



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

Recommendation Followup: Vulnerabilities Continue To Exist in the HHS Small Business Innovation Research Program

OEI-04-18-00230

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oig.hhs.gov

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Recommendation Followup: Vulnerabilities Continue To Exist in the HHS Small Business Innovation Research Program

What **OIG** Found

The Office of Inspector General (OIG) continues to find vulnerabilities in the Department of Health and Human Services (HHS) Small Business Innovation Research (SBIR) program regarding awardee eligibility and duplicative funding, and **OIG** has concerns about the effectiveness of HHS's oversight. Specifically, HHS has taken minimal action to improve policies and procedures for ensuring awardee eligibility and has taken no action to improve policies and procedures for preventing duplicative funding. We also identified inconsistencies in SBIR policies and procedures among HHS Operating Divisions (OpDivs); these inconsistencies may indicate that the Office of the Assistant Secretary for Financial Resources is not fulfilling its responsibilities to coordinate compliance and ensure consistent implementation of SBIR requirements across HHS OpDivs.

Key Takeaway

HHS has taken minimal steps to strengthen program safeguards per **OIG** recommendations, which is allowing potentially ineligible awardees to receive funds and potentially duplicative funding to occur.

To better gauge the impact of these continued vulnerabilities, **OIG** conducted a risk assessment, and we identified 32 awardees (out of a total of 800 awardees that received funds in 2015 or 2016) as high risk. We conducted further analysis on this small sample of awardees and determined that over two-thirds of them (22 of the 32 awardees we found to be high risk) were potentially ineligible or potentially receiving duplicative funding. These 22 awardees have received over \$140 million in HHS SBIR funding. Because of the significance of the vulnerabilities we identified, **OIG** and HHS initiated investigations or audits of over half (13 of 22) of these awardees.

What **OIG** Concludes

The two outstanding **OIG** recommendations—regarding awardee eligibility and duplicative funding—remain unimplemented and HHS's SBIR program continues to have weaknesses in these two areas. To assist HHS in implementing these recommendations, we suggest a number of actions that the Department could take to address these weaknesses.

In response to this report, HHS stated that it considers both outstanding recommendations to be implemented because its policies and procedures are compliant with applicable requirements. However, meeting the minimum requirements does not fulfill **OIG**'s outstanding recommendations, nor does it appear that it sufficiently prevents fraud, waste, and abuse in the SBIR program.

Full report can be found at oig.hhs.gov/oei/reports/oei-04-18-00230.asp

Why **OIG** Did This Review

We conducted this review to determine whether HHS had addressed known vulnerabilities in its oversight of the SBIR program to ensure that program funds were being spent appropriately. In 2014, we reported vulnerabilities with HHS's SBIR program and made four recommendations to improve HHS's oversight. HHS implemented two recommendations from our 2014 report prior to this review. However, HHS had not formally notified **OIG** of any actions to implement the two outstanding recommendations—with which HHS had concurred—regarding awardee eligibility and duplicative funding.

Since implementation of the SBIR program in 1982, HHS has obligated or awarded nearly \$13 billion in awards to small businesses pursuing innovative research ideas.

How **OIG** Did This Review

To assess HHS's progress in implementing the two outstanding recommendations, we reviewed information from HHS regarding actions it had taken specific to these recommendations. Approximately 800 awardees received HHS SBIR funds in 2015 or 2016. Of these awardees, we identified 32 as high risk and conducted further analysis to determine potential vulnerabilities. To determine whether the two outstanding recommendations should be considered implemented, we weighed any improvements that HHS made to its policies, procedures, and/or practices against any concerns that we identified in the award files and the significance of those concerns.

TABLE OF CONTENTS

BACKGROUND	1
Methodology	4
<hr/>	
FINDING	
HHS has not implemented OIG recommendations to ensure SBIR awardee eligibility and prevent duplicative funding	6
<hr/>	
CONCLUSION	10
<hr/>	
AGENCY COMMENTS AND OIG RESPONSE	13
<hr/>	
APPENDIX: AGENCY COMMENTS	14
<hr/>	
ACKNOWLEDGMENTS	16

BACKGROUND

Objective

1. To assess whether the Department of Health and Human Services (HHS) addressed the unimplemented recommendations from a previous Office of Inspector General (OIG) report to ensure that awardees of Small Business Innovation Research (SBIR) program funds are eligible and to prevent duplicative funding.
2. To determine whether HHS funded SBIR awards for ineligible awardees or SBIR awards that were duplicative.

