Managing Your SBIR/STTR Award Effectively

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

- 2024 NIH SBIR/STTR Program Updates
- Panel
  - Roger Miller, PhD –SBIR/STTR Program Coordinator (NIDCD)
  - Kari Ashmont, PhD – Translational Team Lead, Office of Program Evaluation and Strategic Partnerships (NIBIB)
  - Callie Prassinos - Branch Chief/ Contracting Officer, Office of Acquisitions (NIAID)
  - Jonelle Soeffing - Operations Office, Investigations Branch, HHS Office of Inspector General
- Q&A

Webinar Goals

- Discuss best practices for SBIR and STTR award (Grants and Contracts) management
  - Recipient Expectations
  - Points of contact for technical and administrative concerns
  - Avoiding and resolving problems

- Avoiding Fraud, Waste and Abuse
  - Fraud Awareness and Consequences
  - Case Studies
  - How to report FWA concerns

2024 SBIR/STTR Update - Foreign Risk Assessment

New Requirement from the SBIR and STTR Extension Act of 2022

- For applications submitted for due dates on or after **September 5, 2023:** NIH is required to assess security risk (prior to issuing an award) including: Cybersecurity practices, Patent analysis, Employee analysis, Foreign ownership, Financial Ties and Obligations
- Disclosure is required using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries Form

Policy References

- **NOT-OD-24-029:** Clarification of Implementation of the NIH SBIR and STTR Foreign Disclosure Pre-award and Post-Award Requirements
- **NOT-OD-24-149:** Prior Approval Requirement for Changes to Domestic Subawards for the SBIR and STTR Programs

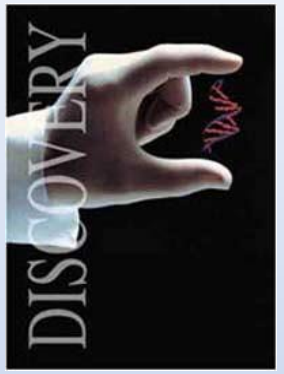
- **For Information and Case Studies:** Foreign Disclosure and Risk Management webpage

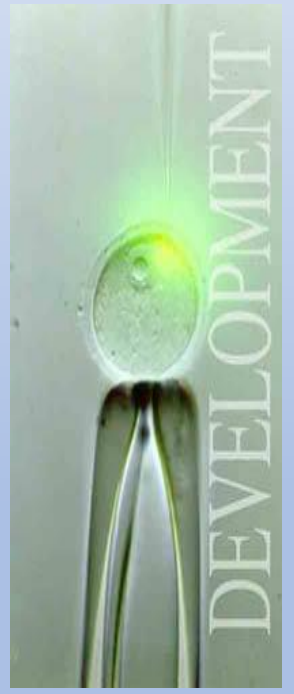
Foreign Disclosure: Post-Award Reporting Requirements

For awards covered by this policy (competitive application submitted for due date on or after September 5, 2023):

- Recipients are responsible for monitoring their relationships with foreign countries of concern post-award, for any changes that may impact previous disclosures
- SBCs receiving an award under the SBIR/STTR program are required to submit an updated disclosure form to report any of the following changes to NIH
  - any change to a disclosure on the disclosure form;
  - any material misstatement that poses a risk to national security; and
  - any change of ownership, change to entity structure, or other substantial change in circumstances of the SBC that NIH determine poses a risk to national security.
- Regular, annual updates are required at the time of all SBIR/STTR annual, interim, and final Research Performance Progress Reports (RPPRs).
- For changes that occur between RPPR submissions, updated disclosure forms are required **within 30 days.**

