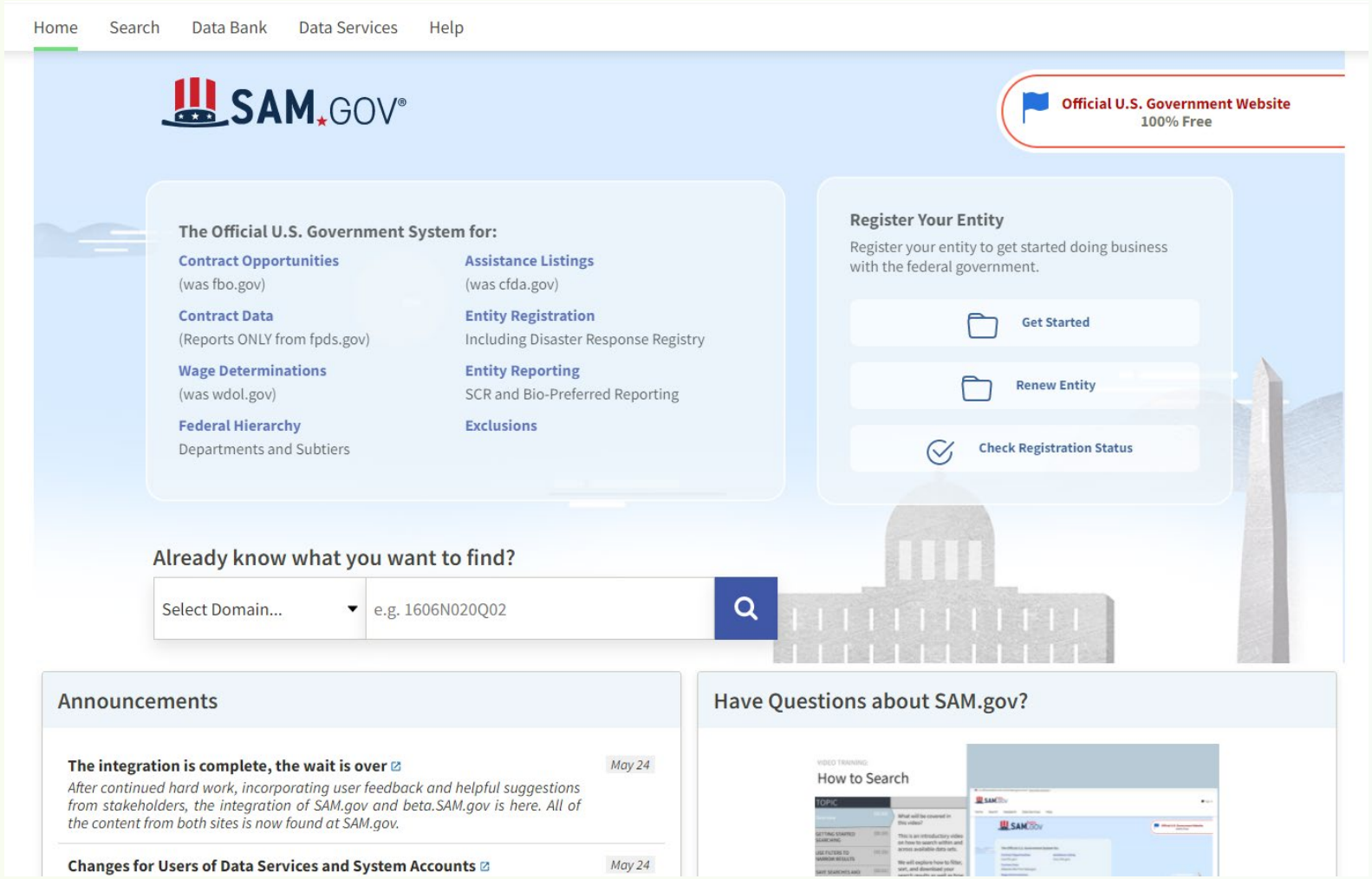
SBIR Contract RFP: SEED Site

NIH SEED site: https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

View Solicitations

Contract Topics	Submission Portal	Amendments
A Solicitation of the National Institutes of Health (NIH) and The Centers for Disease Control and Prevention (CDC) for Small Business Innovation Research (SBIR) Contract Proposals **Proposals are due by 5:00 p.m. EDT on October 18, 2024.**	Electronic Contract Proposal Submission	
NCI SBIR Innovative Concept Award Program **Proposals are due by 5:00 p.m. EDT on September 23, 2024.**	Electronic Contract Proposal Submission	

HHS SBIR Contract RFP: sam.gov



https://sam.gov/

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

PROGRAM SOLICITATION PHS 2025-1

Closing Date: October 18, 2024, 5:00 PM Eastern Daylight Time

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

IMPORTANT

Deadline for Receipt: Proposals must be received by October 18, 2024, 5:00 PM Eastern Daylight Time.

Please read the entire solicitation carefully prior to submitting your proposal.

IMPORTANT: All proposals must be submitted using the electronic contract proposal submission (eCPS) website. **Paper proposals will not be accepted.**

Please go to https://www.sbir.gov/about/policies to read the SBIR/STTR Policy Directive issued by the Small Business Administration for further information.

Attention is directed to the inclusion of a new proposal requirement: Appendix J – Disclosure of Foreign Relationships. Please reference SECTION 13 – APPENDICES within this solicitation, read the document in full, and include a completed disclosure form within your business proposal.

Awarding Components

National Institutes of Health (NIH):

- National Center for Advancing Translational Science (NCATS)
- National Cancer Institute (NCI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism) NIAAA
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute on Mental Health (NIMH)

Centers for Disease Control and Prevention (CDC):

- National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)
- National Center for Immunization and Respiratory Diseases (NCIRD)
- National Center for Injury Prevention and Control (NCIPC)

Proposal Contents – Phase I

TECHNICAL PROPOSAL

Item 1: Technical Element

- Proposal Cover Sheet (Appendix A)
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Draft Statement of Work (Appendix E)

Item 2: Human Subjects and Clinical Trials Information Form and Attachments (Appendix H.2 and, if applicable, H.3)

BUSINESS PROPOSAL

Item 3: Pricing Proposal (Appendix C)

Item 4: SBIR Application VCOC Certification, if applicable (Section 4.6)

Item 5: Proof of Registration in the SBA Company Registry (Section 4.12)

Item 6: Summary of Related Activities (Appendix F)

Item 7: Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries – Required for all offerors (Appendix J)

Proposal Contents – Phase II

TECHNICAL PROPOSAL

Item 1: Technical Element

- Technical Proposal Cover Sheet (Appendix D)
- Table of Contents
- Abstract of the Research Plan, (Appendix B)
- Content of the Technical Element
- Draft Statement of Work (Appendix E)
- Proposal Summary and Data Record (Appendix G)

Item 2: Human Subjects and Clinical Trials Information Form and Attachments (Appendix H.2 and, if applicable, H.3)

BUSINESS PROPOSAL

Item 3: Pricing Proposal (Appendix C)

Item 4: SBIR Application VCOC Certification, if applicable (Section 4.6)

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Item 7: Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries – Required for all offerors (Appendix J)

Foreign Disclosure and Risk Management Requirements

Disclosure is required using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form

- Submitted with the business proposal and ***required*** to receive an award
- Review **Appendix J** for instructions and post-award reporting requirements
- Due Diligence Program to Assess Security Risks considerations are in **Section 6.2**
  - Additional Information - Foreign Disclosure and Risk Management webpage
    - Overview of Risk Areas
    - Case Studies – recently updated

IMPORTANT: SBIR/STTR eligibility criteria HAVE NOT changed- disclosure or finding of foreign affiliations or relationships DOES NOT necessarily disqualify an applicant

Electronic Submission - Page Limits

- **SBIR Phase I** Technical Proposals (Item 1) shall not exceed 50 pages
- **SBIR Phase II** Technical Proposals (Item 1) shall not exceed 150 pages
- **Fast Track** = a complete Phase I + a complete Phase II
- The Human Subjects and Clinical Trials Information form and its attachments (Appendix H.2., and, if applicable, Appendix H.3.) are excluded from these page limits.
- Single-sided, single-spaced pages for entire proposal
- All inclusive [including all pages, cover sheet(s), tables, CVs, resumes, references, pictures/graphics, and all enclosures, appendices or attachments, etc.]
- No exclusions to page limits. Pages in excess of the page limitation will be removed from the proposal and will not be considered or evaluated

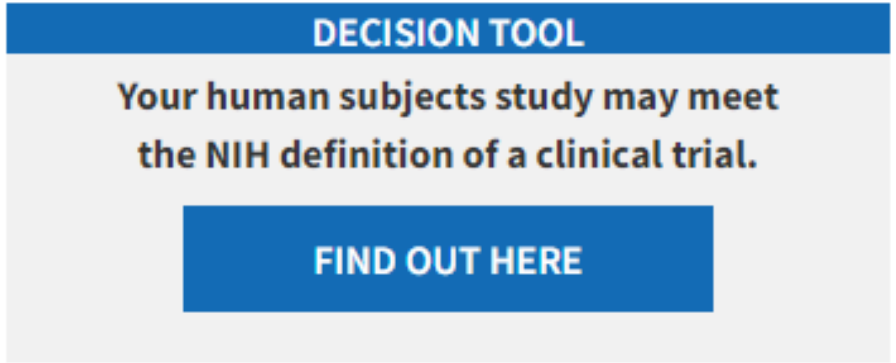
Human Subjects or Vertebrate Animals

- Section 3 – Definitions
- Section 5.2/5.3 – Care of Vertebrate Animals
- Section 5.4/5.5 – Research Involving Human Subjects
- Section 5.6 – Inclusion of Women, Minorities in Research Involving Human Subjects
- Section 5.7 – Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects
- Section 5.8 – Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials
- Section 5.9 Clinical Trial Registration and Results Information Submission
- Section 5.12 Single Institutional Review Board (sIRB)

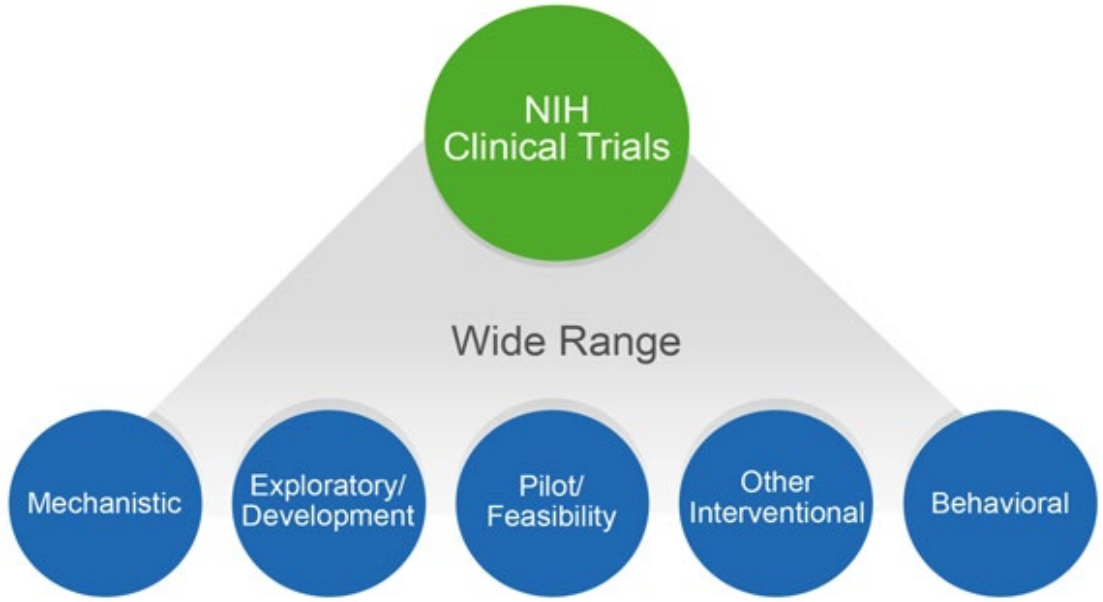
Clinical Trials

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.



https://grants.nih.gov/policy/clinical-trials.htm



#1 Piece of Advice

Read the entire RFP several times!!