Rationale

Since implementation of the SBIR program in 1982, HHS has consistently funded one of the largest amounts of SBIR awards in the Federal government to small businesses pursuing innovative research ideas. The Small Business Administration (SBA), which aids small businesses and coordinates the SBIR program across the Federal government, considers SBIR awards to be high-risk funding.¹ HHS has obligated or awarded nearly \$13 billion in awards since the program began.²⁻³ In 2017 alone, HHS allocated approximately \$870 million in SBIR awards.⁴

In a 2014 OIG report, we raised concerns about vulnerabilities in the HHS SBIR program, including the inability to evaluate the program's success and the reliance on self-reported information to determine whether awardees were eligible and were not receiving duplicative funding from other Federal agencies.⁵ In May 2018, the SBIR awardee MassTech—which had been funded by multiple agencies, including HHS—agreed to a \$1.9 million settlement with the United States to resolve allegations that it had falsely stated its eligibility as a small business.⁶

OIG made four recommendations in the 2014 report. HHS implemented two of these recommendations—the ones for it to (1) create a central office to oversee the SBIR program and (2) collect information to track and assess the commercialization of SBIR-funded projects. The other two recommendations—still outstanding at the time we began this followup review—were for HHS to (1) ensure awardee compliance with SBIR eligibility requirements and (2) improve procedures to check for duplicative awards. HHS concurred with both recommendations, but it has not formally reported to OIG any action to implement them.

Federal SBIR Program

Created by the Small Business Innovation Development Act of 1982, the SBIR program is a competitive awards program that provides Federal funding to small businesses that pursue research for potential commercialization that meets the priorities of the Federal Government.^{7,8} Agencies housed within a Federal department and other independent Federal agencies (hereinafter referred to as “agencies”) must participate in

the SBIR program if they fund over \$100 million in extramural research and development.⁹ Currently, 11 agencies participate in the SBIR program.¹⁰

SBA maintains a public database with SBIR awardee information.¹¹ SBA also issues policy directives that contain requirements to guide Federal agencies' implementation of the SBIR program. SBA reviews agencies' progress and reports program results to Congress annually.¹²

HHS SBIR Participation

Within HHS, four operating divisions (OpDivs) participate in the SBIR program: the National Institutes of Health (NIH); the Centers for Disease Control and Prevention (CDC); the Food and Drug Administration (FDA); and the Administration for Community Living (ACL).¹³ NIH funds the vast majority of HHS SBIR awards.¹⁴ In 2017, NIH obligated approximately \$825 million in SBIR awards, while CDC, FDA, and ACL together obligated approximately \$40 million in total awards.¹⁵

Federal law establishes some requirements for the SBIR program but also allows agencies flexibility in managing their individual programs. In HHS, each OpDiv is responsible for overseeing its own awards, and since 2016, the Office of the Assistant Secretary for Financial Resources (ASFR) has been responsible for coordinating compliance and ensuring consistency in implementation of the OpDivs' SBIR programs. NIH also provides some coordination among the other OpDivs—for example, it solicits SBIR proposals on behalf of CDC and FDA.¹⁶ However, NIH does not oversee the other OpDivs' SBIR programs. OpDivs make their own funding decisions, and each must adhere to SBA's SBIR Policy Directives to ensure program integrity.

SBIR Requirements for Eligibility and Duplicative Funding

In the SBIR Policy Directive for agencies, two of the requirements related to preventing fraud, waste, and abuse pertain to ensuring awardee eligibility and preventing duplicative awards.¹⁷

Ensuring awardee eligibility

As a part of its oversight responsibilities, each agency must ensure that applicants comply with program eligibility requirements before they receive SBIR awards. Among other eligibility criteria, agencies must ensure that the applicant:

- has a principal investigator (the primary researcher who conducts and oversees the research project) who is primarily employed by the small business;¹⁸
- will perform the required amount of research or analytical effort (i.e., does not plan to subcontract a significant portion of the work);
- has 500 or fewer employees, including affiliates;
- maintains a place of business in the United States and operates primarily within the United States; and
- is organized as a for-profit entity.