Tips for Efficiently Managing Your SEED Award





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

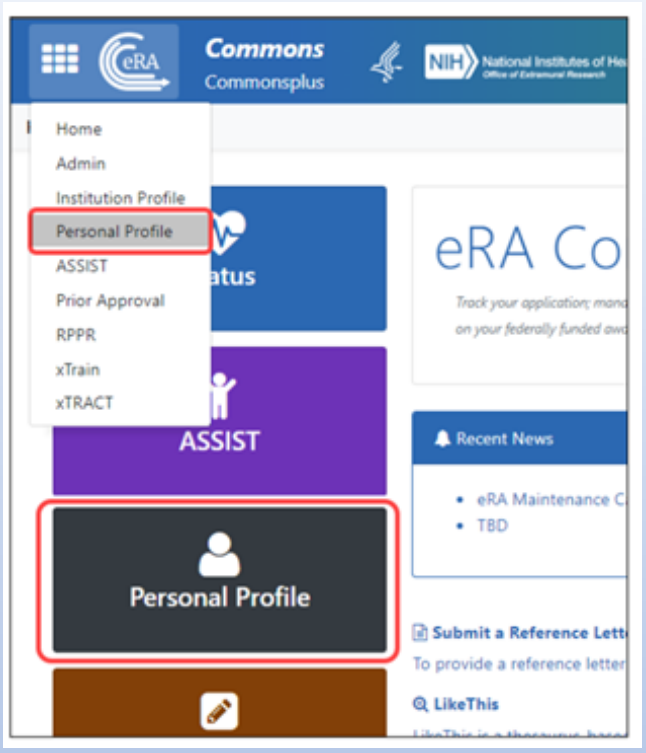
December 2024

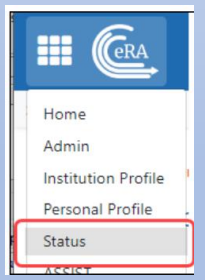
eRA Commons: Essential nexus for official grant updates.

eRA Commons account / website is essential to:

- **Download Summary Statement**
- **Upload Just in Time (JIT) information**
- **Verify HOM email address**
  - Should match email address on face page of an application.
  - The official definition is "PI Home Office Address."
  - NIH's automated business systems will use this for JIT and other requests.
  - Best practice: establish *.com address, (not *.edu).
- **Download Notice of Award (NoA)**
  - Emailed to the Institutional Profile.
  - Principal investigator (PI) and Signing Official (SO) can view NoA from the Status Information screen.

https://www.era.nih.gov/help-tutorials/era-commons/improved-visual.htm
https://www.era.nih.gov/erahelp/Commons/Commons/NavigationAndUI.htm
https://www.era.nih.gov/docs/Commons_UserGuide.pdf





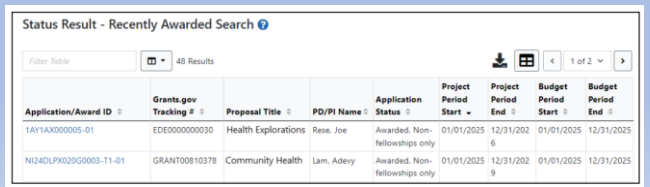


Figure 350: Status search results showing recently awarded Notices of Award

Download Notice of Award (NoA) from eRA

Award Number (11)

Principal Investigator (7)

Authorized Official (8)

Grants Management Officer (9)

Program Officer (10)

Email communications should:

- Sent from PI's HOM email.
- Subject line with grant number.

