

Managing Your SBIR/STTR Award Effectively

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

This presentation may include presenter's notes.

Agenda

Panelist Presentations

- Program Officer - Toyin Ajisafe, Ph.D.
- Grants Management Specialist – Mindy Bixby
- Contracting Officer – Callie Prassinos
- HHS OIG Office of Investigations – Jonelle Soeffing

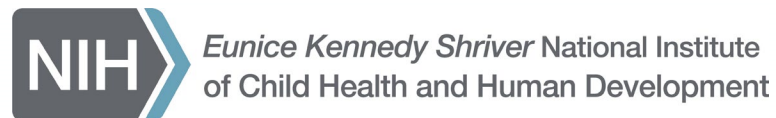
Q&A

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

Toyin Ajisafe, Ph.D.

Program Officer
*National Center for Medical
Rehabilitation Research*

SBIR/STTR Program Coordinator
National Institute of Child Health and
Human Development



November 15, 2023
11:00 AM EST

SBIR Phases

- Phase I – feasibility; proof of concept
 - Total costs capped at \$306,872
 - Project Period: 6 months - 1 year
 - Pilot data not required for Phase I; Absolutely required for Phase II
- Phase II – full research and development (can include efficacy; effectiveness)
 - Total costs over two years capped at \$2,045,816
 - Project Period: 2 - 3 years
 - Commercialization plan is required
 - If applicable clinical trial, design study informed by pre-engagement with FDA




Pre-Notice of Award (NoA)

- Prior to review – do not overpromise in the application
 - reviewers may be okay with overambition (e.g., sample size) but consider practicality
- Following review
 - wait for summary statement to be released
 - ask your program officer about funded scores based on recent history
 - if competitive, start lining up aspects of the project that could mitigate delays if awarded (e.g., IRB)



Notice of Award (NoA)

- Download NoA from eRA Commons;
- NoA is legally binding and establishes:
 - funding level
 - period of support
 - terms and conditions (e.g., human subjects)
 - NIH award contacts
 - Program Officer (PO)
 - Grants Management Specialist (GMS)



Department of Health and Human Services
Operating Division

Notice of Award
FAIN# XXXXXXXXXXXX
Federal Award Date
XX/XX/XXXX

Recipient Information

1. Recipient Name
Name of Recipient
Address Line 1
Address Line 2
City, State, XXXXX-XXXX

2. Congressional District of Recipient
XX

3. Payment System Identifier (ID)
XX-XXXXXX

4. Employer Identification Number (EIN)
XX-XXXXXX

5. Data Universal Numbering System (DUNS)
XX-XXX-XXXX

6. Recipient's Unique Entity Identifier
XXXXXXXXXXXX

7. Project Director or Principal Investigator
Name
Title
email@email.com
XXX-XXX-XXXX

8. Authorized Official
Name
Title
email@email.com
XXX-XXX-XXXX

Federal Agency Information

9. Awarding Agency Contact Information
Name
Title
Operating Division Name
email@email.com
XXX-XXX-XXXX

10. Program Official Contact Information
Name of Program Official
Title
Operating Division Name
email@email.com
XXX-XXX-XXXX

Federal Award Information

11. Award Number
XXXXXXXXXXXX

12. Unique Federal Award Identification Number (FAIN)
XXXXXXXX

13. Statutory Authority
XX XXX XXXX XX XXX

14. Federal Award Project Title
XXXX

15. Assistance Listing Number
XX.XXX

16. Assistance Listing Program Title
XXXX

17. Award Action Type
XXXX

18. Is the Award R&D?
XXXX

Summary Federal Award Financial Information		
19. Budget Period Start Date XX/XX/XXXX – End Date XX/XX/XXXX		
20. Total Amount of Federal Funds Obligated by this Action	\$	0
20a. Direct Cost Amount	\$	0
20b. Indirect Cost Amount	\$	0
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

Research Performance Progress Reports (RPPR)

- RPPR documents accomplishments relative to terms of award
 - must be submitted electronically using the RPPR module in eRA Commons
- Questions include:
 - “What are the major goals of the project?”
 - paste specific aims from application
 - “Have the major goals changed since the initial competing award or previous report?”
 - prior approval is required for changes in scope (sample size; inclusion criteria; outcomes; methods)

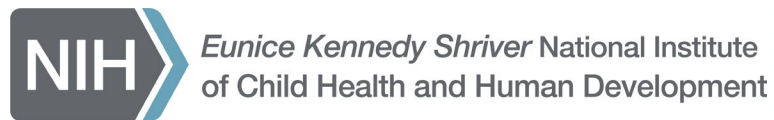


RPPR cont.

