

Funded? Top Tips for Effectively Managing your SBIR/STTR Award

Moderator – Adam Sorkin, MEM, MSE, PE

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

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

Agenda

- Format and Introduction
- Topics
 - Working with your Program Officer
 - Communicating effectively with your Grants Manager
 - Managing your small business contract
 - Tips for efficiently managing your SBIR/STTR award
- Q&A Session

Got Funding: Tips for Efficiently Managing Your SBIR/STTR Award

November 14, 2022

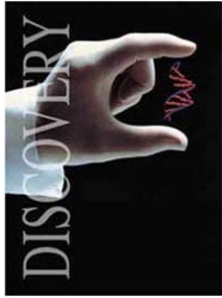
Roger Miller, Ph.D.

SBIR/STTR Program Coordinator (NIDCD)

National Institute on Deafness and Other Communication Disorders,

National Institutes of Health

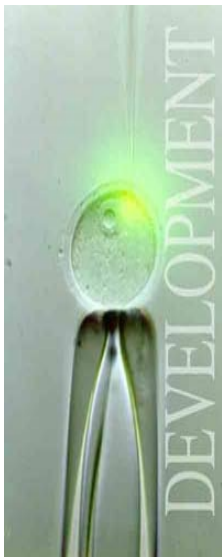
millerr@nidcd.nih.gov



Phase I **Feasibility Study / Proof of Concept**

- Total costs capped at \$275,766
- Project Period: 6 months - 1 year
- *Pilot data not required for Phase I; Absolutely required for Phase II*

Keep scope tight!



Phase II **Full Research & Development**

- Total costs over two years capped at \$1,838,436
- Commercialization plan must be *convincing*
- Product **completed** at end of Phase II
 - IP Licensing strategy
 - Direct vending/ supporting product
- See budget wavier topics for each NIH IC
 - NIDCD: R&D for technologies that require FDA clearance before commercial distribution

Funds spent on work as described within application. e.g. Specific Aims!



Phase III **Commercialization**

- Describe exit strategy in Phase II application
- Provide letters of support from potential licensee(s)
- Marketing costs are ***outside the scope of SEED*** funding



Image Credits: workboat365.com www.northernimages.com
www.startribune.com/duluth-harbor-wind-gust-slams-sailboat-into-lowered-lift-bridge-chopping-mast-in-half/482918681/

- Aim 1. Prepare 4 new analogs of **SW-100** as potential back-up compounds, and conduct (named) assays. Advance the **best of these** to animal studies in Aim 2.
- Aim 2. Conduct a **dose range finding study** of SW-100 and the best back-up compound from Aim 1 to identify a dose in **mouse** chow that causes maximal CNS impact and is well tolerated...
- Aim 3. Test SW-100 and the back-up analog from Aim 1 in Tg4510 mice starting at **two ages** to ascertain...

Details
 Sub-Projects
 Publications
 Patents >
 Outcomes
 Clinical Studies
 News and More
 History

No Patents information available for 1R41AG058283-01

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

In prior work, we demonstrated that Tubastatin A, a selective but modestly CNS penetrant HDAC6 inhibitor partially prevented the development of the tau phenotype in the aggressive Tg4510 model when treated between 5 and 7

<https://seed.nih.gov/small-business-funding/how-to-apply/applying/prepare-your-application>



Download NOA from eRA Commons as it establishes:

Grantee, Principal Investigator (PI), Key Personnel*

Establish .com email, update HOM email in eRA.

NIH Contact Information

Program Officer (PO)

Grants Management Specialist (GMS)

PI uses HOM email address, provide grant number – topic on subject line, route through business official, send to both PO and GMS if change requires official approval.