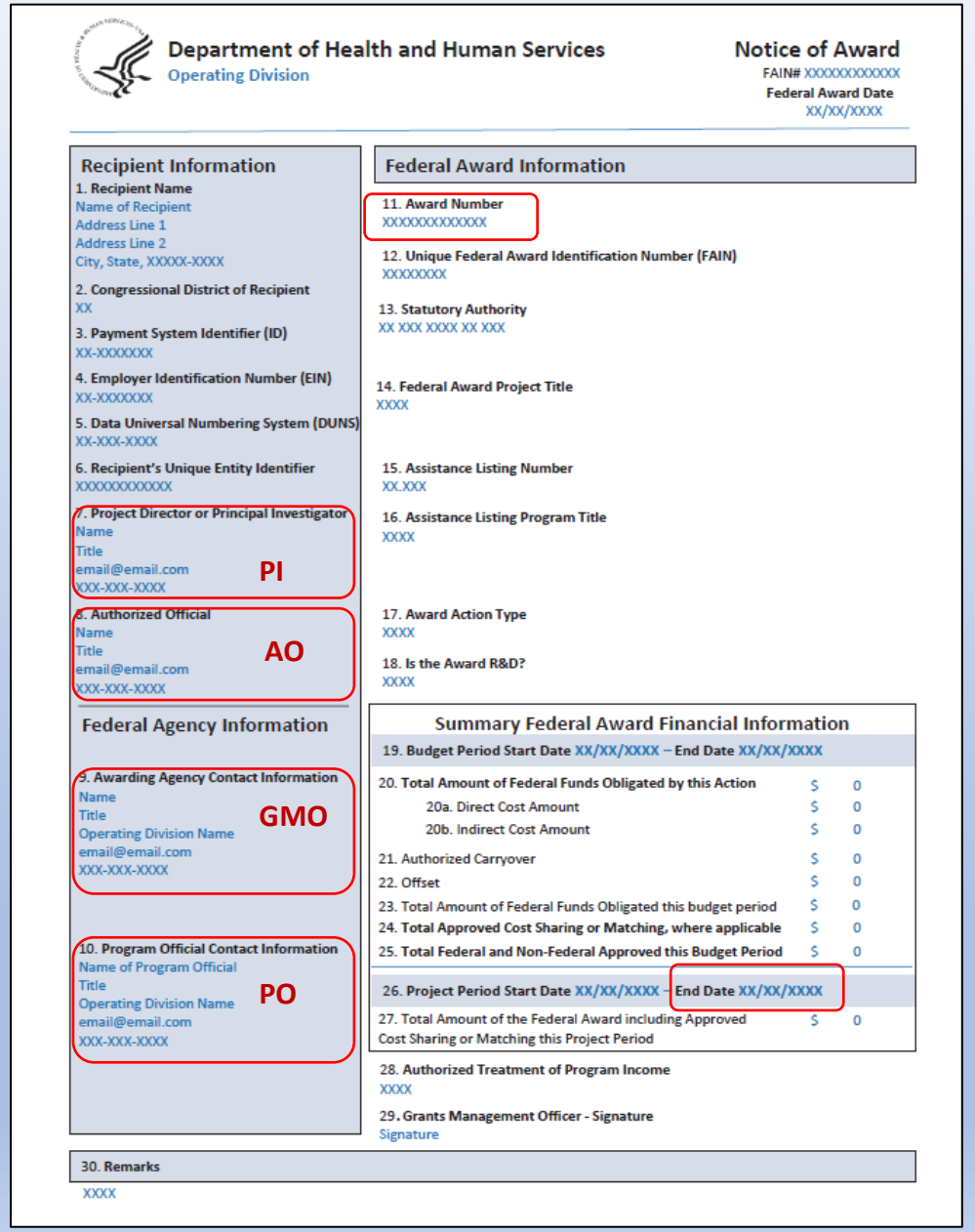
Official responses forwarded though AO

- Include both PO and GMS on official requests.
- Results will be uploaded into the official grant file.

End Date

- No Cost Extension (NCE) possible for up to 12 months
- Link available in eRA 90 days before end date.
- The F-RPPR and I-RPPR must be submitted via eRA Commons no later than 120 calendar days from the period of performance end date.

- www.era.nih.gov/recipients/submit-no-cost-ext.htm
- www.grants.nih.gov/grants/guide/notice-files/NOT-OD-11-098.html



Department of Health and Human Services
Operating Division

Notice of Award
FAIN# XXXXXXXXXXX
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-XXXXXXX

4. Employer Identification Number (EIN)
XX-XXXXXXX

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

6. Recipient's Unique Entity Identifier
XXXXXXXXXXX

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

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

Federal Agency Information

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

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

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

NoA Indicates Funding and Restrictions

Funding level

IC	CAN	2022	2023	2024	2025	2026
DC		$,	$.	$	$	$

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Reductions from requested costs will be reflected here.
Funds provided as grant in aid.
If funds are indicated for future years, Research Performance Progress Report will be needed.
Indirect cost rate will be indicated, and it may not be what was requested.