- Additional questions include:
 - “What was accomplished under these goals?”
 - include graphs with data acquired, photographs of prototype
 - list any relevant publications in appropriate section (provide MyNCBI Public Access Compliance Report)
 - “What do you plan to do during the next reporting period to accomplish these goals?”
- Click this [link](#) for the OER RPPR webpage
- Engage with your PO and GMS early and often to mitigate issues



Thank you!
toyin.ajisafe@nih.gov



Working with your Grants Management Specialist

Mindy Bixby

Grants Specialist Small Business Point of Contact, NICHD



Read your Notice of Award

Read your Notice of Award (NoA) and make sure you understand all the Terms and Conditions.

- Your award may have been issued with restrictions.
 - Animal research, pending OLAW approval
 - Human Subject Research, pending IRB

Funds cannot be spent on restricted items until information is submitted and approved, and a revised NoA is issued.

- What else is in my NoA:
 - Budget/Project Periods
 - Funding Commitments
 - GMS and Program Official (PO) Contact Information
 - Closeout Information



Payment Management System (PMS)

Accepting your Award

- When you draw down funds from PMS you are accepting your award.
 - To access grant funds, you first must set up a PMS account. This is where you draw down funds. [PMS New User Request](#)
 - To check your User Access Request:
 - New User Status: Go to [PMS.PSC.GOV](#) → select Request Access → Retrieve Existing Request. Provide the requested information to check the status of your request.
- You will also need to complete a [SF-1199A](#) and submit it to the Product Service Center. Instructions on how to complete the form can be found [HERE](#).

More information: Information on how to make a [Payment Request](#).

- [PMS Help Desk](#) or Locate your [PMS Liaison](#)