At the time of our 2014 report, HHS OpDivs ensured that awardees were eligible by requiring them to certify that they intended to meet all eligibility requirements at the time of award. NIH also used a procedure to request additional self-reported information, as needed, from applicants before giving them funding.¹⁹ In addition, when agencies that grant SBIR awards identify an applicant that may not meet eligibility requirements at the time of the award, the agencies are required—and continue to be required—to file a request with SBA. SBA then assesses the applicant’s eligibility on all requirements.²⁰

In 2014, we reported concerns with the effectiveness of HHS procedures to ensure applicant eligibility. Using a stratified, projectable sample of nearly 1,000 SBIR awards funded across HHS OpDivs in 2011, we found that 31 percent of awardees appeared to have questionable or unverified eligibility for at least one requirement, according to independent research we conducted.²¹ All of these awardees had certified their eligibility to HHS at the time of award.

As a result, we recommended that HHS ensure awardee compliance with SBIR eligibility requirements.²² We suggested that to do this, HHS could:

1. implement a standardized process for verifying that a random sample or risk-based sample of awardees meet all eligibility requirements at the time of the award,
2. require applicants to provide proof that they will meet eligibility requirements at the time of the award, and
3. request SBA assistance to verify awardee eligibility.

Since OIG’s 2014 report, the SBIR Policy Directive has added new standards related to ensuring awardee eligibility:

- *Lifecycle certifications.* The SBIR Policy Directive now requires agencies to ensure awardee eligibility not just at the time of the award but also at various points throughout the lifecycle of the award.²³ This helps ensure that as the award progresses, the awardee’s status has not changed in a way that affects its eligibility to continue receiving SBIR funds (e.g., if the principal investigator had changed to someone who is not primarily employed by the awardee, or if the small business had been purchased by a large corporation). Increasingly, the Department of Justice is requiring lifecycle certifications before proceeding with criminal and civil prosecutions.
- *Fraud indicators.* The SBIR Policy Directive now directs agencies to “work with the agency’s OIG with regard to its efforts to establish fraud detection indicators.”²⁴ However, the requirement does not indicate that agencies must use or implement these fraud indicators in practice. Identifying a standard set of fraud indicators and assessing each applicant on those indicators may be a useful way to identify applicants or awardees that pose a high risk for fraud, waste,

or abuse. NIH worked with our office, as well as with CDC and FDA, to develop a list of indicators of possible fraud for SBIR applicants and awardees.²⁵ At the time that NIH developed this list, ACL was not funding SBIR awards, so NIH did not solicit ACL for input.

Ensuring that awards are not duplicative

Each participating agency must also develop policies and procedures to avoid funding SBIR work that is essentially equivalent (i.e., duplicative) to work funded by another agency or the same agency.²⁶ This includes projects funded with SBIR money or any other Federal funds.

At the time of our 2014 report, NIH stored data on HHS SBIR awardees and their projects on an internal HHS database that the other OpDivs could access. NIH also provided all HHS awardee data to SBIR.gov. NIH required applicants to disclose other active and pending financial support as part of its procedures to solicit additional self-reported information for grants. However, NIH did not require applicants to provide information on past awards, and it did not independently verify that applicants had disclosed all other active and pending financial support.

In 2014, OIG found that within HHS, only NIH checked for duplicative funding within HHS, and no OpDivs completed the required check for duplicative awards across all Federal agencies.²⁷ We therefore recommended that HHS improve procedures to check for duplicative awards. We specifically suggested that HHS develop procedures beyond NIH's practice of requiring awardees to self-report additional information. We also noted that the new procedures should be consistent across HHS OpDivs to ensure that all SBIR applicants receive the same scrutiny regarding duplicative awards.

Related Work

In 2017, the Government Accountability Office (GAO) found that NIH had implemented minimum requirements regarding ensuring awardee eligibility and preventing duplicative funding.²⁸ However, OIG believes that meeting the minimum requirements alone may not be enough to adequately protect this program. In addition, GAO identified activities that agencies conducted to prevent fraud, waste, and abuse in their respective SBIR programs.²⁹ These included conducting in-person or virtual site visits of SBIR awardees; establishing offices or working groups within the agency specific to preventing fraud, waste, and abuse; holding orientation meetings with awardees to discuss rules and requirements; and requiring more certifications and reporting of awardee information than what is required in the policy directive. GAO did not identify HHS as conducting any of these additional activities.

Methodology

We reviewed the progress that HHS has made regarding the two outstanding recommendations from our 2014 report. We collected information from HHS to assess its current policies, procedures, and practices to ensure that awardees are eligible and that awards are not

duplicative. We determined the extent to which these policies, procedures, and/or practices address the vulnerabilities identified in the 2014 report and whether we should consider the two recommendations to be implemented.