Award Conditions

Animal studies?

Was the award restricted?

Human studies?

Was the award restricted?

Clinical Trial?

Prepare to register at clinicaltrials.gov

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	○ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	○ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	○ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

The grantee or principal investigator must register the applicable clinical trial at clinicaltrials.gov no later than 21 days after enrolling the first subject. Registration consists of submitting four categories of data elements: (1) descriptive information, (2) recruitment information, (3) location and contact information, and (4) administrative information.

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Helping Innovators Turn Discovery Into Health

Research Performance Progress Reports (RPPR) Elements

Annual, Interim, and Final Research Performance

Progress reports document the grantee recipient's accomplishments
Show compliance with terms of award.
Must be submitted electronically through eRA Commons.

Submit via eRA 120 days before the end of the "period of performance."

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

Paste relevant section of specific aims from application, don't modify.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

Upload PDF about two pages in length.
Organize results by Aims / milestones; state no changes in aims.
Include photographs of prototype, circuit boards, software user interface.
Provide graphs with preliminary data acquired.
Describe challenges and efforts taken to overcome issues.
…Supply chain delays
…enrolment of humans subjects slower than anticipated
… expect to request a 12 month no cost extension

C.1 PUBLICATIONS

Provide MyNCBI Public Access Compliance Report.
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-079.html
https://www.nlm.nih.gov/pubs/techbull/jf10/jf10_issue.pdf
https://www.nlm.nih.gov/pubs/techbull/nd12/nd12_myncbi_pdf.html

Publications Reported for this Reporting Period

NIH Public Access Compliance	Citation
In process at NIHMS	Lee J, Sharei A, Sim WY, Adamo A, Langer R, Jensen KF, Bawendi MG. Nonendocytic Delivery of Functional Engineered Nanoparticles into the Cytoplasm of Live Cells Using a Novel, High-Throughput Microfluidic Device. Nano Lett. 2012 Nov 16;PubMed PMID: 23145796; NIHMSID: 421917.
Complete	Song JW, Daubriac J, Tse JM, Bazou D, Munn LL. RhoA mediates flow-induced endothelial sprouting in a 3-D tissue analogue of angiogenesis. Lab Chip. 2012 Oct 30;12(23):5000-6. PubMed PMID: 23073300; PubMed Central PMCID: PMC3490212.
In process at NIHMS	Wei H, Bruns OT, Chen O, Bawendi MG. Compact zwitterion-coated iron oxide nanoparticles for in vitro and in vivo imaging. Integr Biol

Human Subjects Enrollment Table

Is enrollment on track based on plans noted in the application?

https://grants.nih.gov/sites/default/files/rppr_instruction_guide.pdf
https://www.era.nih.gov/sites/default/files/RPPRs-Who-Does-What.pdf
https://www.era.nih.gov/recipients/submit-no-cost-ext.htm

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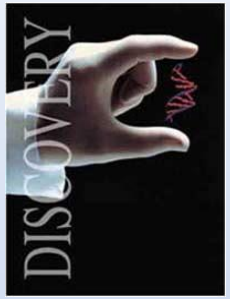
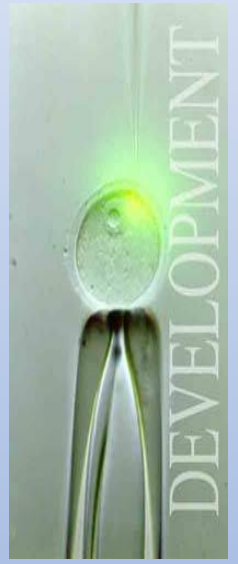
Program staff verify that funds are spent *within scope* of the peer-reviewed application



Phase I Award: Feasibility Study / Proof of Concept (POC)

- Total costs capped at $306,872 total costs.
- Project Period: 6 months - 1 year
  - Pilot data not required for Phase I application.
  - Proof of Concept data absolutely required for Phase II application.