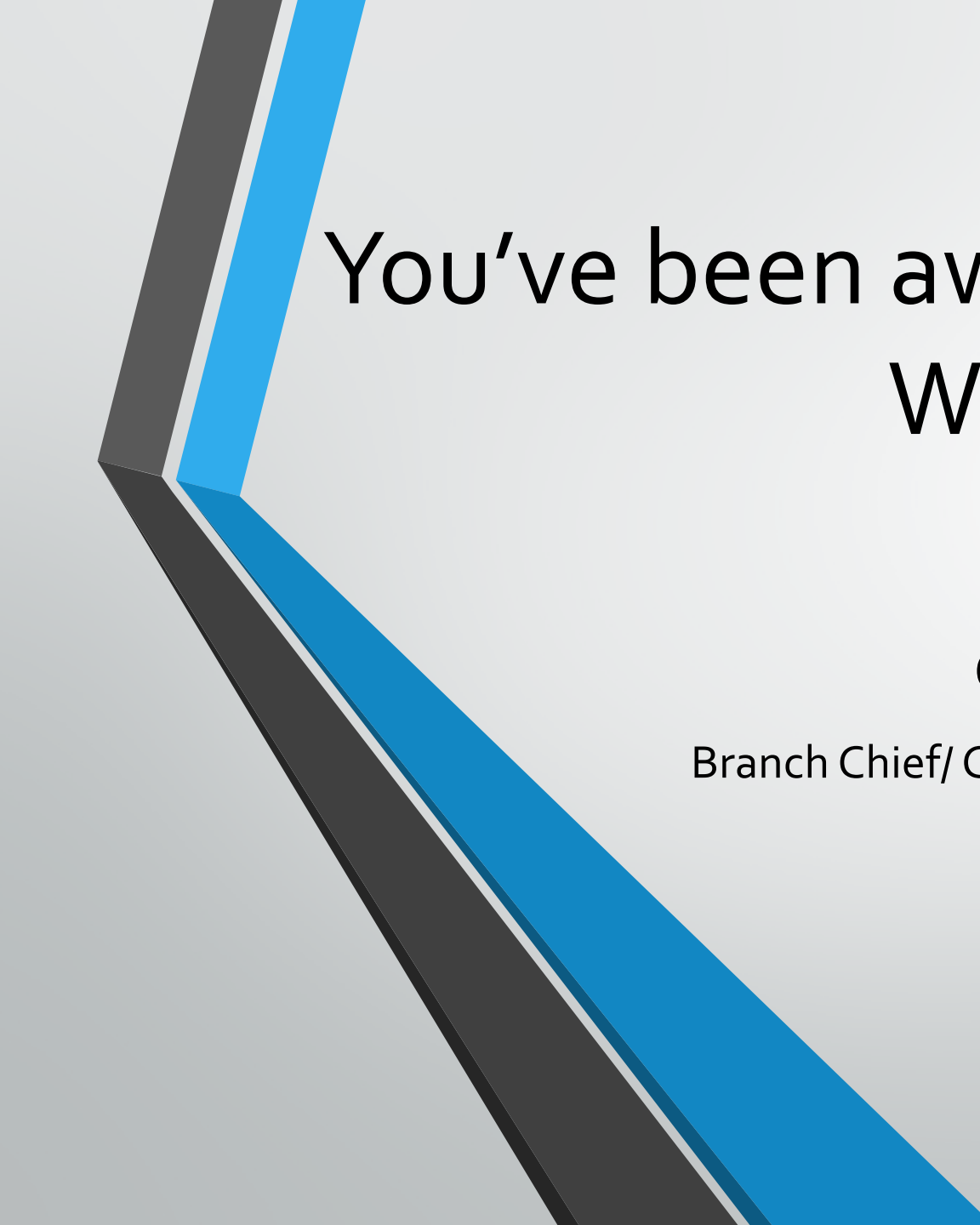
Prior Approval Request

- HELP! Something changed, in my project!
 - All requests must be sent in writing (by email) 30 days before proposed change. PIs are not allowed to submit prior approval requests. All request must come from the AOR.
- Examples of Prior Approval (but not limited too)
 - Change in project budget
 - Change in approved animal model
 - Change from a multiple PD/PI to a single PD/PI model
 - Change from a single PD/PI to multiple PD/PI model
 - Change in the level of effort of key personnel listed on NoA
 - Second No Cost Extension

More information

- For additional activities that require prior approval see Grants Policy Statement 8.1.2 .
- Some prior approval actions are completed in Prior Approval Module





You've been awarded a SBIR Contract! What's next?

Callie Prassinos

Branch Chief/ Contracting Officer, OA, NIAID, NIH

Overview

- Contract and its clauses
- Contract Obligations/ Limitation
- Roles of the Contracting Officer and Contracting Officer's Representative
- Statement of Work
- Contract Changes
- Key Personnel
- Invoice Submission and Payment
- Reporting Requirements/ Deliverables
- Evaluation of Contractor Performance (CPARS)
- Moving to Phase II and Fast track

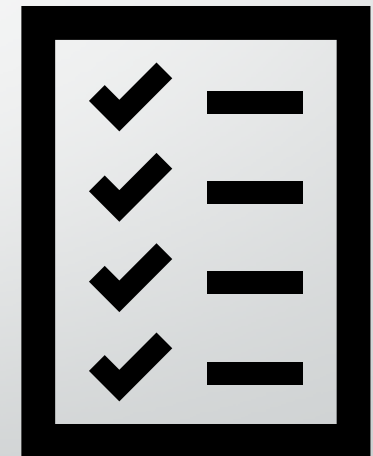
Contract and its clauses

A contract is a legally binding agreement between the two parties, your organization and the government. There will be specific performance requirements in the statement of work and deliverable schedule with details on due dates and expectation for performance.

Usually, contracts are organized by the following sections:

Cover page - Contract #, Contractor's Name, Dates, Signatures

- 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





Contract Obligations and Limitations

- The mutual obligations of the Government and the Contractor are established by, and limited to, the written stipulations in the contract document.
- Unless specifically authorized by the Contracting Officer, the Contractor shall not assume any obligations or take any action not specifically required or authorized by the contract.

Roles of the Contracting Officer & Contracting Officer's Representative

CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The COR is responsible for:

- Monitoring technical progress
- Recommending changes in requirements to the Contracting Officer (CO). The COR cannot make any changes to the Statement of Work or reporting requirements, only the CO may do this.
- Interpreting technical performance requirements
- Performing required inspection and acceptances
- Assisting in the resolution of technical problems encountered during performance
- The COR may not authorize increases in the negotiated costs.