To obtain HHS's policies and procedures, we requested from each OpDiv documentation of all actions it had taken since 2014 (e.g., formal, informal, or draft policy and procedure documents, emails, training materials) to ensure compliance with SBIR eligibility requirements and to check for duplicative awards. We also requested documentation regarding ASFR's monitoring and oversight of HHS OpDivs regarding checks to ensure eligibility and prevent duplicative funding.

To assess HHS practices, we reviewed a sample of 32 SBIR awardees that we identified as high risk. To do this, in June 2016, we downloaded from the publicly available database at SBIR.gov the population of SBIR awards that HHS funded during award years 2015 or 2016. This population consisted of 1,074 awards for approximately 800 awardees, and these awards were for various lengths spanning 2014 through 2019. We determined whether each award in this population demonstrated certain fraud indicators (e.g., the company address in the SBIR.gov data appeared to be a residential address). We conducted additional Internet research on the resulting 92 awards—representing 70 awardees—to identify any initial concerns with eligibility and/or duplicative funding.³⁰ From the results of our Internet research, we identified 32 awardees in our sample as high risk. We then obtained and reviewed the HHS award files for these awardees to identify potential concerns regarding eligibility or duplicative funding. For any concerns that we identified, we coordinated with other OIG components and with HHS—primarily, NIH's Office of Management Assessment—to determine whether the vulnerabilities warranted opening audits or investigations.

To determine whether the two remaining recommendations should be considered implemented, we weighed any improvements that HHS made to its policies, procedures, and/or practices against any concerns we identified in the award files and the significance of those concerns.

Limitations

We did not independently verify the completeness of the award files we received from HHS. However, if we suspected that documentation was missing, we followed up and requested those documents. For example, we requested correspondence between HHS and awardees for all awardees in our sample. For some awardees, we did not receive any correspondence from HHS, so we followed up and requested it again. In some cases, we received this additional documentation.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

HHS has not implemented OIG recommendations to ensure SBIR awardee eligibility and prevent duplicative funding

Since our 2014 report, HHS has taken only limited action to address the vulnerabilities we identified regarding awardee eligibility and duplicative funding. Specifically, HHS OpDivs have taken minimal action to improve policies and procedures for ensuring awardee eligibility, and they have taken no action to improve policies and procedures for preventing duplicative funding. Further, OpDivs' current practices in both of these areas are not effective, as we identified a total of 22 awardees that appeared to be ineligible and/or to be receiving duplicative funding. (All 22 awardees appeared ineligible, and 1 of the 22 also appeared to be receiving duplicative funding.) We also identified inconsistencies among OpDivs in their SBIR policies and procedures, which indicates that ASFR is not fulfilling its responsibilities to coordinate compliance and ensure consistency in implementation of the OpDivs' SBIR programs.

HHS allowed potentially ineligible awardees to receive SBIR funds

In response to our 2014 recommendation for HHS to ensure that awardees comply with SBIR eligibility requirements, HHS has taken limited action. For example, some of the HHS OpDivs have conducted limited trainings and established checklists for staff to use when making eligibility determinations. However, these checklists vary across the OpDivs, and when we reviewed award files, we did not see consistent use of these checklists in practice. Further, although ASFR provided a document that outlined its coordination and oversight responsibilities, ASFR did not provide any documentation or other evidence demonstrating actions that it has taken to implement this policy (e.g., efforts it has taken to coordinate compliance and ensure consistency in oversight of awardee eligibility across the OpDivs).

Further, HHS has not taken other actions we recommended in 2014 that could help ensure awardees comply with eligibility requirements. Specifically, HHS has not implemented a standardized process for verifying that a random sample or risk-based sample of awardees meet all eligibility requirements at the time of the award, nor has HHS required applicants to provide proof that they will meet eligibility requirements at the time of the award. Although HHS must request SBA assistance when an applicant does not appear to meet eligibility requirements, NIH explained to us that it does this only on a case-by-case basis.³¹ Further, HHS has requested SBA assistance for only four applicants since 2014. Since our 2014 report, the share of such requests out of the total number of awards that HHS has funded has actually decreased. See Exhibit 1.

Exhibit 1: Since 2014, HHS has decreased the percentage of SBIR awardees for which it has sought SBA eligibility determinations



Source: OIG analysis in 2018 of SBIR.gov and HHS's documentation of SBA eligibility checks in 2011 and 2014-2018.

* The 2014 report used data for awards funded in 2011.