Maintain focus on POC.



Phase II Award: Full Research & Development

- Total costs over two years capped at $2,045,816 total costs.
  - See budget wavier topics for each NIH IC.
- Project Period: varies, 2+ years.
- Product development ***complete*** at end of Phase II
  - IP Licensing strategy? Provide letters of support from potential licensee(s).
  - Direct vending/ customer support for novel product.
- Technical and Business Assistance (TABA)

Funds spent as described in application.

Phase III Commercialization

- Commercialization plan provided with application.
- Consider NIH SEED Innovator Consultation.
- Commercialization Readiness Pilot (CRP) can help.

Marketing costs are outside the scope of SEED funding.

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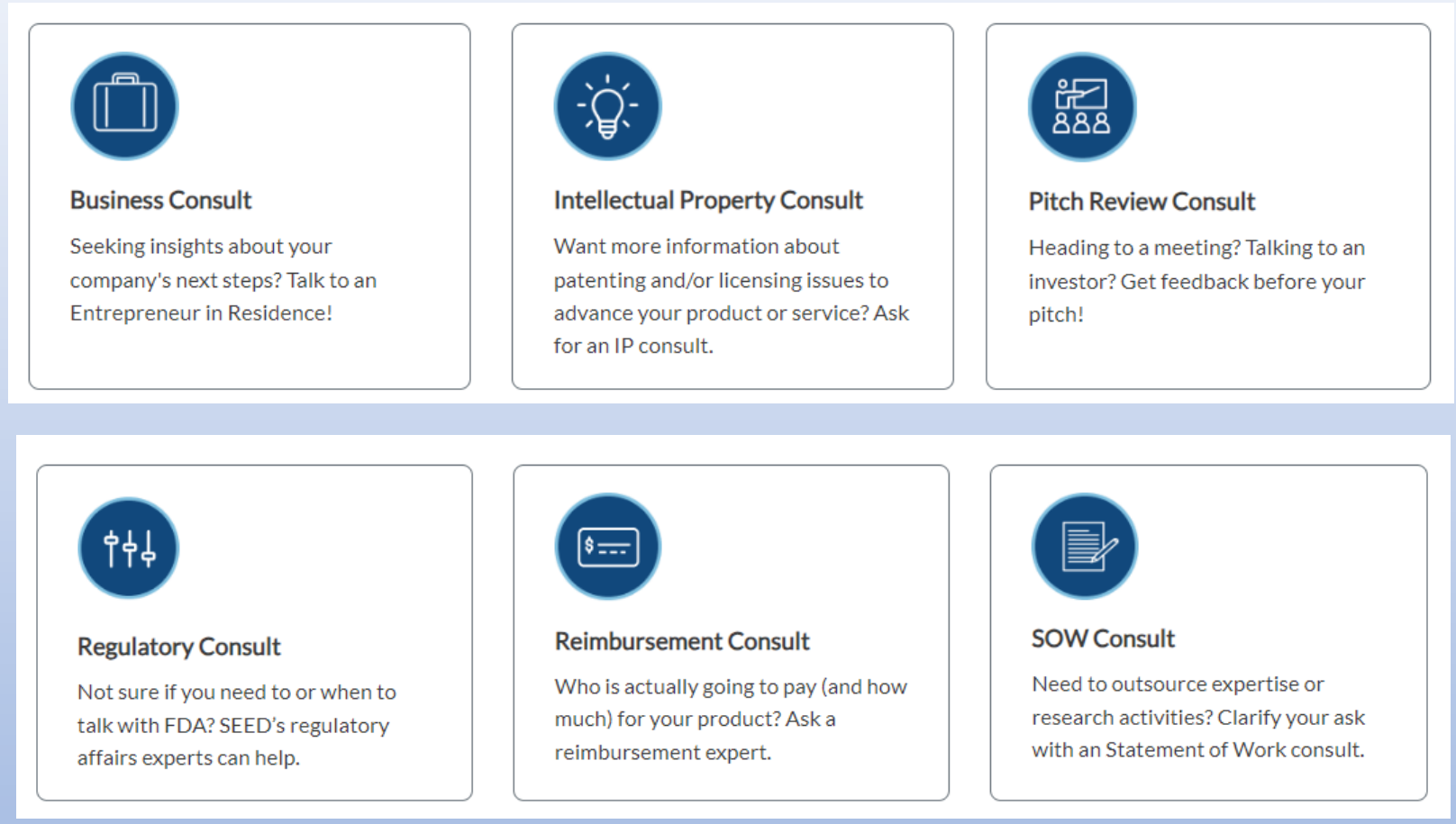
PI may request NIH SEED Innovator Consultation.