Establishes funding level

grant in aid

Establishes period of support

extensions can be granted

Sets forth terms and conditions

Animal studies

Human studies

Department of Health and Human Services Operating Division		Notice of Award FAIN# XXXXXXXXXX Federal Award Date XX/XX/XXXX	
Recipient Information		Federal Award Information	
1. Recipient Name Name of Recipient Address Line 1 Address Line 2 City, State, XXXX-XXXX XX		11. Award Number XXXXXXXXXXXXXX 12. Unique Federal Award Identification Number (FAIN) XXXXXXXXXX	
2. Congressional District of Recipient XX		13. Statutory Authority XX-XXX-XXXX, XX-XXX-XXXX	
3. Payment System Identifier (ID) XX-XXXX-XXXX		14. Federal Award Project Title XXXX	
4. Employer Identification Number (EIN) XX-XXXX-XXXX		15. Assistance Listing Number XX-XXXX	
5. Data Universal Numbering System (DUNS) XX-XXXX-XXXX		16. Assistance Listing Program Title XXXX	
6. Recipient's Unique Entity Identifier XXXXXXXXXXXXXX		17. Award Action Type XXXX	
7. Project Director or Principal Investigator Name Title email@email.com XXX-XXX-XXXX		18. Is the Award R&D? XXXX	
8. Authorized Official Name Title email@email.com XXX-XXX-XXXX		Summary Federal Award Financial Information	
Federal Agency Information		19. Budget Period Start Date XX/XX/XXXX – End Date XX/XX/XXXX	
9. Awarding Agency Contact Information Name Title Operating Division Name email@email.com XXX-XXX-XXXX		20. Total Amount of Federal Funds Obligated by this Action 20a. Direct Cost Amount \$ 0 20b. Indirect Cost Amount \$ 0	
10. Program Official Contact Information Name of Program Official Title Operating Division Name email@email.com XXX-XXX-XXXX		21. Authorized Carryover \$ 0 22. Offset \$ 0 23. Total Amount of Federal Funds Obligated this budget period \$ 0 24. Total Approved Cost Sharing or Matching, where applicable \$ 0 25. Total Federal and Non-Federal Approved this Budget Period \$ 0	
		26. Project Period Start Date XX/XX/XXXX – End Date XX/XX/XXXX	
		27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period \$ 0	
		28. Authorized Treatment of Program Income XXXX	
		29. Grants Management Officer - Signature Signature	
30. Remarks XXXX			

Progress reports document the grantee recipient's accomplishments and compliance with terms of award and must be submitted electronically using the Research Performance Progress Report (RPPR) module in eRA Commons.

Face page:

Human Subjects: (No) Vertebrate Animals: (No)

Inventions/Patents? (Yes) If yes, previously reported (No)

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

(paste specific aims from application)

B.1.a Have the major goals changed since the initial competing award or previous report?

(No)

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

(two pages, include graphs with data acquired, photographs of prototype)

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

(... focus on Aim 2, ...prepare data for FDA submission)

C.1 PUBLICATIONS

(provide MyNCBI Public Access Compliance Report)



OER's [RPPR webpage](#)



Communicating Effectively with your Grants Manager

Artisha Wright

November 14, 2022

Other Transaction Authority Lead Agreement Specialist

GMB/NICHD



Read your Notice of Award!

1. What is the Notice of Award (NoA)?

- Legal Document issued to notify the organization that an award has been made.
- Issued for the initial budget period

2. What does the Notice of Award Contain?

- Budget/Project Period Dates
- Funding Commitment
- Terms and Conditions
- Grants Management Specialist and Program Official Contact Information