** The 2019 report uses data for awards funded between 2014 and 2018.

HHS has made limited progress in addressing the new requirements that the SBIR Policy Directive added regarding awardee eligibility. The actions that HHS took in these areas were in addition to our recommendations from 2014, as the SBIR Policy Directive's new requirements went into effect after the time period of our 2014 review.

- Lifecycle certifications. As of 2018, NIH's practice was to require awardees to complete lifecycle certifications and keep them on file at the awardee's location; NIH did not collect the certifications from awardees.³² Effective January 2019, NIH, CDC, and FDA are requiring awardees to submit lifecycle certifications to the respective OpDiv funding the award.³³ However, the revised policy does not indicate whether OpDiv staff will review and independently research the information on these certifications to ensure that awardees continue to be eligible.³⁴ The policy also does not indicate whether or how followup will occur if there are eligibility concerns. In addition, the new 2019 procedures do not include ACL. Currently, ACL requires awardees to complete the lifecycle certifications and keep them on file at the awardee's location. ACL requests that the awardee email or upload the lifecycle certification to the project officer, but it does not require them to do so.
- Fraud indicators. NIH distributed to CDC, FDA, and ACL the list of SBIR fraud indicators that NIH had developed in collaboration with OIG. However, neither the OpDivs nor ASFR has provided guidance to staff on how to use this list of fraud indicators (e.g., what sources to use to determine whether the fraud indicators are present for

an awardee, what action to take if any fraud indicators are identified). Further, we did not see any consistent evidence in the award files that OpDiv staff consulted the list of fraud indicators while reviewing award files—we did not find completed checklists or other notes to show that staff found the same fraud indicators that we found in our examination of award files.

Despite the actions that HHS has taken, we continue to identify potentially ineligible awardees that received HHS SBIR funds. Of the 32 awardees we identified as high risk, 22 awardees appeared to not meet at least 1 SBIR eligibility requirement. The specific eligibility concerns we identified among these 22 awardees are:

- 15 awardees had principal investigators who appeared to be primarily employed by a company other than the SBIR awardee;
- 4 awardees appeared not to be performing the required amount of research or analytical effort themselves (i.e., the awardees planned to subcontract a significant portion of the work);
- 4 awardees (including affiliates) appeared to be employing more than 500 individuals;
- 2 awardees appeared to be operating primarily outside the United States; and
- 0 awardees appeared to be nonprofit entities; however, 3 awardees appeared to be relying significantly on resources from nonprofit entities.

These 22 awardees have received over \$140 million in HHS SBIR funding.³⁵ Partly because of the significance of the eligibility concerns we identified, OIG and HHS initiated investigations or audits of 13 of these awardees.

HHS may have funded SBIR awards that were duplicative of other awards

HHS has not taken action in response to our recommendation to improve policies and procedures to ensure HHS does not fund duplicative awards. Specifically, since 2014, none of the OpDivs has provided evidence that it has improved policies or procedures to check for duplicative awards across all Federal agencies.

- NIH did not provide any documentation to demonstrate that it had made any improvements to its policies or procedures. Further, we did not see evidence in grant files that NIH had made improvements. That is, NIH did not document in any files we reviewed that it had independently verified awardees' self-reported information or whether applicants disclosed all other active and pending financial support.

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- CDC provided documentation that demonstrated potential improvements to its policies and procedures. However, this documentation appeared to have been created in response to our data request and did not appear to be formal CDC policy. We did not review CDC grant files to determine the extent to which this document reflects actual CDC practice.
 - FDA stated that it now adheres to NIH's policies and procedures; however, it did not provide evidence of these improvements, and we did not review FDA grant files to determine if any improvements had been made.
 - We did not include ACL in our 2014 report, and we therefore cannot determine whether it has improved its policies since that time. ACL has stated that it adheres to NIH's policies and procedures, but we did not see evidence of it in the grant files we reviewed.

Further illustrating the insufficiency of these actions in accomplishing effective oversight, the current methods allowed at least one potentially duplicative award in our review. This awardee also had at least one eligibility concern that we identified. The awardee received over \$1.6 million in HHS SBIR funding since 2010, as well as funding from other Federal agencies. Partly as a result of concerns about the potentially duplicative funding we identified, multiple Federal agencies, including HHS OIG, have initiated an investigation of this awardee.