Request A 1-hour Consultation:

Understanding Reporter.NIH.gov and the Award Lifecycle

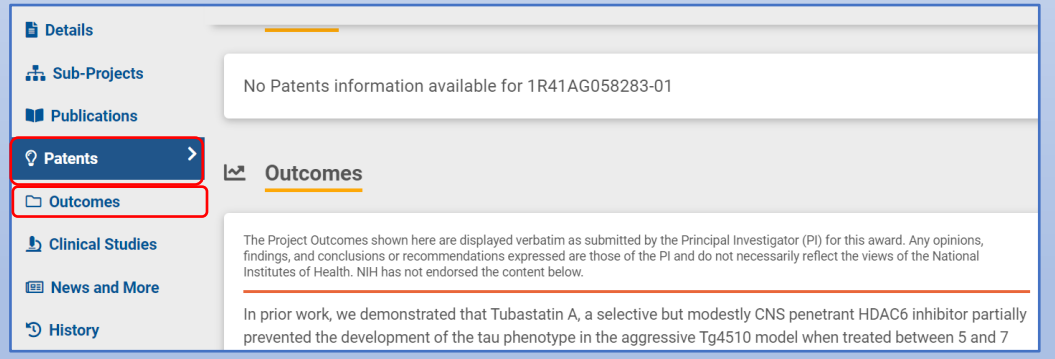
Description:

- **Entry will be copied verbatim from application's abstract.**

Publications:

"… all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication."

https://sharing.nih.gov/public-access-policy



Outcomes:

- **Entry will be copied verbatim from Final Research Progress Report (FRPPR)**
- **Use concise and comprehensible language.**
- **Avoid jargon; write for the general public.**
- **Do not include proprietary, confidential information, or trade secrets.**

www.niaid.nih.gov/grants-contracts/sample-applications#r43r44 Kozikowsky R41AG058283 (2017)
https://reporter.nih.gov/search/rRylhktDCU286W6Xt1BsRA/project-details/9463081

Working with NIH to Manage your SBIR/STTR Award

Kari Ashmont, PhD

Translational Team Lead | NIBIB

NIBIB-SBIR@mail.nih.gov

This presentation may include presenter's notes.

Be Informed!

Read your Notice of Award (NOA) Carefully

- What is the Notice of Award (NoA)?
  - Legal Document issued to notify the organization that an award has been made.
- Why is it important?
  - Budget/Project Periods
  - Funding Commitments
  - Terms and Conditions
  - GMS and Program Official (PO) Contact Information
  - Restrictions - funds cannot be spent on restricted items!
  - Closeout Information
- How does award acceptance occur?
  - Draw down or request of funds from the Payment Management System

Contact your Grants Management Specialist with questions or concerns!