Electronic Submission

SBIR Contract proposals must be submitted **electronically**, via the electronic Contract Proposal Submission (eCPS) website

REQUIRED REGISTRATIONS

- System for Award Management (SAM) and Unique Entity Identifier (Company)
- SBA Company Registry at SBIR.gov

Two-Factor Authentication is Required

login.gov

Use the same login.gov account for eRA, Grants.gov, and SAM

Deadline for Questions

- Deadline for Questions is September 24, 2023 - close of business
- Reminder, your only contact should be with the Contracting Officer (CO) listed in **Section 10** for each IC
- Questions must be submitted in writing (email) to the CO
- Q&A amendment will issue in ~ early October at SAM.GOV and on NIH SEED websites
  - Yes, your questions and the answers will be posted to the public
- Additional questions will be answered at the discretion of the CO

Disbursement of Funds

- **Unlike a grant, funds are not disbursed at the time of award**
- Invoices are submitted after completion of activities or submission of reports
- **Each funding Institute or Center** may set up the payment schedule differently
- **Bottom line:** the company needs to have enough resources to begin work and receive interim payments as work progresses

Deadline for receipt of **ALL** Proposals

Friday, October 18, 2024

5:00 PM EDT

Electronic submission must be complete

No paper submissions

Submit proposals a day early if possible

Technical and Business Assistance (TABA) Programs

Phase I | **TABA Needs Assessment**

Request Post-Award

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

Phase II | **TABA Funding**

Request in Application

$50,000 to hire vendor(s) for Technical and Business Assistance (Follow Instructions to request funds in the application)

https://seed.nih.gov/TABA

Product Development Support

NIH SEED

Innovator CONSULTING

Business Consult

Seeking insights about your company's next steps? Talk to an Entrepreneur in Residence!

Intellectual Property Consult

Want more information about patenting and/or licensing issues to advance your product or service? Ask for an IP consult.

Pitch Review Consult

Heading to a meeting? Talking to an investor? Get feedback before your pitch!

Regulatory Consult

Not sure if you need to or when to talk with FDA? SEED's regulatory affairs experts can help.

Reimbursement Consult

Who is actually going to pay (and how much) for your product? Ask a reimbursement expert.

SOW Consult

Need to outsource expertise or research activities? Clarify your ask with an Statement of Work consult.

Company SHOWCASE

SEED Support for Investor Meetings

The SEED Innovator Support Team provides resources and pitch coaching consultations to grantees matched to upcoming industry events.

BIOTECH SHOWCASE™

LIFE SCIENCE NATION
Connecting Products, Services & Capital

BIO International Convention

LIFESCIENCES™ SUMMIT

RESI REDEFINING EARLY STAGE INVESTMENTS

4D Drugs Devices Diagnostics Digital Health MEETS AI

LONGEVITY HEALTH & INNOVATION

THE MEDTECH CONFERENCE
Powered by AdvaMed

MedTechColor

VIVE

ACA
ANGEL CAPITAL ASSOCIATION

Landmark Angels

seed.nih.gov/showcase

Entrepreneurial Support Programs

NIH Entrepreneurship BOOTCAMP

Introduce early-stage (pre-SBIR, pre-company) innovator teams to entrepreneurship, customer discovery, and business model validation

seed.nih.gov/bootcamp

Helps medical device innovators translate biomedical technologies from the lab (concept) to the market (clinic)

nibib.nih.gov/research-program/c3i-program

Funding for Small Businesses to Diversify the Entrepreneurial Workforce

Support research and entrepreneurial experiences for individuals from diverse backgrounds by providing $5,000 to $100,000 depending on their career level

seed.nih.gov/diversity_supp

I-CORPS™ AT NIH

Phase I SBIR/STTR teams conduct 100 interviews over 8 weeks to develop a business model canvas

seed.nih.gov/I-corps-at-NIH

Connect with SEED

Online
http://seed.nih.gov/

Email us
SEEDinfo@nih.gov

@nihseed
https://twitter.com/nihseed

NIH SEED
https://www.linkedin.com/company/nihseed

Sign up for NIH and SEED updates:
https://seed.nih.gov/subscribe

The NIH Guide for Grants and Contracts:
http://grants.nih.gov/grants/guide/listserv.htm

Krishna “Balki” Balakrishnan, Ph.D., M.B.A.

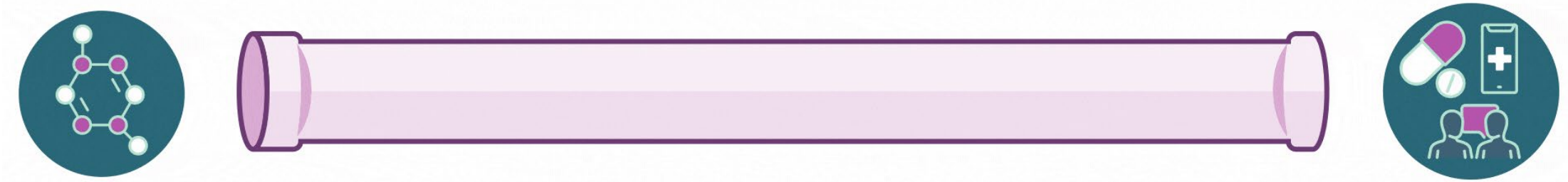
Director, Office of Strategic Alliances (OSA)

Program Solicitation PHS-2025-1

NCATS FY25 Contract Topics

Re-engineering the Translational Pipeline

NCATS addresses long-standing bottlenecks in the translational research pipeline so that new treatments reach people faster.



Bottlenecks:

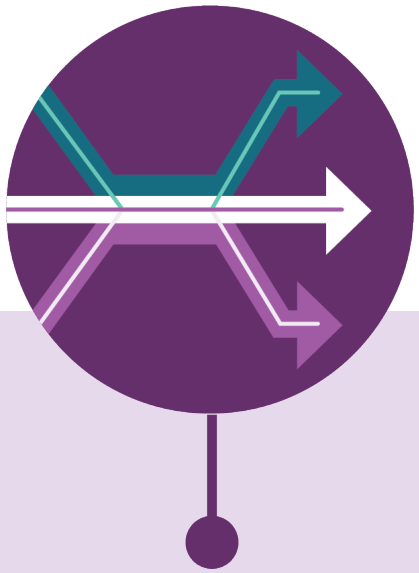
- Incompatible databases
- Administrative burden for study start-up
- Insufficient tools and technologies to predict toxicity and efficacy of new drugs

NCATS Solutions:

- Data interoperability and integration
- Streamlined business processes
- Models that mimic the structure and function of human tissues

National Center for Advancing Translational Sciences

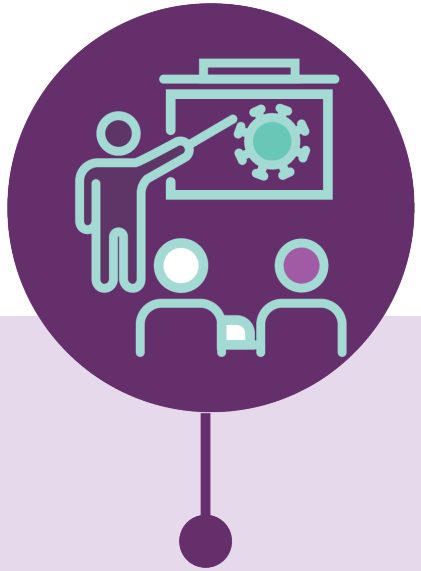
Key NCATS Approaches



Understanding what's similar across diseases to spur development of multiple treatments at a time

Developing models that better predict a person's reaction to a treatment

Enhancing clinical trials so the results more accurately reflect the patient population



Leveraging real-world data and data science approaches to address public health needs

NCATS encourages you to apply for two Contract opportunities that fuel the development of innovations that accelerate the generation of new treatments and cures.

The deadline to apply is October 18, 2024, 5:00 p.m. EDT.

National Center for Advancing Translational Sciences

Topic 025 - Development of a versatile small footprint benchtop device to perform batch evaporation

NCATS seeks to support development of a compact, efficient benchtop device capable of rapid batch evaporation, designed for integration into automated chemical synthesis (ACS) workflows. The ideal solution will enhance the throughput and efficiency of ACS and address current bottlenecks by enabling:

- Simultaneous evaporation of multiple high recovery vials
- 90% evaporation in under 10 minutes
- Full automation compatibility

Budget (total cost per award)	Fast-Track Proposals	Anticipated awards
Phase I: $325,000 – 9 months Phase II: $2,000,000 – 2 years	Not accepted	Phase I: 1-3

Phase II information is provided only for informational purposes to assist Phase I offerors with their long-term strategic planning.

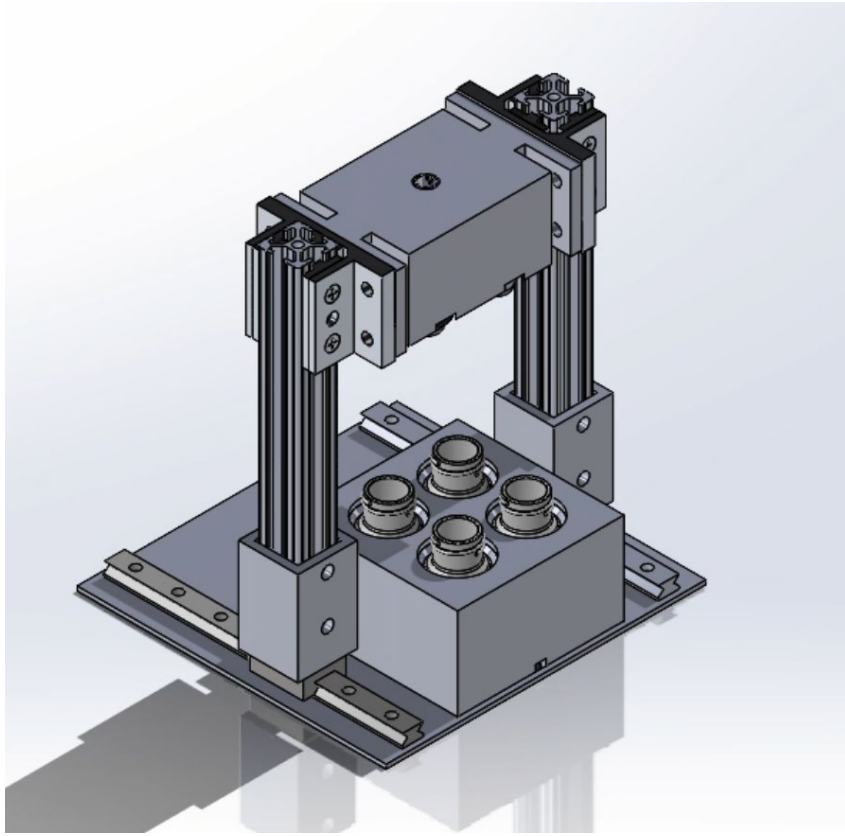
NIH National Center for Advancing Translational Sciences

Topic 025 - Development of a versatile small footprint benchtop device to perform batch evaporation

Summary

NCATS proposes this concept to develop a batch evaporation device capable of evaporating multiple high recovery vials at once for an organic chemical synthesis process.