CONCLUSION

The SBIR program provides high-risk funding to startups and small businesses, and the program has specific eligibility requirements. Therefore, it is crucial that HHS ensure consistent and effective oversight of the program. In 2014, we identified several vulnerabilities within the program and recommended that HHS implement actions to address these concerns. However, HHS has taken limited action since 2014 regarding these vulnerabilities, and we continue to have concerns about HHS's oversight of the SBIR program. Specifically, our two recommendations that were outstanding at the time we began this review remain unimplemented:

- HHS should ensure awardee compliance with SBIR eligibility requirements.
- HHS should improve procedures to check for duplicative awards.

Although GAO found in 2017 that NIH is meeting the minimum requirements regarding checking eligibility and duplicative funding, our findings indicate that meeting the minimum requirements alone does not adequately protect the SBIR program. Furthermore, because HHS funds one of the largest SBIR programs in the Federal government, the Department should be at the forefront of efforts to prevent fraud, waste, and abuse in the program. However, HHS's oversight is lacking compared to that of other agencies whose activities GAO described.

We continue to advise HHS that to implement both of our unimplemented recommendations, it should take the four actions we listed in our 2014 report. In this 2019 report, we provide further clarification regarding those actions. (Additionally, we will be sending separately to HHS a list of all the awardees that are not being investigated by OIG, so that HHS can address the vulnerabilities identified in this report.) Specifically, we suggest that OpDivs do the following to implement OIG's two outstanding recommendations:

- Implement a standardized process for verifying that a random sample or risk-based sample of awardees meet all eligibility requirements at the time of the award and during the lifecycle of the award.

To do this, each OpDiv could conduct a risk assessment of each awardee both pre-award and at various points throughout the lifecycle of the awards. We reviewed the award files for a small percentage of HHS SBIR awardees in 2015 or 2016. This review demonstrates the effectiveness of this type of risk assessment, as over two-thirds of the awardees (22 of 32 awardees) that we identified as high risk were ones that we later determined

to be potentially ineligible or potentially receiving duplicative awards. These 22 awardees have received over \$140 million in HHS SBIR funding. Further, OIG and HHS initiated investigations or audits of over half of these awardees (13 of 22 awardees).

As a part of the risk assessment, OpDivs could conduct independent research on the applicants and awardees beyond the information that awardees self-report. In addition, the OpDivs could collect proof of applicant and awardee eligibility both at the time of the award and throughout the lifecycle of the award. For example, OpDiv staff could conduct in-person or virtual site visits for applicants or awardees that have reported what the OpDiv deems to be questionable information as to the location where the awardee will perform the work. That is, these site visits could help ensure that the awardees have sufficient space to do the research described in the application, that the location matches the location listed in the application, and that the awardee has access to the space listed in the application.

In addition, in light of new SBIR Policy Directive requirements since 2014, OpDivs could use—at a minimum—the fraud indicators and lifecycle certifications when conducting the risk assessments. Because the fraud indicators are relevant to both of our recommendations, this risk assessment could both evaluate an awardee's eligibility and identify any potential duplicative funding. ASFR could also standardize the risk assessments across and within OpDivs so that each awardee is assessed fairly and consistently within HHS. In developing the risk assessments, HHS will need to define "high risk." In creating this definition, HHS may wish to consider factors such as the dollar amounts of an awardee's current award and overall awards and any previous performance problems. As an interim measure—until HHS establishes these definitions and a process for identifying high-risk awardees in a standardized manner—each OpDiv could independently verify that a random sample of its SBIR awardees meet all eligibility requirements at the time of the award and during the lifecycle of the award.

- Request SBA assistance to verify awardee eligibility.

The OpDivs may wish to do this only for applicants or awardees that it identifies as "high risk."

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- Develop procedures—beyond collecting only self-reported information—to check for duplicative funding immediately before funding awards.

OpDivs could proactively search award sites—both internal HHS award sites and external Federal award sites—to determine the extent to which awards are duplicative within HHS, across Federal agencies, and over time. These searches could reveal potential duplicative funding that awardees failed to self-report.

In 2014, we recommended that HHS create a central office to oversee the SBIR program and facilitate the consistent implementation of our remaining recommendations. Though HHS implemented this recommendation by allocating to ASFR the responsibility for compliance, oversight and consistency across HHS’s SBIR program, we continue to see and be concerned by inconsistencies that we identified across HHS OpDivs. We believe that in its new role coordinating OpDivs, ASFR could continue to address these concerns by taking a larger coordinating role in both implementing these recommendations and ensuring consistency across OpDivs. For example—once ASFR has taken the suggested actions to address these unimplemented recommendations—ASFR may want to ensure that HHS OpDivs conduct training for all staff who review SBIR awards on the new procedures, and that they do so at regular intervals (e.g., upon initial employment and annually thereafter). Additionally, ASFR may also want to ensure that the OpDivs monitor that these new procedures are being consistently used in practice and are being documented in all awardee grant files.