3. How does award acceptance occur?

- Draw down or request of funds from the Payment Management System

***Contact your Grants Management Specialist with any questions or concerns regarding the information in the NoA!**

Post Award Communication with Grants Management

1. Issues with Payment Management
System setup/access
2. Prior Approvals
3. Eligibility

Managing your Small Business Contract

Christine Biser
Contracting Officer
National Cancer Institute

Anatomy of your contract

Cover page

Section B – Prices, Advance Understandings

Section C – SOW, Reporting Requirements, Invention Reporting

Section D – Marking

Section E – Inspection and Acceptance

Section F – Period of Performance, Deliveries

Section G – Contract Administration

Section H – Special Contract Requirements

Section I – FAR Clauses

Section J – Attachments

Section K – Representations and Instructions

Modifications

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES		
2. CONTRACT (Procurement, instruction, identification) NUMBER		3. EFFECTIVE DATE		4. REQUESTOR/PURCHASE REQUEST/PROJECT NUMBER			
5. ISSUED BY CODE		6. ADMINISTERED BY (if other than Item 5)		CODE			
7. NAME AND ADDRESS OF CONTRACTOR (Number, Street, County, State and ZIP Code)				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
				10. SUBMIT INVOICES (4 copies unless otherwise specified to THE ADDRESS SHOWN IN ITEM 7)			
CODE		FACILITY CODE					
11. SHIP TO/MARK FOR		CODE		12. PAYMENT WILL BE MADE BY CODE			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) () <input type="checkbox"/> 41 U.S.C. 3304(a) ()		14. ACCOUNTING AND APPROPRIATION DATA					
15A. ITEM NUMBER		15B. SUPPLIES/SERVICES		15C. QUANTITY			
				15D. UNIT			
				15E. UNIT PRICE			
				15F. AMOUNT			
15G. TOTAL AMOUNT OF CONTRACT ▶ \$							
16. TABLE OF CONTENTS							
(X)	SECTION	DESCRIPTION	PAGES	(X)	SECTION	DESCRIPTION	PAGES
<input type="checkbox"/>	I	PART I - THE SCHEDULE		<input type="checkbox"/>	J	PART II - CONTRACT CLAUSES	
<input type="checkbox"/>	A	SOLICITATION/CONTRACT FORM		<input type="checkbox"/>	K	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	
<input type="checkbox"/>	B	SUPPLIES OR SERVICES AND PRICES/COSTS		<input type="checkbox"/>	L	LIST OF ATTACHMENTS	
<input type="checkbox"/>	C	DESCRIPTIONS/SPECIFICATIONS/WORK STATEMENT		<input type="checkbox"/>	M	PART IV - REPRESENTATIONS AND INSTRUCTIONS	
<input type="checkbox"/>	D	PACKAGING AND MARKING		<input type="checkbox"/>	N	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERS	
<input type="checkbox"/>	E	INSPECTION AND ACCEPTANCE		<input type="checkbox"/>	O	INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS	
<input type="checkbox"/>	F	DELIVERIES OR PERFORMANCE		<input type="checkbox"/>	P	EVALUATION FACTORS FOR AWARD	
<input type="checkbox"/>	G	CONTRACT ADMINISTRATION DATA					
<input type="checkbox"/>	H	SPECIAL CONTRACT REQUIREMENTS					
17. <input type="checkbox"/> CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
18. <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ Including additions or changes made by you after additions or changes are set forth in full above, is hereby accepted as to the terms listed above and to any continuation sheets. This award consummates the contract which consists of the following documents, all of the Government's solicitation and your bid, and (c) this award contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed bid contract.)							
19A. NAME AND TITLE OF SIGNER (Type or Print) 19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign) 19C. DATE SIGNED _____ 19D. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer) 19E. DATE SIGNED _____							
STANDARD FORM 26 (REV. 3/2013) Prescribed by GSA - FAR (48 CFR) 53.214(a)							

Section B – Supplies/Services and Prices/Costs

Supplies/Services

- Firm fixed-price contracts (payment fixed to a deliverable)
- Cost reimbursement contracts- (payment fixed to objectives) allowable and allocable cost categories (DL, FB, ODC, OH, G&A, Fee)

Advanced Understandings

- (SBIR certifications, subcontracting, travel, indirect cost rate agreements)

Section C – Description/Statement of Work (SOW)

- Statement of Work - lists the technical endpoints the contractor has agreed to deliver
- Contractor progress on the SOW technical endpoints is reported in Technical Reports, which are described in Reporting Requirements
- Due dates will appear in Section F
- References to the Federal Acquisitions Regulations (FAR) and the U.S. Code of Federal Regulations (USC):

FAR: <https://www.acquisition.gov/browse/index/far>

USC: <https://uscode.house.gov/>

also: Cornell (<https://www.law.cornell.edu/cfr/text>)

Section D – Packaging, Marking and Shipping

- Reference contract number and Contractor name on deliverables and correspondence

Section E – Inspection and Acceptance

- Can contractor assume acceptance?