This is an exciting opportunity for NCATS to have a device for use in-house and for other research organizations working on ACS to overcome a key bottleneck in the process.



NCATS Batch Evaporator

National Center for Advancing Translational Sciences

Topic 026 - Scalable Generation of Liver and Brain Organoids Derived from Human iPS Cells

NCATS seeks to support development of a scalable, cost-effective and reproducible method for generating high-quality live and brain organoids from human induced pluripotent stem (iPS) cells. This technology will:

- Provide researchers with robust tools for disease modeling and drug development, particularly for rare diseases
- Enable in-depth studies of disease mechanisms and drug efficacy/toxicity
- Create a platform for multi-omics analysis and target identification

Budget (total cost per award)	Fast-Track Proposals	Direct to Phase II Proposals	Anticipated awards
Phase I: $325,000 – 9-12 months Phase II: $2,000,000 – 2 years	Not accepted	Not accepted	Phase I: 1-3

Phase II information is provided only for informational purposes to assist Phase I offerors with their long-term strategic planning.

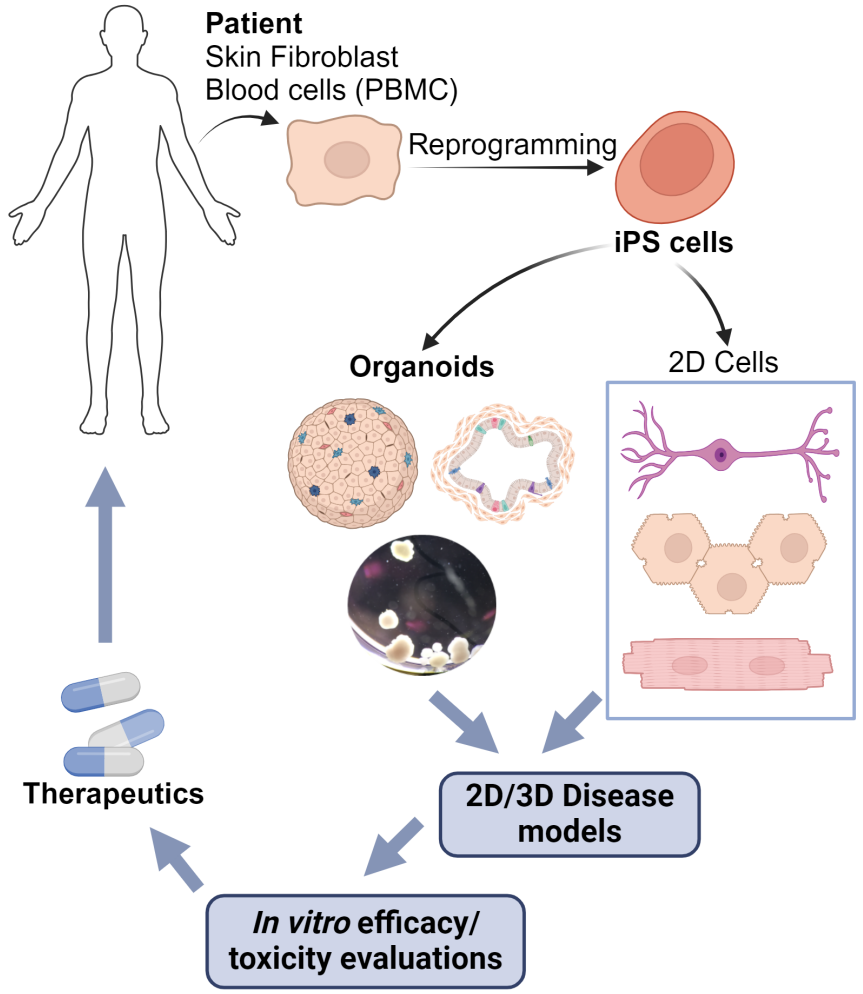
National Center for Advancing Translational Sciences

Topic 026 - Scalable Generation of Liver and Brain Organoids Derived from Human iPS Cells

Summary

NCATS DPI proposes this concept to improve efficiency of the methods and reduce costs in the generation of iPS cell derived liver and brain organoid for disease modeling

This is an exciting opportunity to meet the growing demand for high-quality organoids in drug development by overcoming challenges in production, scalability and reproducibility.



National Center for Advancing Translational Sciences

Thank You!

Learn More Today

Visit us at https://ncats.nih.gov/funding/small-business-programs

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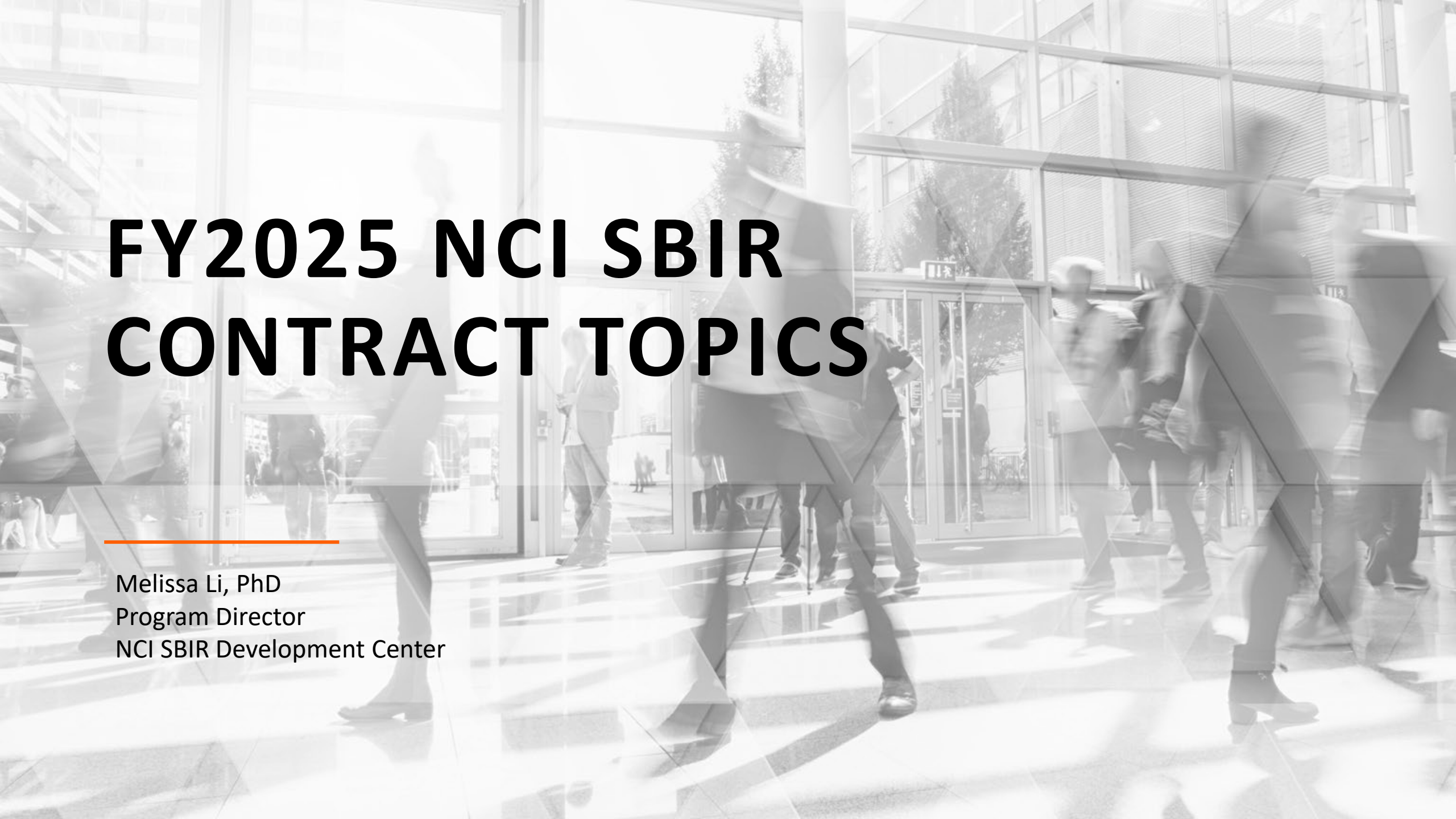
- @ncats.nih.gov
- NCATSMedia

National Center for Advancing Translational Sciences



FY2025 NCI SBIR CONTRACT TOPICS

Melissa Li, PhD
Program Director
NCI SBIR Development Center

CONTRACTS FY2025 – NIH/NCI TOPICS

NIH/NCI Topic Number	Phase I Allowed?	Fast Track Allowed?	Direct to Phase II Allowed?	Topic Title
466	Yes	**No**	Yes	Novel Delivery Systems for RNA-based Cancer Vaccines
467	Yes	Yes	Yes	Development of Cancer Immunoprevention Agents
468	Yes	Yes	Yes	Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies
469	Yes	Yes	Yes	Development of Novel Therapeutics for HPV-related Precancer
470	Yes	Yes	Yes	Precision Nutrition Interventions to Reduce Cancer-Related Symptoms
471	Yes	Yes	Yes	Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention
472	Yes	Yes	Yes	Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer
473	Yes	Yes	**No**	Point of Care Detection of Antibodies Against HPV16/18 E6 and E7 Oncoproteins in Oropharyngeal Cancer
474	Yes	Yes	**No**	Point of Care Technologies for GI Cancer Prevention and Early Detection
475	Yes	**No**	Yes	Development of Digital Biomarkers and Endpoints for Clinical Cancer Care
476	Yes	Yes	Yes	Digital Twin Software for Optimization of Cancer Radiation Therapy
477	Yes	**No**	Yes	Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment
478	Yes	Yes	**No**	Advanced Biomaterials to Improve Cancer Modeling for Research

NIH/NCI 466: Novel Delivery Systems for RNA-based Cancer Vaccines

Fast Track Allowed?	No
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Support the development of new delivery systems with enhanced properties to accelerate the development of RNA-based cancer vaccines.