AGENCY COMMENTS AND OIG RESPONSE

HHS considers the two outstanding recommendations from the 2014 OIG report to be fully implemented. HHS reiterates its belief that its policies and procedures for ensuring SBIR awardee eligibility and identifying duplicative funding are fully compliant with all applicable requirements. HHS also points to the 2017 GAO report that found NIH to have met all minimum requirements regarding ensuring awardee eligibility and preventing duplicative funding.

HHS states that furthermore, it is constantly working to maintain successful implementation of, compliance with, and oversight of the program. It states that it will continue efforts to ensure compliance, oversight, and consistency across OpDivs to strengthen the SBIR program. For example, HHS is considering leveraging technology resources that may provide greater support in ensuring compliance throughout the SBIR award life cycle.

OIG continues to consider both of the recommendations from our 2014 report to be unimplemented because HHS has not taken sufficient action to address the vulnerabilities we identified. HHS has not implemented a standardized process for verifying that a random sample or risk-based sample of awardees meet all eligibility requirements, as recommended by OIG. HHS also has not developed procedures to check for duplicative funding beyond collecting self-reported information from applicants regarding current awards, pending awards, and past awards.

Meeting the minimum requirements does not fulfil OIG's outstanding recommendations, nor does it appear to be sufficiently preventing fraud, waste, and abuse in the SBIR program. Despite the actions that HHS has taken, OIG identified 22 awardees that were potentially ineligible or potentially receiving duplicative awards.

For the full text of ASFR's comments, see the Appendix.

APPENDIX: Agency Comments



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary
Washington, DC 20201

FEB 15 2019

Ms. Suzanne Murrin
Deputy Inspector General for Evaluations and Inspections
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Murrin:

The Department of Health and Human Services' (HHS) appreciates the opportunity to review and respond to the Office of Inspector General's (OIG) draft report entitled, "Recommendation Follow-up: Vulnerabilities Continue to Exist in the HHS Small Business Innovation Research Program" (OEI-04-18-00230).

HHS values the Small Business Innovation Research Program (SBIR) and is constantly working to maintain successful implementation of, compliance with, and oversight of the program. As described in the draft report, the National Institutes of Health (NIH) awards the majority of the HHS SBIR awards while three Operating Divisions (OPDIVs) award minimal funding.

In response to a prior OIG report recommendation ("Vulnerabilities in the HHS Small Business Innovation Research Program" (OEI-04-11-0530)), HHS created a central office to ensure compliance, oversight, and consistency across OPDIVs for the SBIR program. We will continue these efforts to strengthen the SBIR program as well as review our internal policies and procedures for further improvements to identify and fix any potential fraud, waste, and abuse with SBIR. For example, HHS is considering leveraging current technology resources that may provide greater support in ensuring compliance throughout the SBIR award life cycle.

HHS has stated in our prior responses, and reiterates here that our policies and processes for SBIR eligibility and duplication checks fully comply with all applicable SBIR, NIH, and HHS Laws and Regulations. A 2017 Government Accountability Office (GAO) study, "Small Business Research Programs: Additional Actions Needed to Implement Fraud, Waste, and Abuse Prevention Requirements" (GAO-17-337), found that minimum requirements are being met to protect the program at HHS. OIG and GAO have acknowledged HHS' SBIR eligibility and duplication checks are in full compliance with applicable laws and regulations and stated this determination in this and other reports. Therefore, HHS considers these two OIG recommendations to be fully implemented.

OIG Recommendation 1:

HHS should ensure awardee compliance with SBIR eligibility requirements.

HHS Response:

HHS follows all applicable SBIR, NIH, and HHS Laws and Regulations for eligibility checks using our application, pre-award, Funding Certification and Life Cycle certification processes. Per Small Business Administration (SBA) requirements and legislation, eligibility is determined at time of award. HHS currently checks eligibility of applicants that OPDIVs intends to fund in the pre-award negotiation stages. If such an applicant is found ineligible prior to award, the award is not made. If an awardee becomes ineligible after award, the award may continue at the scientific discretion of the program official, including for any non-competing awards. This flexibility is provided by SBA. If HHS determines that fraudulent information lead to an OPDIV award, then the agency will take appropriate actions that adhere to compliance procedures for award fraud and abuse.