CONTRACTING OFFICER (CO)

The CO is the only person with the authority to:

- Direct or negotiate any changes to the Statement of Work
- Modify or extend the period of performance
- Change the delivery schedule
- Change the terms and conditions of the contract.



STATEMENT OF WORK

- The Statement of Work defines the work to be performed under the contract and acts as a framework for what costs are covered under the contract.
- The Contractor should be intimately familiar with all details of the Statement of Work.
- Any changes to the Statement of Work must be approved in writing by the Contracting Officer.
- If the Contractor receives a request from the Government to perform a task or activity that will change the Statement of Work, the Contractor must inform the Contracting Officer before beginning work on this task/activity.

Changes to the Contract

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	1	OF	PAGES
				N/A			
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE [see block 16C, below]	4. REQUESTION/PURCHASE REG NO.	5. PROJECT NO. (if applicable)				
			N/A				
6. ISSUED BY National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Contract Management Program Room 3214, MSC 7612 6700-B Rockledge Drive Bethesda, MD 20892-7612	CODE	7. ADMINISTERED BY (if other than item 6)	CODE	N/A			
8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP Code)				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				10A. MODIFICATION OF CONTRACT/ORDER NO.			
				10B. DATED (SEE ITEM 13)			
CODE				FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
<input type="checkbox"/> The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 9 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.							
12. ACCOUNTING AND APPROPRIATION DATA (if required)							
EIN	SOCC 25.55	DOC #300N1A1	CAN	\$	LOC #		
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.							
() A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.							
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.102(b).							
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:							
D. OTHER (Specify type of modification and authority)							
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)							
PURPOSE:							
EXPIRATION DATE: _____ TOTAL CONTRACT AMOUNT: _____							
FUNDED THROUGH: _____ TOTAL OBLIGATED AMOUNT: _____							
<small>(Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remain unchanged and in full force and effect.)</small>							
15A. NAME AND TITLE OF SIGNER (Type or print)				15A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)			
15B. CONTRACTOR/OFFEROR				15C. DATE SIGNED		15B. UNITED STATES OF AMERICA	
BY _____ <small>(Signature of person authorized to sign)</small>				BY _____ <small>(Signature of Contracting Officer)</small>		15C. DATE SIGNED	
NIN 7540-01-152-003 PREVIOUS EDITION UNUSABLE				33-105 Computer Generated		STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243	

- Any changes in the terms or conditions of the Contract, including the Statement of Work, changes in Key Personnel, or delivery schedule must be accomplished by a written modification.
- The contractor should submit their formal requests in writing to the Contracting Officer for review. The Contracting Officer will review the request, obtain recommendation from the COR and provide consent, decline, or request further information from the Contractor.

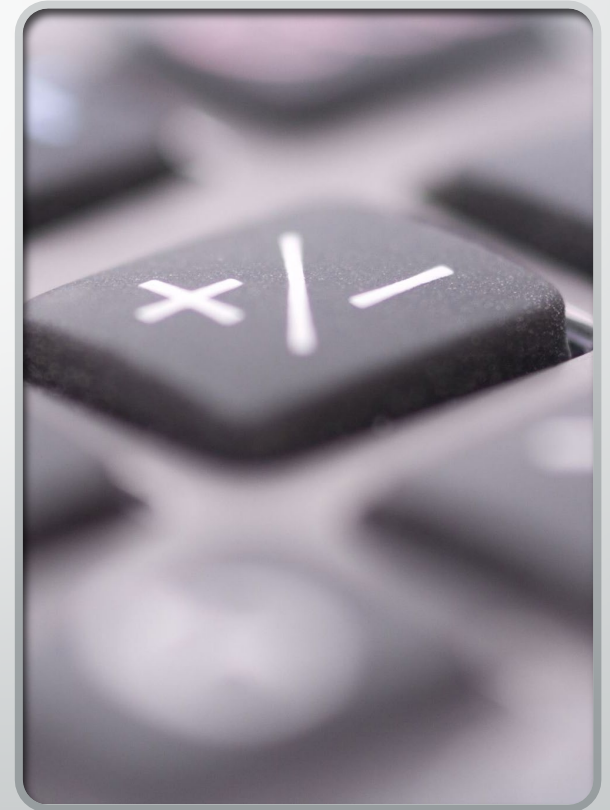


Key Personnel

- Prior to diverting from the individual identified as Key Personnel under Article G of the contract, the Contractor shall notify the CO in advance of replacing Key Personnel. The request should include sufficient information (CV including qualifications), to authorize replacement and avoid negative impact to the program/contract.
- No diversion shall be made by the Contractor without the written consent of the CO.