Phase I Activities and Deliverables Include:

- Design and generate a novel RNA delivery system suitable for formulating and delivering RNA-based vaccines for cancer indications.
- Demonstrate the loading capacity of the system using mRNAs mimicking those that would be used to generate RNA-based cancer vaccines (i.e., mRNAs harboring common nucleoside modifications).

Phase II Activities and Deliverables Include:

- Perform studies in an animal model demonstrating the capacity of the delivery system to deliver one or more mRNAs and elicit a high-magnitude T cell response against a cancer-relevant target antigen(s).

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 467: Development of Cancer Immunoprevention Agents

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Advance the development of novel, safe, and efficacious immunopreventive vaccines (DNA, mRNA, peptide) or immunomodulatory drugs (small molecules or biologics) for cancer prevention and interception in well-identified high-risk cohorts (e.g., Lynch syndrome, BRCA, FAP, smokers, asbestos exposed, precancers such as PanIN, IPMN, STIC, PIN, CIN, adenoma, Barrett's esophagus).

Phase I Activities and Deliverables Include:

- Preclinical in vivo efficacy, safety, PK/PD, and toxicity evaluation (non-GLP) studies in appropriate animal models

Phase II Activities and Deliverables Include:

- Perform IND-enabling studies as appropriate for the agent under development

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 468: Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Development of safe and effective synthetic microbial-based IO therapies for clinical use. This topic will support development of the synthetic microbe for use as single-agent IO therapy or for combination therapy as an adjuvant to existing IO treatments.

Phase I Activities and Deliverables Include:

- Evaluate potential cross-reactivity of the therapeutic delivered by the engineered microbe between human and mouse (as appropriate).
- Confirm tumor specificity and biocontainment of the selected synthetic microbe, as well as stable and controlled expression of the therapeutic cargo or adjuvant activity.

Phase II Activities and Deliverables Include:

- Optimize dose, frequency, and route of administration for use as single-agent or in combination with existing IO product(s) (as appropriate).
- Optimize genetic modifications to ensure optimal attenuation, tumor tropism, as well as adequate and controlled delivery of the therapeutic payload or immunomodulatory activity (as appropriate).

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 469: Development of Novel Therapeutics for HPV-related Precancer

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	3-5
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Develop effective HPV therapeutics that can treat chronic HPV infections and/or cause regression of precancers by preventing HPV-related cancers from developing at relevant organ sites (e.g., cervical, anogenital, oropharyngeal).

Phase I Activities and Deliverables Include:

- Demonstrate in vitro efficacy for the agent in appropriate models.
- Conduct structure-activity relationship (SAR) studies, medicinal chemistry for small molecules, protein engineering for biologics, and/or lead biologic optimization (as appropriate).

Phase II Activities and Deliverables Include:

- Perform animal pharmacokinetic and pharmacodynamic studies to optimize dosing regimen.
- Characterization of immune responses to immunomodulatory agents.
- Preclinical IND-enabling GLP toxicology studies.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 470: Precision Nutrition Interventions to Reduce Cancer-Related Symptoms

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-3
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Support the development of new targeted nutritional products for patients experiencing nutrition impact symptoms to help clinical care teams maintain patient's nutritional status, quality of life, and bolster a patient's tolerance for cancer treatment.

Phase I Activities and Deliverables Include:

- Demonstrate the safety of the new food or ingredient. Demonstrate that any ingredients used in the product are safe and contain Generally Recognized As Safe (GRAS) /Food grade materials.
- If the food ingredient is not GRAS, submission of a Food Additive Petition to the FDA is required.

Phase II Activities and Deliverables Include:

- Complete experiments and assessments according to the plan developed in Phase I (e.g., demonstration of desired function, safety assessment, and GMP manufacturing).

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 471: Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Develop oral preventative agents for high-risk patients with Inflammatory Bowel Disease (IBD), like ulcerative colitis and Crohn's disease, to prevent colon cancer. Projects supported under this contract topic should extend the formulation development and testing of carrier particles in suitable in vivo animal models for oral delivery of cancer prevention agents to the colon.

Phase I Activities and Deliverables Include:

- Demonstrate that the carrier particle formulation is orally administrable in vivo.
- Demonstrate that the agent-loaded carrier particles show preliminary efficacy in preventing colon cancer in a suitable IBD animal model.

Phase II Activities and Deliverables Include:

- Perform pharmacokinetic studies of the agent, including, but not limited to, ADME, PK, and bioavailability.
- Perform pharmacodynamic testing to demonstrate that the agent remains active in the carrier particle formulation in the colon.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 472: Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	3-5
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Improve efficacy of ADCs by labeling them with radionuclides and for a new theranostic treatment strategy that includes diagnostic, imaging-based patient selection followed by two-armed therapy (chemical- and radiation-based).

Phase I Activities and Deliverables Include:

- Demonstrate that the carrier particle formulation is orally administrable in vivo.
- Demonstrate that the agent-loaded carrier particles show preliminary efficacy in preventing colon cancer in a suitable IBD animal model.

Phase II Activities and Deliverables Include:

- Perform pharmacokinetic studies of the agent, including, but not limited to, ADME, PK, and bioavailability.
- Perform pharmacodynamic testing to demonstrate that the agent remains active in the carrier particle formulation in the colon.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 473: Point of Care Detection of Antibodies Against HPV16/18 E6 and E7 Oncoproteins in Oropharyngeal Cancer

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	No
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Support the development and validation of a rapid, point of care (POC) test for Human Papillomavirus (HPV)-related oropharyngeal cancers that includes the separate detection of antibodies against HPV16 and 18 E6 and E7 proteins.

Phase I Activities and Deliverables Include:

- Applying user-centric design principles, develop prototype of POC device/test kit to detect antibodies against HPV16/18 E6 and E7 oncoproteins from appropriate biospecimens.

Phase II Activities and Deliverables Include:

- Conduct studies to evaluate and test user acceptability and feasibility in high-risk of populations (i.e., number of (oral) sexual partners, older men, etc.) as well as general population.
- Offerors should establish a collaboration or partnership with a research group or medical facility that can provide relevant patient access; offerors must provide a letter of support from the partnering organization(s) in the proposal.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 474: Point of Care Technologies for GI Cancer Prevention and Early Detection

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	3-5
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Advance the development of an affordable and scalable point of care (POC) test that can effectively screen for precancerous conditions and early cancers in the gastrointestinal (GI) tract (esophagus, stomach, small and large intestine, rectum, anus).

Phase I Activities and Deliverables Include:

- Demonstrate a working relationship with the site(s) where the clinical validation study will take place.
- Conduct studies to establish analytical performance (analytical sensitivity, specificity) and other performance characteristics as required (e.g., limit of detection, consistency, reproducibility).

Phase II Activities and Deliverables Include:

- Establish GLP, GMP practices, and quality management systems.
- Optimize and produce functional prototype, while adhering to good laboratory practices (GLP) and/or good manufacturing practices (GMP).

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 475: Development of Digital Biomarkers and Endpoints for Clinical Cancer Care

Fast Track Allowed?	No
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Facilitate the commercial development of digital biomarkers and/or endpoints that can help clinical care teams improve patient care (e.g., remote monitoring of a patient's response to treatment). Digital biomarkers will utilize data from digital health technologies (e.g., heart rate, oxygen saturation, sleep, physical activity, etc.) and demonstrate clinical utility for patients.

Phase I Activities and Deliverables Include:

- Establish a project team including proven expertise in: DHTs for physiological monitoring, health data management, biostatistics/bioinformatics, oncology, and clinical workflows.

Phase II Activities and Deliverables Include:

- Evaluate the digital biomarker(s) and/or endpoint(s) response to a therapeutic or behavioral intervention.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 476: Digital Twin Software for Optimization of Cancer Radiation Therapy

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Development digital twin software that can inform radiation therapy in patient care by utilizing multi-scale data (e.g., molecular, cellular, organ, organism, societal, geographic, modalities available, family history, cost and toxicity) for treatment optimization purposes.

Phase I Activities and Deliverables Include:

- Develop a DT model that can accurately model appropriate and relevant parameters on a small training core of patients or normal controls. Offerors should establish key metrics for the DT model proof of concept, and also provide a clear rationale for the proposed metrics. At a minimum, the proof-of-concept study can be based on retrospective datasets, but approaches that propose to use prospective data will be permitted.

Phase II Activities and Deliverables Include:

- Validate the performance of the DT model prospectively in relevant patient population. Offerors should establish metrics for expected performance of the model and provide a clear rationale for the proposed metrics.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 477: Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment

Fast Track Allowed?	No
Direct to Phase II Allowed?	Yes
Number of Anticipated Awards	3-5
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Facilitate the commercial development of wearable sensors that can provide remote patient monitoring and assist clinical care teams in identifying cancer treatment-related toxicities early on.

Phase I Activities and Deliverables Include:

- Provide a clear description for the patient treatment monitoring scenario being targeted, including a description of the patient population being targeted, the kinds of treatments and their known and/or suspected adverse effects that are being tracked in current clinical work practices. Offerors should provide a description for the anticipated improvement in patient outcomes that are anticipated, should the proposed monitoring technology be successful (as proposed).

Phase II Activities and Deliverables Include:

- Design and perform properly powered clinical studies in relevant cancer populations to establish the clinical utility and performance of the prototype system.

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

NIH/NCI 478: Advanced Biomaterials to Improve Cancer Modeling for Research

Fast Track Allowed?	Yes
Direct to Phase II Allowed?	No
Number of Anticipated Awards	2-4
Phase I Max Budget	$400K up to 12 months
Phase II Max Budget	$2.25M up to 2 years

Goal: Advance the development of versatile and accessible biomaterial-based tools (kits and reagents) for cancer researchers. Biomaterials should be able to change or adapt in response to tumor initiation, progression, or metastasis (e.g., adaptable response to tumor, changes in stiffness, strain or crosslinking, etc.).

Phase I Activities and Deliverables Include:

- Conduct appropriate proof-of-concept studies for potential uses of the technology.
- Characterize the proposed biomaterial-based technology

Phase II Activities and Deliverables Include:

- Benchmark the technology to the current existing methods in terms of feasibility, cost, throughput, safety.
- Show feasibility to scale production of the technology at a price point that is compatible with market success and widespread adoption by the basic cancer research community and/or clinical labs (as appropriate).

… see remaining Phase I and Phase II activities and deliverables in PHS 2025-1

CONTRACTS LINKS

- **Check PHS 2025-1 contracts solicitation:**
  https://sam.gov/opp/b6c0bad2a0924520a704bb1bca846615/view

- **Check NCI individual contract topics:**
  https://sbir.cancer.gov/small-business-funding/contracts/current-solicitation

- **Check NIH SEED for updates on solicitation:**
  https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

Questions about NCI SBIR Contracts?
Email Tanya Renwick
ncioasbir@mail.nih.gov
(Please reference solicitation PHS 2025-1 and the Topic number with any questions.)