Review the NIH Welcome Wagon Material and Grants Policy Statement

- Welcome Wagon summarizes key requirements, referrals to important sources of information, and identification of NIH and other Department of Health and Human Services (HHS) offices with responsibility for certain administrative functions
- NIHGPS collates the policy requirements that serve as a term and condition of NIH grant awards

Prior Approvals

Changes Requiring Prior Approval:

- Change in project scope
- Change in project budget
- Change in approved animal model
- Change in the level of effort of key personnel *listed on NoA*
- Change in recipient organizational status*
- See Grants Policy Statement 8.1.2 for additional items and information

Requesting Prior Approval:

- Prior Approval Module
  - Change in PD/PI
  - No Cost Extensions
  - Carryover requests
- Email requests
  - Sent 30 days before proposed change
  - All requests must come from the Authorized Organizational Representative (AOR) to the GMS with the PO copied

Unsure? Reach out to your PO and GMS!

* See additional information on next slide

Eligibility

- 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 and independently operated <OR>
  - >50% owned and controlled by other business concerns that are >50% 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 >50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Determined at the time of award- Applicants provide either an SBIR or STTR Funding Agreement Certification

Changes in Eligibility

- Legal action that changes the organizational status of a company
  - Merger
  - Acquisition
  - Successor-in-Interest
- Company can no longer receive additional funds from existing awards, including noncompeting continuation awards and supplements to award
- Company can no longer receive new awards
- NOT-OD-22-143

Lifecycle Certification

- What is Lifecycle Certification?
  - Attestation an awardee continues to meet program-specific requirements
    - PI employment status
    - Work requirement, etc.
- When is Lifecycle Certification Required?
  - Phase I: At the time of receiving final payment or disbursement
  - Phase II: Prior to receiving more than 50% of total award amount and prior to final payment or disbursement.
  - When the F-RPPR and I-RPPRs are due and submitted via eRA Commons
    - No later than 120 calendar days from the period of performance end date
    - SBIR/STTR recipients should not select the "Nothing to Report" box in Section G.1: Special Notice of Award and Funding Opportunity Announcement Reporting Requirements)
- NOT-OD-19-025

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

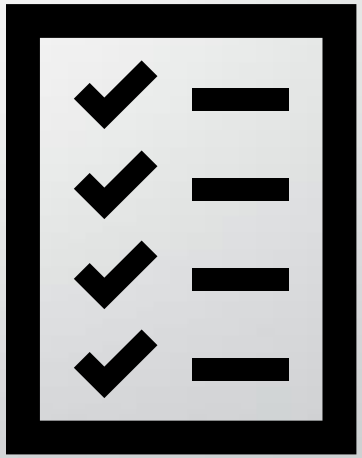
Contract and its clauses

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)