Section F – Deliveries or Performance

- Period of Performance
- Deliverable due dates, recipients and addresses

Section G – Contract Administration Data

- Contracting Officer's Representative (COR)
- Key Personnel
- Invoice Submission (also see Section J Attachments):
What to include in the invoice; invoice naming convention;
submission addresses;
- Contract performance evaluations

Section H – Special Contract Requirements

Contract terms for:

- Human Subjects
- Use of vertebrate animals
- Press releases/publications
- this list is not exhaustive

Section I Contract Clauses

Most clauses are listed in Section I, but also check Sections E, F (incorporated by reference), G (Government property), H (Options, HS, Vertebrate animals), K (reps and certs)

- FAR and HHSAR
- Clauses are updated periodically

FAR: <https://www.acquisition.gov/browse/index/far>

HHSAR: <https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html>

USC: <https://uscode.house.gov/>

also: Cornell (<https://www.law.cornell.edu/cfr/text>)

- Four sections (applicable to both FAR and HHSAR):
 - I.1 Incorporated by reference
 - I.2 Authorized substitution of clauses
 - I.3 Additional Contract Clauses
 - I.4 Clauses in full text

Section J – List of Attachments

- SOW
- Contract administration instructions
- Deliverables templates
- Government Forms

Section K – Representations and Certifications

- FAR Clauses
- Human Subjects/Vertebrate Animal clearance data
- SAM.gov representations/NIH representations

Contract modifications

- Use the contract number in box 2 on all correspondence
- **Effective Date**
- Your POC for all contracting matters is shown in Box 20A and their address is shown in Box 6.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
2. AMENDMENT/CONTRACT ORDER NUMBER		3. EFFECTIVE DATE	4. REQUEST/CONTRACT ORDER NUMBER
5. ISSUED BY		6. PROJECT NUMBER (if applicable)	
7. CODE		8. ADMINISTERED BY (if other than item 6)	
9. NAME AND ADDRESS OF CONTRACTOR (number, street, county, state and ZIP Code)		10. CODE	
11. NAME AND ADDRESS OF CONTRACTOR (number, street, county, state and ZIP Code)		12. NAME AND ADDRESS OF CONTRACTOR (number, street, county, state and ZIP Code)	
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97. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS		98. THIS ITEM ONLY APPLIES TO MODIFICATIONS OF CONTRACTS/ORDERS	
99. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS		100. THIS ITEM ONLY APPLIES TO MODIFICATIONS OF CONTRACTS/ORDERS	

- Box 10 Contract #
- Box 2 Modification #
- **Box 3 Effective Date**
- Box 13 Authority ~ unilateral or bilateral modification
- Box 14 purpose of the modification and contract sections affected
- **Box 16A Contracting Officer's name**
- Mods contains only the base award text that is being modified

Questions on your contract? Ask your Contracting Officer

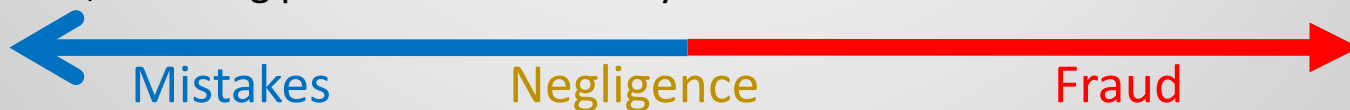
Communication is Key to Avoiding Fraud, Waste and Abuse

Presented by:
Jonelle Soeffing
OIG, HHS



HHS-OIG Mission

- OI's mission is to protect the integrity of HHS programs. OI conducts Criminal, Civil, Administrative investigations of fraud, waste, abuse and misconduct.
- Fraud, waste and abuse typically fall into one or more of three general categories:
 - Conflicts of Interest
 - Theft of government funds/Embezzlement
 - Failing to Properly Support the Use of Funds
- Fraud: intentional or deliberate act to deprive another of property or money by deception or other unfair means.
- Waste: practices that, directly or indirectly, result in unnecessary costs, such as overusing services and misusing resources.
- Abuse: Intentional or unintentional, thoughtless or careless expenditure, consumption, mismanagement of government resources; Excessive or improper use of government resources, including position and authority.