Rajesh Kumar, PhD

Program Officer, Office of Small Business Research

National Institute on Aging

NIA Research Topics: FY2025 SBIR Contracts Solicitation

Topic #	Topic Title & Budget	Phase Eligibility		
		Phase I	Fast-Track	Direct to Phase II
NIH/NIA 011	Digital Technologies as Tools to Screen and Monitor Alzheimer's Disease (AD) and Related Dementias (ADRD) *Budget (total costs, per award, up to 3 fast-track awards):* *Phase I: up to $500,000 for 12 months; Phase II: up to $2.5 million for 2 years*	✗	✓	✗
NIH/NIA 012	Modeling Aging through Microphysiological Systems *Budget (total costs, per award, up to 2 awards):* *Phase I: up to $400,000 for 12 months; Phase II: up to $2.25 million for 2 years*	✓	✓	✓
NIH/NIA 013	Leveraging Multimodal and Generative Artificial Intelligence to Advance the Application of Social Robotics in Caregiving (AD) *Budget (total costs, per award, up to 2 awards):* *Phase I: up to $500,000 for 12 months; Phase II: up to $2.5 million for 2 years*	✓	✓	✗

NIH/NIA 011: Digital Technologies as Tools to Screen and Monitor Alzheimer's Disease (AD) and Related Dementias (ADRD)

Background

- With regards to AD/ADRD, there are gaps related to i) screening, ii) early detection, iii) enrollment in clinical trials, iv) monitoring, and v) evaluation of the treatment effectiveness.
- Mobile or monitoring and sensory devices that analyze gait, speech, eye movement, hearing etc., for example, can provide simple, cost-effective tests that can fill the above-described gaps.
- This topic supports development of **tools for the evaluation of medical devices** for the FDA's Medical Device Development Tool (**MDDT**) program.

Scope of Work

- The goal of this contract topic is to stimulate the participation of small businesses in the FDA's Medical Device Development Tools (MDDT) program to develop and demonstrate the utility of digital technologies as a measure of AD/ADRD screening and monitoring as qualified MDDTs to assess medical devices subject to regulation by the Center for Devices and Radiological Health (CDRH).

NIH/NIA 011 - Digital Technologies as Tools to Screen and Monitor Alzheimer's Disease (AD) and Related Dementias (ADRD)

Phase I:

- **Prepare an MDDT Proposal** including specific requirements and activities with respect to the proposed MDDT.
- Demonstrate suitability of the proposed tool for the test population and planned reference standard(s).
- **Submit a complete Qualification Plan** to the FDA's MDDT Program. The plan to collect evidence for qualification of the dataset should include details on the data source and planned patient population for the specified context of use.

Phase II:

- Prepare and submit a **Full MDDT qualification package** which includes the validation evidence package as well as data collected according to the FDA-accepted MDDT proposal.

NIH/NIA 012 - Modeling Aging through Microphysiological Systems

Background

- The majority of aging research has been conducted using static cell cultures and animal models that only partially recapitulate aging in humans.
- Microphysiological Systems (MPS) could provide more translationally-relevant and cost-effective models to supplement or replace 2-D cell cultures and animal models in basic aging research and drug development.
- This SBIR contract solicitation will invite small businesses currently working in the MPS space to create self-contained systems that maintain 3-D tissue constructs to allow for human-relevant modeling of molecular and cellular aging processes and/or drug discovery for geroprotectants and treatments for aging-related diseases.

Scope of Work

- The goal of this contract topic is to leverage existing technology in the small business space to develop and eventually validate microphysiological systems (MPS) that recapitulate cell and tissue aging starting with primary cells from human donors and/or human induced pluripotent stem cell (hiPSC)-derived cells/tissues.

NIH/NIA 012 - Modeling Aging through Microphysiological Systems

Phase I:

- **Develop an MPS** that recapitulates human molecular and/or physiological **aging phenotypes**. MPS must:
  - Include co-culture of **multiple cell types** closely resembling the tissue of origin, and may include the vasculature and/or immune and/or neuronal cells
  - Recapitulate key aspects of human organ structure and function such as vascular perfusion, innervation and stimulation, and spatiotemporal chemical gradients
  - Maintain 3D tissue constructs for **extended periods of time**
  - Aging phenotypes must include one or more of the hallmarks of aging: genomic instability, telomere attrition, epigenetic alterations, loss of proteostasis, etc.
- **Develop a sensor** for data acquisition and real-time detection and analysis for longitudinal and/or high-throughput measurements, if necessary

Phase II:

- Benchmark performance of the MPS against applicable in vivo animal model(s) and known human aging research or intervention studies
- Conduct pre-market and end-user testing
- For proposed MPS already in advanced staged of development, initiate the process of FDA qualification

NIH/NIA 013 - Leveraging Multimodal and Generative Artificial Intelligence to Advance the Application of Social Robotics in Caregiving

Background

- The burden of caregiving for persons with dementia (PwD) arising from psychological and non-psychological stressors is overwhelming.
- Assistive technologies can attenuate caregiving burden. However, most solutions are mobile or web-based that
    - are limited to specific domains of need/tasks
    - cause cognitive overload, and
    - have dependencies such as device accessibility/literacy, an abstract two-dimensionality, constrained within a digital space, all of which is devoid of sensory-richness and fails to replicate physical reality.
- These limitations reduce meaningful PwD engagement.

Scope of Work

- The long-term goal of the project is to yield a deployable social robot that is a meaningful advancement over the capabilities of currently available solutions to aid the caregiving process in PwD.

NIH/NIA 013 - Leveraging Multimodal and Generative Artificial Intelligence to Advance the Application of Social Robotics in Caregiving

Phase I:

- Evidence demonstrating iterative development that incorporates stakeholder feedback
- Evidence of a functional architectural framework that leverages Multimodal and Generative AI.
- Evidence of adapting existing monolithic system architecture to a modular architecture
- Evidence of real-world and AI generated training data repositories and training environments.

Phase II:

- Evidence of enhanced functionalities and deployability in preliminary real-world testing.
- Rigorous real-world testing and refinement of a social robot in a caregiving situation
- Evidence of architectural flexibility (i.e., demonstrate modularity and reusability)

CONTRACT SOLICITATION

Development of Alcohol-Related Technology Through NIAAA SBIR/STTR Funding

Megan Ryan, M.B.A.
SBIR/STTR Program Director
NIAAASBIRSTTR@mail.nih.gov

National Institute on Alcohol Abuse & Alcoholism (NIAAA)
SBIR/STTR Program

September 23, 2024

niaaa.nih.gov/research/niaaa-sbir

National Institute on Alcohol Abuse and Alcoholism

NIAAA Mission and Research Focus

Mission

To generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being, and apply that knowledge to improve diagnosis, prevention, and treatment of alcohol-related problems, including ***alcohol use disorder***, across the lifespan.

Alcohol Use Disorder (AUD): AUD is a chronic disease characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences.

28.1M	American adults aged 18 and older had AUD in the past year in 2023
178K	deaths in the US attributable to alcohol use, making alcohol one of the leading preventable causes of death in the US
$249B	problem for AUD in the US alone
2.4M	global deaths (males and females) were attributable to alcohol consumption in 2019

Program Solicitation PHS-2025-1

Topic 020: Alcohol Activated Locking Systems for Firearms and Firearm Storage Units

NIAAA seeks to support the development of an alcohol-activated locking system for firearms and/or firearm storage units. The ideal solution will enhance firearm safety and prevent alcohol-related firearm injuries and fatalities by enabling:

- **Reliable detection** of blood alcohol levels
- **Ease of use** with minimal training required
- **Affordability** and durability

Budget

Phase I: $400,000 for up to 12 months
Phase II: $2,000,000 for up to 2 years

Direct-to-Phase II proposals

Fast Track proposals

Phase I proposals

Anticipate 1 to 2 awards

Program Solicitation PHS-2025-1

Topic 021: Data Science Tools for Accelerating Alcohol Research

NIAAA seeks to support the development of data science tools to collect, clean, harmonize, integrate and analyze existing datasets to predict alcohol use associated conditions, evaluate interventions, and guide treatment strategies. The solution should leverage advanced techniques like machine learning, deep learning, neural networks, and large language models. Solutions may include:

- **Generation and implementation of new algorithms** for use with existing datasets
- **Software tools** for data processing, analysis, and visualization
- **Computation models** predicting outcomes of alcohol use

Budget

Phase I: $250,000 for up to 6-12 months

Direct-to-Phase II proposals

Fast Track proposals

Phase I proposals

Anticipate 1 to 2 awards

Program Solicitation PHS-2025-1

Topic 022: Non-invasive Wearable Alcohol Sensor

NIAAA seeks to support the development of a non-sweat based (e.g., infrared), discreet, non-invasive wearable alcohol sensor capable of real-time blood alcohol concentration (BAC) measurement and recording to enhance the accuracy and reliability of alcohol consumption monitoring in clinical research and treatment settings by enabling:

- **Passive,** continuous detection
- **Accurate real-time** or near real-time measurement
- **Secure data storage** and wireless transmission

Budget

Phase I: $500,000 for up to 1 year
Phase II: $2,045,816 for up to 2 years

Direct-to-Phase II proposals

Fast Track proposals

Phase I proposals

Anticipate 1 to 3 awards

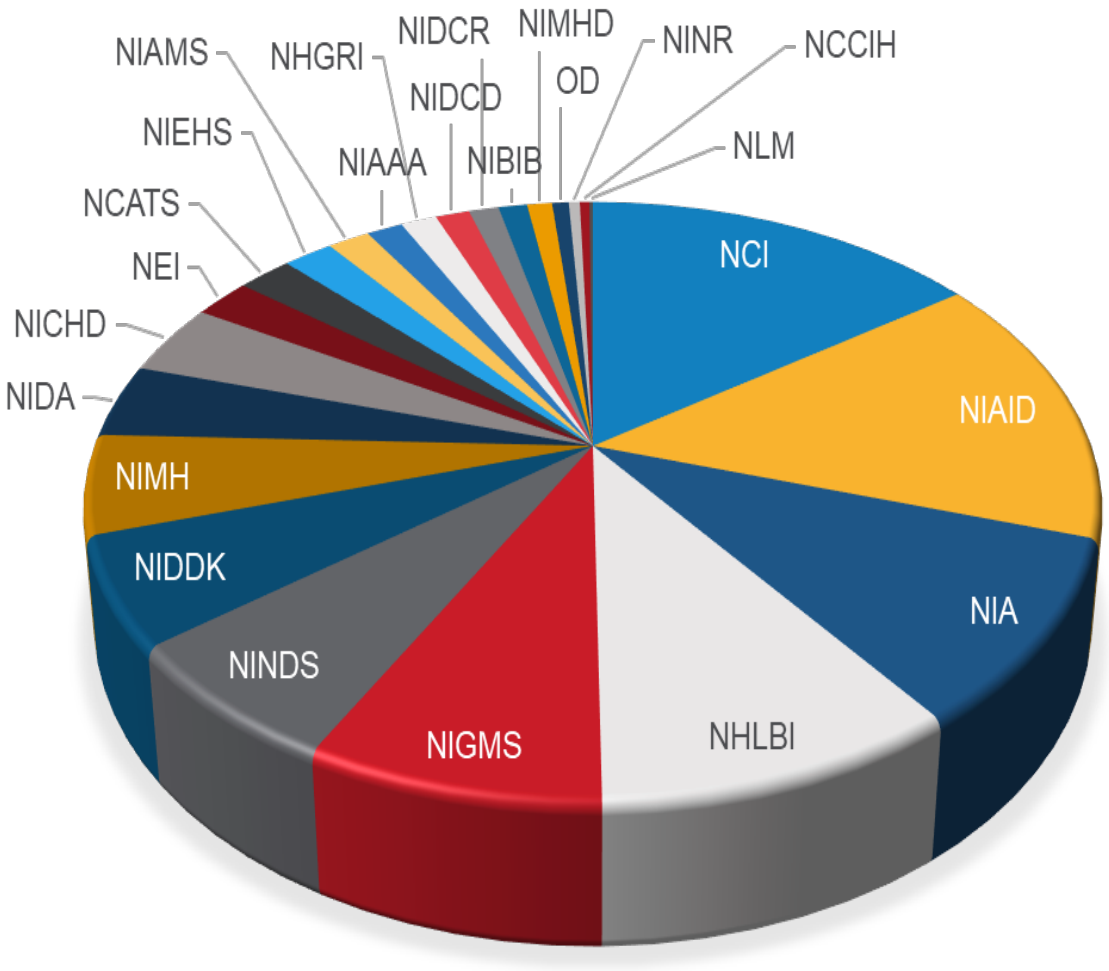
National Institute of Allergy and Infectious Diseases