Invoice Submission and Payment

- The Government shall make payments, including invoice and contract financing payments, by electronic funds transfer (EFT).
- Payments on fixed price contracts may be made based on the satisfactory completion, receipt, and acceptance of contract deliverables.
- Payments on cost-reimbursement contracts may be made pursuant to receipt of proper invoices of allowable costs incurred which may be submitted no more frequently than on a monthly basis unless otherwise authorized by the Contracting Officer.
- For all contracts, final payment will not be made until all reports and deliverables included in the contract have been delivered and accepted by the Government.



Reporting Requirements/ Deliverable

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work in SECTION C of the contract and upon delivery and acceptance by the Contracting Officer, (and the COR), of items in accordance with the stated delivery schedule found in Article C. Reporting Requirements & Article F. Deliveries

Examples of some deliverables –

Technical Progress Reports

- ✓ Monthly Progress Report
- ✓ Final Report
- ✓ Summary of Salient Results (to be submitted with the Final Report)

Other Reports/Deliverables

- ✓ NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification
- ✓ Final Invention Statement



Evaluation of Contractor Performance (CPARS)

Article G. Post Award Evaluation Of Contractor Performance

- Interim (annual) and Final Evaluations of Contractor performance will be prepared accordance with FAR Subpart 42.15.
- Evaluation Factors:
 - Technical/ Quality of Product or Service
 - Cost Control
 - Schedule/ Timelines
 - Management / Business Relations
 - Regulatory Compliance
- All evaluations will be provided to the Contractor and will be permitted thirty days to review the document and to submit additional information or a rebutting statement.
- Copies of the evaluations, Contractor responses, and review comments, if any, will be retained, and may be used to support future award decisions.





Moving to Phase II and Fast Track

- Phase I Contractors, that did not get awarded a Fast Track contract, will be informed of the opportunity to apply for Phase II from the Awarding Components after (or close to) the expiration of the Phase I contract.
- Phase I awardees will be provided with the Phase II proposal submission requirements with the details on the due date, content, and submission requirements of the Phase II proposal.
- Only one Phase II award may result from a single Phase I SBIR contract.
- A Fast Track contracts are awards for Phase I with a contractual option for Phase II. The Government is not obligated to fund the Phase II portion unless and until the Awarding Component exercises that option at the end of the Phase I contract option.

Congratulation
on your
SBIR Contract award!



U.S. Department of Health & Human Services
Office of Inspector General



Managing your SBIR/STTR Award Effectively

Presented by:
Jonelle Soeffing, Operations Officer



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

- Awareness of fraud is important, to safeguard Federal funds.
- Fraudsters utilize SBIR funds that may otherwise be given to legitimate awardees. Compliance with Federal Regulations, establishment of internal controls, and other compliance measures may reduce your risk.
- Use the grant money for what you said it would be used for - no more, no less - and there won't be a problem.
- Disclosure and communication with HHS Grants Officials is key.



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.
- 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

PRESS RELEASE

Two Biotech Firms And Their Co-Founder To Pay \$10 Million To Resolve Allegations Of Mischarging Federal Grants

Wednesday, December 21, 2022

Share



For Immediate Release

U.S. Attorney's Office, Northern District of California

FOR IMMEDIATE RELEASE

Monday, March 29, 2021

Davis Man Pays \$635,000 in Civil Settlement to Resolve Allegations of False Statements to Obtain Grant Frauds

SACRAMENTO, Calif. — Owen Hughes, the sole proprietor of Eon Research Corporation in Davis, 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.

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/>



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SEEDinfo@nih.gov



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The NIH Guide for Grants and Contracts:

<http://grants.nih.gov/grants/guide/listserv.htm>