Fraud Schemes

- False information on grant applications, progress reports, etc.
- Creating fictitious records: fabricated companies and invoices
- Using funds for unauthorized purposes
- Not doing any work
- Kickbacks
- PI outside employment
- Awardee company size misrepresentation

Specific examples of what NOT to do:

- Operate out of your residence (without authority)
- Use grant funds for personal expenses
- Pay others to do ALL of the proposed research
- NOT pay institutions who did do the proposed work but still draw down the grant funds
- Lie to the awarding entity – including on your biosketch

Fraud Awareness

- Without understanding what fraud, waste, or abuse “looks” like, you may inadvertently commit it and be on the radar.
- Fraudsters utilize SBIR funds that may otherwise be given to legitimate awardees, so in essence they are stealing from everyone listening.
- Use the grant money for what you said it would be used for - no more, no less - and there won't be a problem.
- If you see something, say something

Fraud Consequences

Criminal Prosecution:

18 USC 641 Criminal Embezzlement and Theft of Public Money

- Knowingly converting funds or items to your use without the authority to do so.
- Government must prove it was an intentional act.
- Federal grant money is still the property of the US government even after it has been deposited in a grantee's bank account.
- Criminal Penalties – Prison, Fines, Restitution

18 USC 1001 False Statements

- Grant application signature and certifications, and in the quarterly financial statements made when drawing down funds.

Civil Prosecution:

31 USC 3729 False Claims

- Knowingly present, or cause to be presented, a false or fraudulent claim or payment or approval.
- Actual knowledge, reckless disregard or deliberate ignorance.
- Government does not need to prove fraudulent intent, preponderance of evidence.
- Triple damages plus penalties between \$5,500 to \$11,000 per offense.

Administrative Action:

- Civil Monetary Penalties
- Exclusion
- Suspension
- Debarment

HHS-OIG Case Examples

FOR IMMEDIATE RELEASE

Monday, March 29, 2021

[REDACTED] Pays \$635,000 in Civil Settlement to Resolve Allegations of False Statements to Obtain Grant Frauds

SACRAMENTO, Calif. — [REDACTED] agreed to pay the United States \$635,000 to resolve allegations that he knowingly submitted false statements to the National Institute of Environmental Health Sciences to secure Small Business Innovation Research grant funds, Acting U.S. Attorney Phillip A. Talbert announced.

[REDACTED] and His Companies Agreed to Pay \$50,000 and Be Excluded for 5 Years for Allegedly Violating the Civil Monetary Penalties Law by Inappropriately Drawing Down Funds from NIH Small Business Innovation Research Grants

On October 13, 2020, [REDACTED], Pulsus Medical, LLC, and Nexeon Medsystems Puerto Rico Operating Company, Inc. (collectively, "Nexeon"), entered into a settlement agreement with OIG in which they agreed to pay \$50,000 and be excluded from participation in all Federal health care programs for five years under 42 U.S.C. 1320a-7a and 42 U.S.C. 1320a-7(b)(7). The settlement agreement resolves allegations that Nexeon drew down funds from the HHS Payment Management System from National Institutes of Health (NIH) Small Business Innovation Research (SBIR) awards that were: (1) sent to an overseas affiliate without NIH approval, in violation of



Report Suspected Fraud, Waste or Abuse to HHS OIG



HHS OIG Hotline
<http://www.oig.hhs.gov>
1-800-HHS-TIPS
(1-800-447-8477)

- A Hotline complaint is an *allegation*.
- Hotline complaints are treated with privacy and discretion.
- OIG conducts independent investigations and hotline complaints can provide helpful information.



Questions & Answers

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>