Natalia Kruchinin Ph.D.

SBIR/STTR Program Coordinator, Team Lead, ORTSP, DEA

National Institute of Allergy and Infectious Diseases

NIAID SBIR/STTR Budget Allocation FY24



FY24 NIAID SBIR/STTR

Budget - $193.8M

SBIR - 3.2% STTR - 0.45%

NIAID Organization

Office of the Director (OD)

1. Division of AIDS (DAIDS)
2. Division of Allergy, Immunology, and Transplantation (DAIT)
3. Division of Microbiology and Infectious Diseases (DMID)
4. Division of Extramural Activities (DEA)

5 Division of Clinical Research (DCR)

6. Division of Intramural Research (DIR)

7. Vaccine Research Center (VRC)

These program Divisions direct and managed the extramural research portfolio. Most of the NIAID budget supports research at academic and research institutions through grants, contracts and cooperative agreements

DEA oversees policy and management activities related to funding grants and contracts and conducts initial peer review for grants and contracts that address NIAID specific needs or focus.

High-Priority Areas of Interest

FY25 SBIR Contract Topics NIAID – Pages 120-136

Topic 137 - New Drug Classes with Novel Mechanisms of Action for HIV, Hepatitis B, and Tuberculosis
Topic 138 - Devices and Materials-Based Platforms for the Delivery of Broadly Neutralizing Antibodies
Topic 139 - Rapid Diagnostic Assays for Self-Monitoring of Acute or Rebound HIV-1 Infection
Topic 140 - Adjuvant Discovery and Down-Selection for Vaccines against Infectious and Immune-Mediated Diseases
Topic 141 - Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models
Topic 142 - Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases
Topic 143 - Development of Diagnostics for *Mycoplasma genitalium* Infection
Topic 144 - Development of Medical Interventions for Treating Non-Tuberculosis Mycobacterial (NTM) Infections
Topic 145 - Diagnostics to Detect Host Immunity to Coccidioidomycosis (Valley fever) or Histoplasmosis
Topic 146 - Discovery and Development of Oral Small-molecule Direct-acting Antivirals Targeting Viruses of Pandemic Potential
Topic 147 - Software or Web Services to Assess Quality and Reproducibility of Data and Information about Therapeutics and Vaccines

- **Summary of HHS Components - Anticipated Number and Time of Award - NIAID page 73**

ANTICIPATED NO. OF AWARDS	ANTICIPATED TIME OF AWARD
21-41	Scientific and Technical Merit Review: March 2025 Anticipated Award Date: August 2025

- **Pages 6-7 – Summary table regarding whether Fast-Track or Direct to Phase II are allowed**

- **Check budget limits for each topic: NIAID pages 120-136**

Example:

Fast Track Proposals will be accepted
Direct to Phase II will not be accepted
Number of anticipated awards: 1-3 Budget (total costs)
Phase I: $300,000 for up to 1 year; Phase II: $2,000,000 for up to 3 years

DIVISION OF AIDS (DAIDS)

Topic # and Title (pages 120-124)

Topic 137 - New Drug Classes with Novel Mechanisms of Action for HIV, Hepatitis B, and Tuberculosis

Topic 138 - Devices and Materials-Based Platforms for the Delivery of Broadly Neutralizing Antibodies

Topic 139 - Rapid Diagnostic Assays for Self-Monitoring of Acute or Rebound HIV-1 Infection

DIVISION OF Allergy, Immunology, and Transplantation (DAIT)

Topic # and Title (pages 124-130)

Topic 140 - Adjuvant Discovery and Down-Selection for Vaccines against Infectious and Immune-Mediated Diseases

Topic 141 - Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models

Topic 142 - Adjuvant Development for Vaccines and for Autoimmune and Allergic Diseases

DIVISION OF Microbiology and Infectious Diseases (DMID)

Topic # and Title (pages 130-134)

Topic 143 - Development of Diagnostics for *Mycoplasma genitalium* Infection

Topic 144 - Development of Medical Interventions for Treating Non-Tuberculosis Mycobacterial (NTM) Infections

Topic 145 - Diagnostics to Detect Host Immunity to Coccidioidomycosis (Valley fever) or Histoplasmosis

Topic 146 - Discovery and Development of Oral Small-molecule Direct-acting Antivirals Targeting Viruses of Pandemic Potential

Office of Data Science and Emerging Technologies (ODSET)

Topic # and Title (pages 134-136)

Topic 147 - Software or Web Services to Assess Quality and Reproducibility of Data and Information about Therapeutics and Vaccines

NIAID Contracting Officer Contact

For all technical questions regarding the NIAID topics included in this solicitation, please contact:

Jonathan Bryan, Contracting Officer
Office of Acquisitions, DEA, NIAID

Phone: (240) 669-5180

Email: jonathan.bryan@nih.gov

NIAID SBIR Program Contact Information

To learn more about the SBIR program at NIAID

- **Contact:** Dr. Natalia Kruchinin, SBIR/STTR Program Coordinator, Team Lead, NIAID, NIH
  - **Email:** kruchininn@niaid.nih.gov
- **Visit our website:** SBIR/STTR NIAID
- NIAID Small Business Program Team

NIH/NIMH 001 – Anti-retroviral Therapy Drug Adherence Assays

Dr. Vasudev Rao

SBIR-STTR Program Director

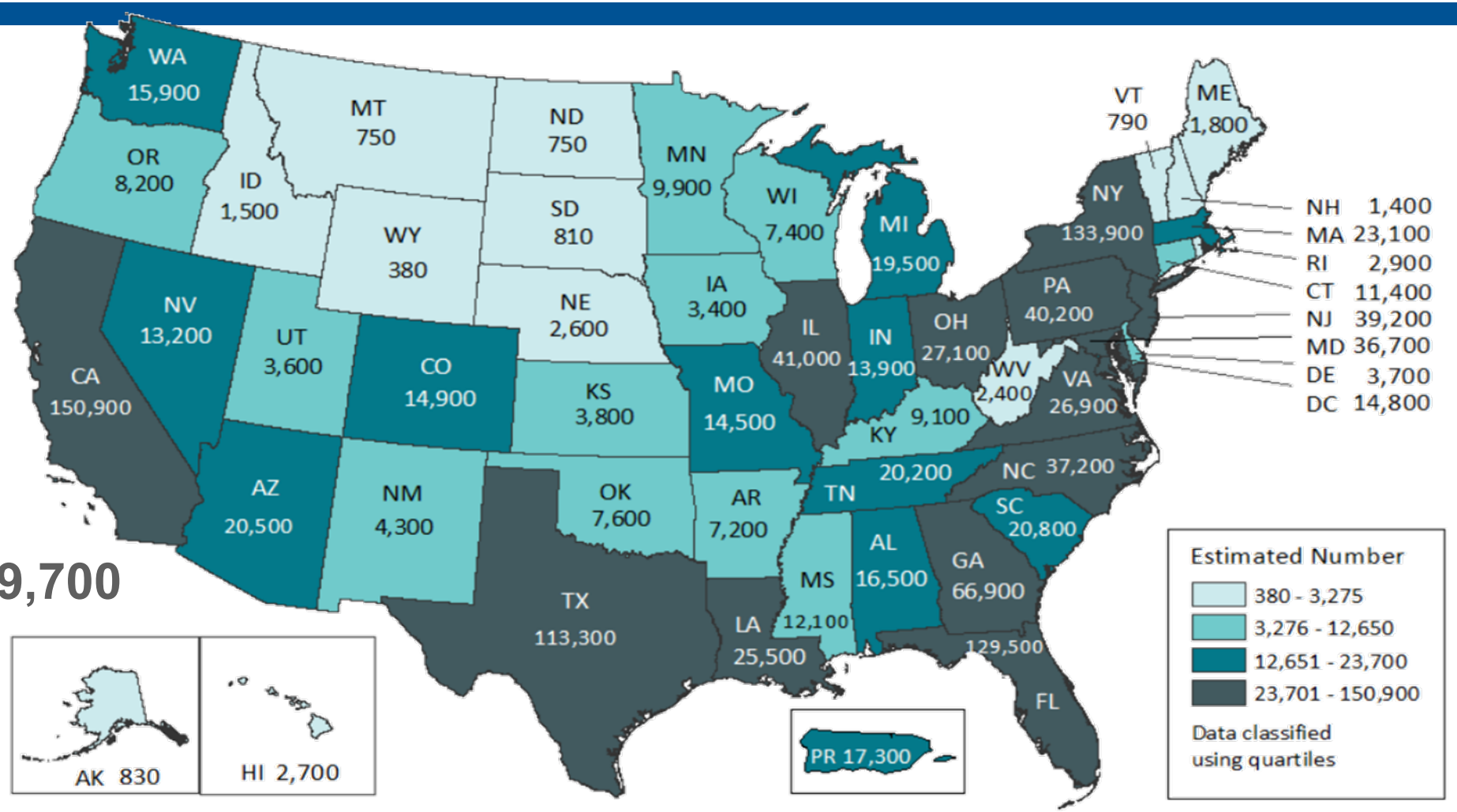
Division of AIDS Research, NIMH

HHS SBIR Contracts Solicitation (PHS-2025-1) Webinar

09/23/2024

National Institute of Mental Health

Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence 2019—United States and Puerto Rico†