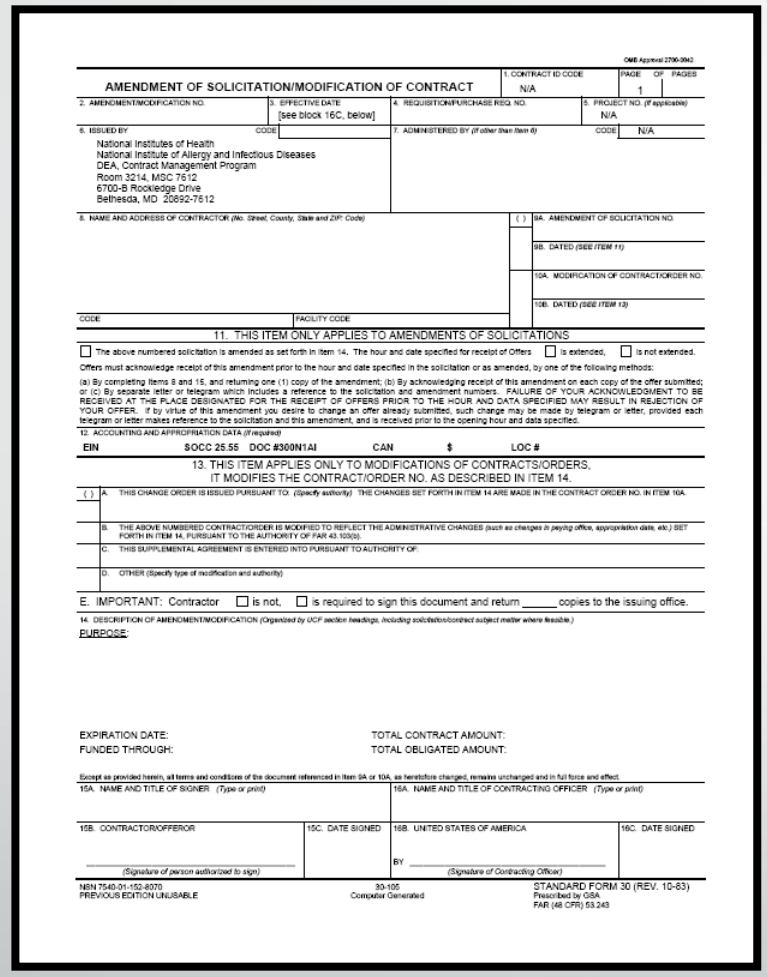
The CO is the only person with the authority to:

- 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: N/A | PAGE 1 OF PAGES

2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE: [see block 16C, below] | 4. REQUISITION/PURCHASE REQ. 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

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

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ 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 8 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 DATA 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 data specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

EIN | SOCC 25.55 | DOC #309N1AI | 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 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☐ 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:

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)

15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED

(Signature of person authorized to sign) | BY (Signature of Contracting Officer)

NSN 7540-01-152-8070 PREVIOUS EDITION UNUSABLE | 30-105 Computer Generated | STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

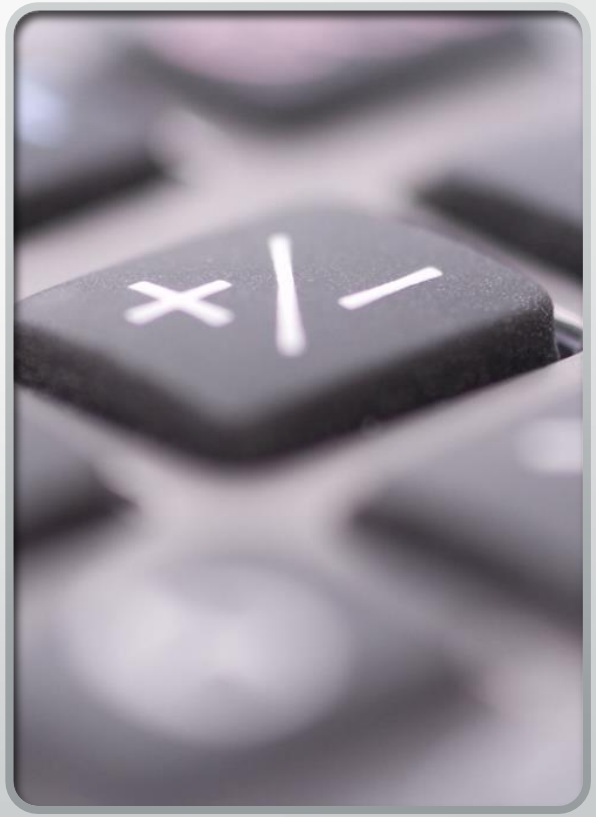
- Any changes in the terms or conditions of the Contract, including the Statement of Work, changes in Key Personnel, or delivery schedule must be accomplished by a written modification.
- The contractor should submit their formal requests in writing to the Contracting Officer for review. The Contracting 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.

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

Preventing Fraud Waste and Abuse in your SBIR/STTR Award

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

HHS-OIG Mission

- 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 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, in order 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
- 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

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oig.hhs.gov/fraud/hotline

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

Q&A Session

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