Total = 1,189,700

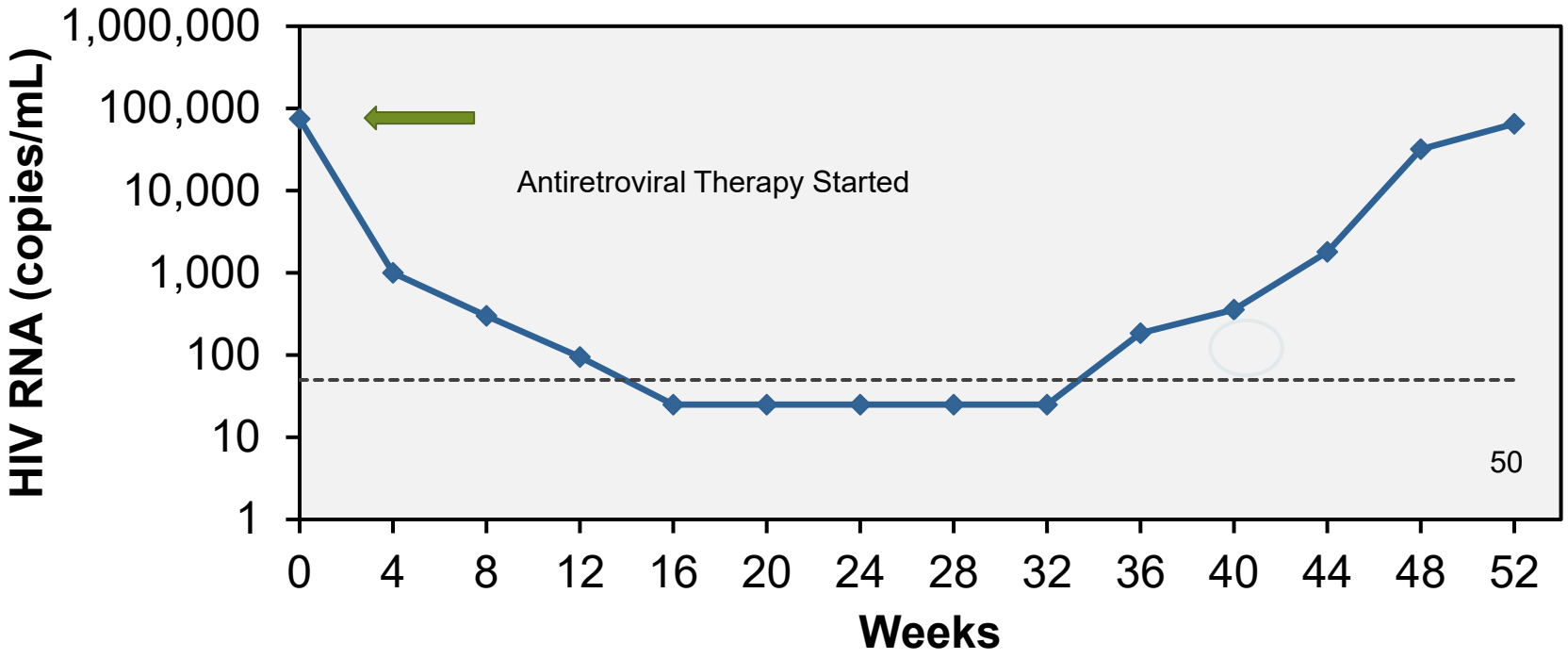
Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty. Estimates for the year 2019 are preliminary and based on deaths reported to CDC through December 2020. Estimates should be interpreted with caution due to incomplete death ascertainment for Kansas, Massachusetts, Mississippi, Nevada, North Dakota, and Vermont.

†Total estimate for the United States does not include data for Puerto Rico.

Antiretroviral therapy has transformed management of HIV

CDC DHHS Guidelines:

- ART should be initiated as close to time of diagnosis as possible



 DHHS AIDS INFO, 2016

Pharmacological Adherence Monitoring

- Rapid point-of-care and pharmacy based assays that measure long-term (> 7 days) adherence to antiretrovirals.
- Need to be able to measure drug levels in various biological matrices, e.g., urine, hair, dried blood spots, etc.
- Ability to monitor
  - PrEP adherence
  - ART adherence to trigger adherence interventions
  - Drug levels of long-acting ART or PrEP formulations
  - Monitor blood donations for PrEP or ART drug levels (as a risk indicator of HIV exposure or infection)

NIH/NIMH 002 – Development of novel In-vitro and In-vivo Models to support NeuroHIV Research

Dr. Vasudev Rao

Division of AIDS Research, NIMH

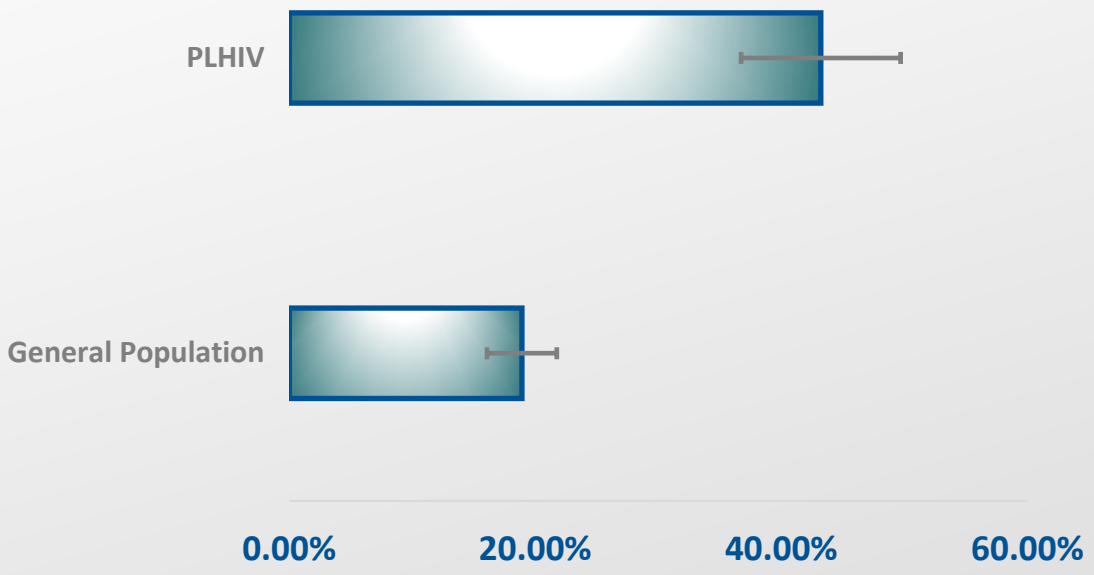
HHS SBIR Contracts Solicitation (PHS-2024-1) Webinar

09/27/2023

National Institute of Mental Health

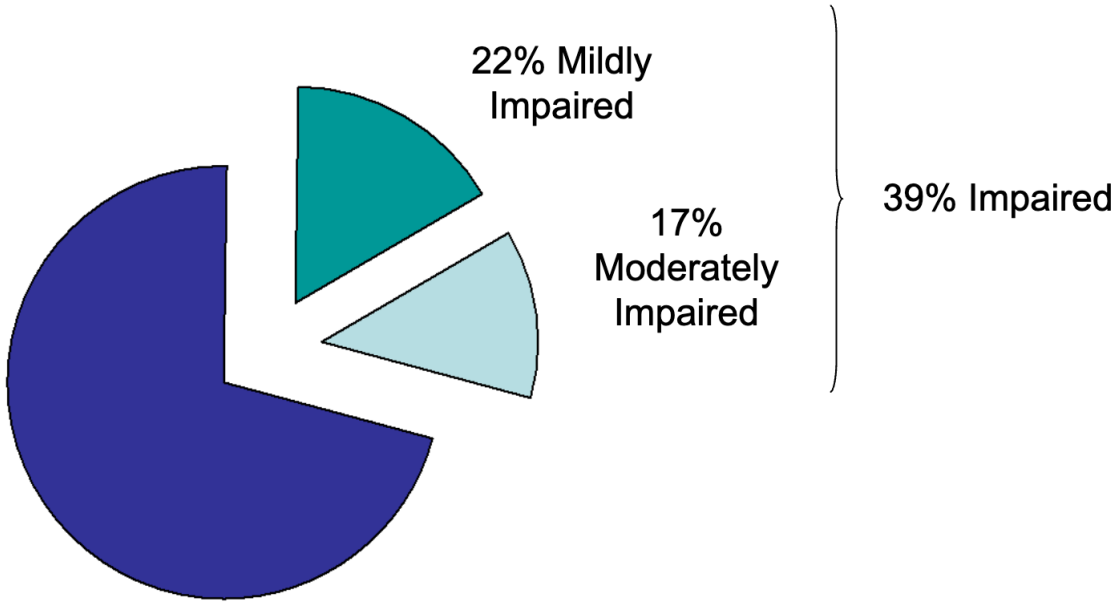
NeuroHIV: Neuropsychiatric impairments in people with HIV

PREVALENCE OF MENTAL HEALTH RELATED DISORDERS IN PEOPLE WITH HIV



DATA FROM SAMHSA

PREVALENCE OF COGNITIVE DYSFUNCTION IN PEOPLE WITH HIV



VALCOUR, V CROI 2018

National Institute of Mental Health

Develop Novel models for NeuroHIV research

- Organoid models incorporating human immune cells amenable to HIV infection and neuronal cells with measurable neuro-modulatory outcomes;
- Humanized small animal models with systemic and CNS immune cells amenable to HIV infection that can be used to understand mechanisms such as neuroimmune dysfunction in the context of long-term infection with HIV and to comprehend the role of the CNS viral reservoirs;
- Develop Blood brain barrier systems using organoid based framework with human immune cells, neuronal cells and vascular components to help comprehend the pathways leading to adverse CNS outcomes in the context of HIV and ART;
- Develop in-vitro and in-vivo models to test the impact of HIV associated immune dysfunction on synaptic transmission and plasticity.

SBIR 2025-1 Contract Solicitation Informational Webinar

Diana Bartlett, MPH, MPP
Small Business Innovation Research (SBIR) Program
Office of Science (OS)
September 23, 2024

CDC’s Mission

- CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

- CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats and responds when these arise.

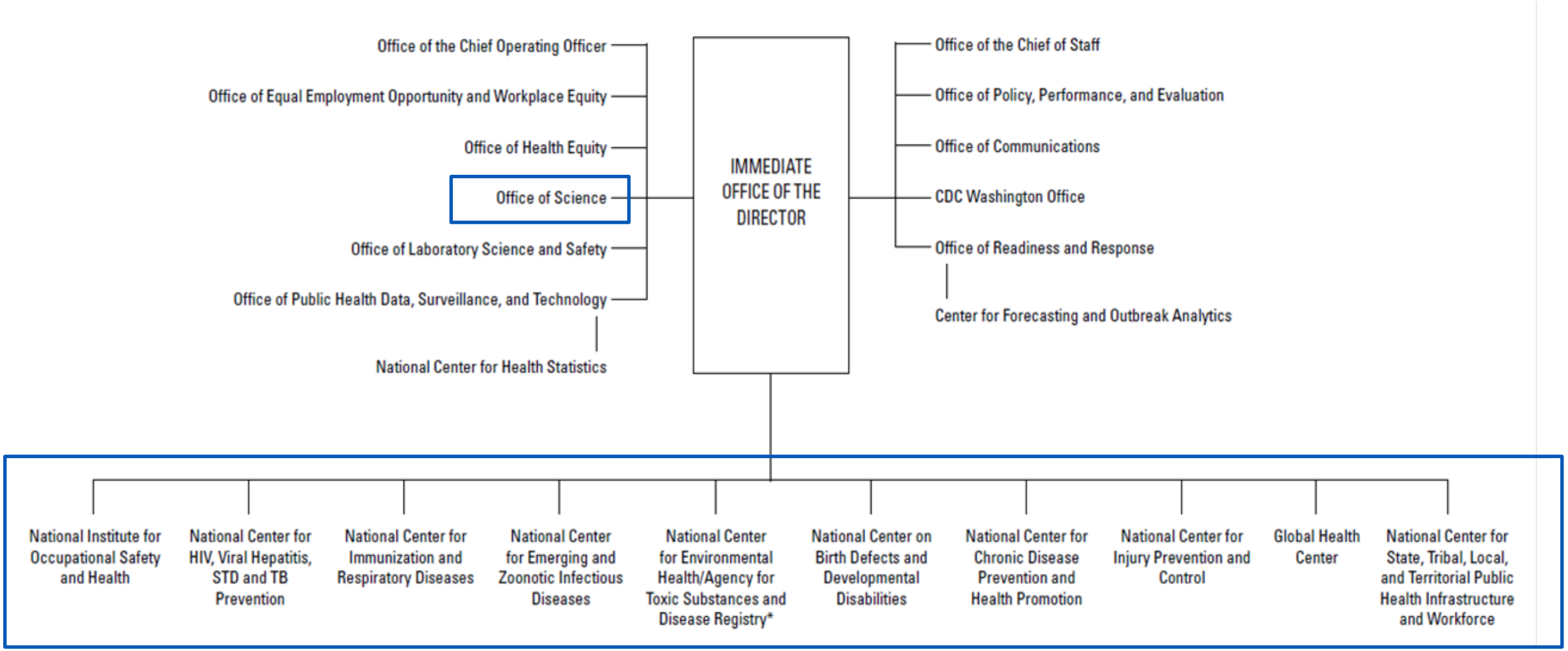
Mission, Role, and Pledge | About | CDC

CDC's Strategic Framework

- CDC's 2022-2027 CDC Strategic Plan advances science and health equity and consists of five core capabilities:
  - Diverse public health workforce
  - World-class data and analytics
  - State-of-the-art laboratories
  - Rapid response to outbreaks at their source
  - Strong global capacity and domestic preparedness

CDC Roybal Entrance. L Bishop

CDC's Centers, Institutes, and Offices



CDC SBIR Program Overview

- CDC participates in both the SBIR HHS Omnibus Grant Solicitations (PA-24-245 & PA-24-246) and the HHS SBIR Contract Solicitation (PHS-2025-1)

- Budget - CDC SBIR set-aside is approximately ~$10 million (FY24)
  - Phase I contract budget is $243,500 — 6-month project period
  - Phase I grant budget is $306,872 — 6-month project period
  - Phase II contract and grant budgets are $2,045,816 — for a 2-year project period

- CDC also participates in PA-21-345, Administrative Supplements to Promote Diversity in Research and Development - Small Businesses-SBIR/STTR (Admin Supp Clinical Trial Not Allowed) – NCEH, NCIPC & NIOSH

- CDC does not participate in the Small Business Technology Transfer (STTR) Program, Fast Track, Direct to Phase II, Phase II B, or Commercialization Readiness Pilot (CRP) Program

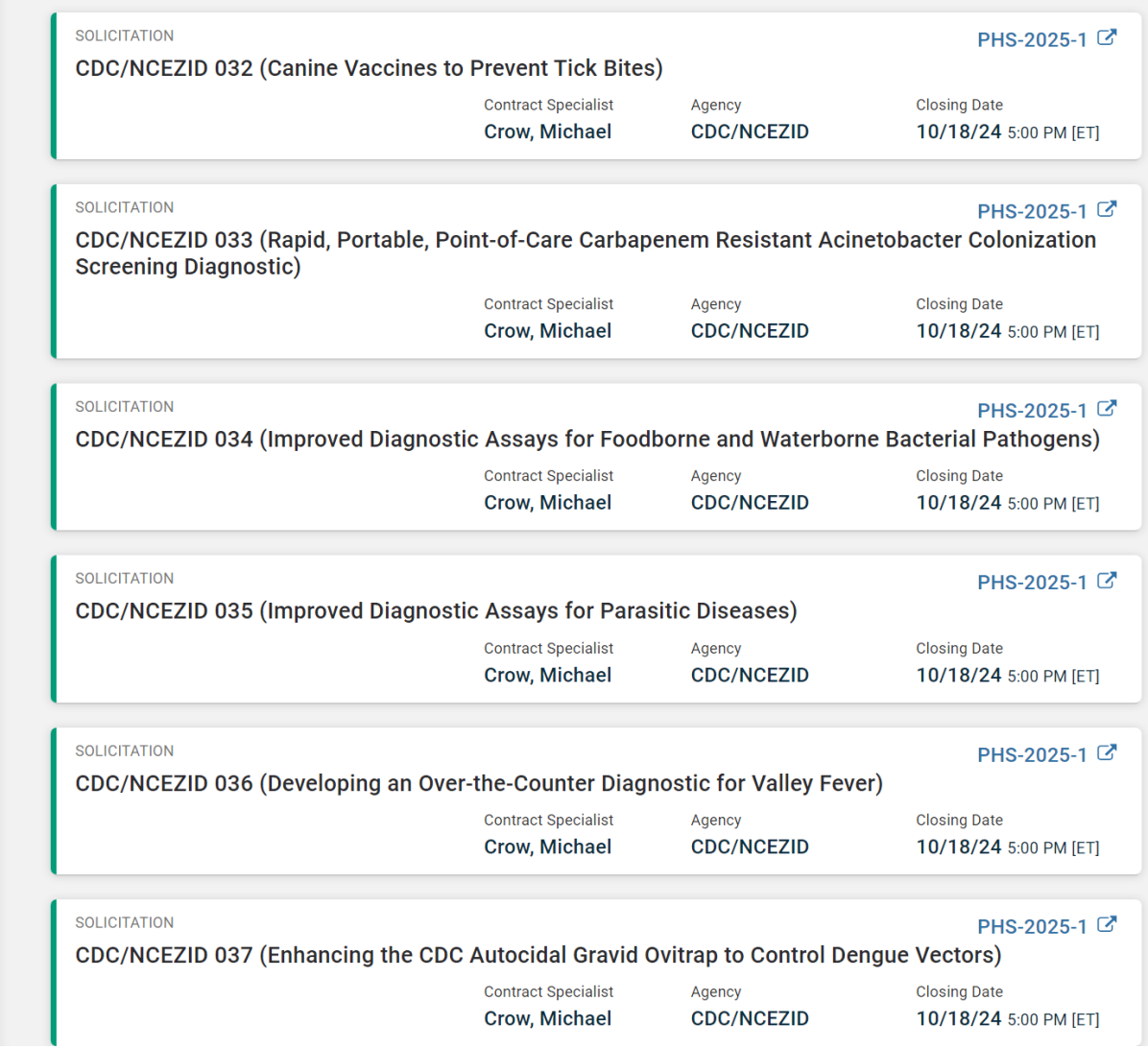
CDC SBIR Program Overview

- Technical and Business Assistance (TABA) –
  - Budget — Funding in addition to the award
    - Phase I – $6,500 for the project period
    - Phase II – $50,000 for the project period

- NIH Technical and Business Assistance (TABA) Needs Assessment Program
  - No cost for this report
  - Minimal time commitment

- I-Corps at NIH program
  - The National Center for Emerging and Zoonotic and Infectious Diseases (NCEZID) is participating in this contract solicitation.

2025-1 SBIR Contract Solicitation- CDC/NCEZID topics



SOLICITATION PHS-2025-1
CDC/NCEZID 032 (Canine Vaccines to Prevent Tick Bites)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

SOLICITATION PHS-2025-1
CDC/NCEZID 033 (Rapid, Portable, Point-of-Care Carbapenem Resistant Acinetobacter Colonization Screening Diagnostic)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

SOLICITATION PHS-2025-1
CDC/NCEZID 034 (Improved Diagnostic Assays for Foodborne and Waterborne Bacterial Pathogens)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

SOLICITATION PHS-2025-1
CDC/NCEZID 035 (Improved Diagnostic Assays for Parasitic Diseases)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

SOLICITATION PHS-2025-1
CDC/NCEZID 036 (Developing an Over-the-Counter Diagnostic for Valley Fever)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

SOLICITATION PHS-2025-1
CDC/NCEZID 037 (Enhancing the CDC Autocidal Gravid Ovitrap to Control Dengue Vectors)
Contract Specialist: Crow, Michael | Agency: CDC/NCEZID | Closing Date: 10/18/24 5:00 PM [ET]

- CDC only accepts applications via NIH's eCPS (electronic Contract Proposal Submission) secured system
- NCEZID Topics 32-37

2025-1 SBIR Contract Solicitation – CDC/NCIRD topics

- CDC only accepts applications via NIH's eCPS (electronic Contract Proposal Submission) secured system
- National Center for Immunization and Respiratory Diseases Topics 38 and 39

SOLICITATION

PHS-2025-1

CDC/NCIRD 038 (Development of a Molecular Panel to Detect Febrile Rash Illnesses)

Contract Specialist	Agency	Closing Date
Crow, Michael	CDC/NCIRD	10/18/24 5:00 PM [ET]

SOLICITATION

PHS-2025-1

CDC/NCIRD 039 (Synthetic IgM Antibody Controls for Measles, Mumps, and Rubella Assays)

Contract Specialist	Agency	Closing Date
Crow, Michael	CDC/NCIRD	10/18/24 5:00 PM [ET]

2025-1 SBIR Contract Solicitation – CDC/NCIPC topic

- National Center for Injury Prevention and Control topic 001

SOLICITATION

PHS-2025-1

CDC/NCIPC 001 (Data Science Solutions to Characterize Polysubstance Use Behavior from Online Sources)

Contract Specialist	Agency	Closing Date
Crow, Michael	CDC/NCIPC	10/18/24 5:00 PM [ET]

CDC SBIR Program Overview

- Please read the contract solicitation and any future amendments to the solicitation carefully. We encourage you to apply early!

- If you have questions after today's webinar, during the open question/answer period, please contact the CDC contracting specialists/officers listed in the solicitation.

- When sending e-mail inquiries, please reference the solicitation (SBIR PHS 2025-1) and the CDC topic number with your specific question(s).

For more information, contact CDC's Office of Science
SBIR: 404-718-1386
www.cdc.gov; www.cdc.gov/sbir

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.

Deadline for receipt of **ALL** Proposals

Friday, October 18, 2024

5:00 PM EDT

Electronic submission must be complete

No paper submissions

Submit proposals a day early if possible

Questions?