OIG Recommendation 2:

HHS should improve procedures to check for duplicative awards.

HHS Response:

HHS has robust procedures for duplicate awards checks that comply with all applicable SBIR, NIH, and HHS Laws and Regulations. HHS checks and has access to current, pending, and past award information from applicants. For example, NIH has extensive policies, procedures (including Other Support, checklists and Just in Time procedures) and guidance in place geared toward the extramural community and NIH staff that are designated to monitor and manage potential scientific, budgetary, and commitment overlap in funding.

Sincerely,



Andrea Brandon (Feb 14, 2019)

Andrea Brandon
Deputy Assistant Secretary for the Office of Grants
and Acquisition Policy and Accountability

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¹ SBA, *SBIR/STTR Program Basics*, Course 1, Tutorial 1. Accessed at <https://www.sbir.gov/tutorials/program-basics/tutorial-1> on March 15, 2019.

² OIG analysis of SBIR.gov Dashboard data from 1982 through 2017.

³ Since HHS's SBIR program funds both grants and contracts, we use the term "awards" to refer to grants or contracts.

⁴ NIH, *Overview of the HHS SBIR/STTR Program*, Presentation at the 19th Annual NIH SBIR/STTR Conference, November 7-9, 2017. Accessed at https://ctsi.mcw.edu/images/2_Matthew-Portnoy_NIH-Annual-Overview.pdf on April 2018.

⁵ OIG, *Vulnerabilities in the HHS Small Business Innovation Research Program*, OEI-04-11-00530, April 2014. Accessed at <https://oig.hhs.gov/oei/reports/oei-04-11-00530.pdf> on October 10, 2018.

⁶ U.S. Department of Justice, *Masstech, Richard Lee, and Arnold Lee to Pay U.S. \$1.9 Million to Settle False Claims Act Allegations Relating to Small Business Innovation Research Awards*, May 2018. Accessed at <https://www.justice.gov/usao-md/pr/masstech-richard-lee-and-arnold-lee-pay-us-19-million-settle-false-claims-act-allegations> on May 9, 2018.

⁷ The Small Business Technology Transfer (STTR) program is modeled after the SBIR program and was created by the Small Business Technology Transfer Act of 1992. Though the STTR program is similar in concept to SBIR, we did not include STTR in our review. SBA, *About SBIR and STTR*. Accessed at: <https://www.sbir.gov/about> on April 23, 2018.

⁸ SBA, *SBIR/STTR Program Basics*, Course 1, Tutorial 1. Accessed at <https://www.sbir.gov/tutorials/program-basics/tutorial-1> on May 8, 2018.

⁹ Ibid.

¹⁰ The 11 agencies that participate in the SBIR program are the Department of Agriculture, the Department of Commerce, the Department of Defense, the Department of Education, the Department of Energy, HHS, the Department of Homeland Security, the Department of Transportation, the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation.

¹¹ SBA, *SBIR 2014 Policy Directive*, p. 4. Accessed at: https://sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf on April 10, 2018.

¹² Ibid, p. 42.

¹³ The Administration for Children and Families (ACF) previously met the threshold to have an SBIR program and was included in our 2014 report. However, since 2016, ACF's extramural research and development budget has not exceeded \$100 million, so it does not currently fund SBIR awards. In addition, we did not include ACL in our 2014 report because it was not funding SBIR awards at that time.

¹⁴ In 2017, NIH funded approximately 95 percent of HHS's SBIR awards.

¹⁵ OIG analysis of SBIR.gov Dashboard data from 2017.

¹⁶ NIH, *SBIR/STTR Funding—2018 Solicitations*. Accessed at: <https://sbir.nih.gov/funding> on April 12, 2018.

¹⁷ SBA, *SBIR 2014 Policy Directive*, p. 30. SBA includes 10 minimum requirements on which agencies must take action in order to prevent fraud, waste, and abuse in their respective SBIR programs.

¹⁸ To be considered "primarily employed" by a company, the principal investigator must spend more than half of his or her time in the employ of the company at the time of the award and during the proposed project. Occasionally, deviation from this requirement may occur; such deviation must be approved in writing. SBA, *SBIR 2014 Policy Directive*, p. 15.

¹⁹ NIH, *Grants Policy Statement—October 2010*, pp. 154-155. Accessed at: https://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on January 17, 2019.

²⁰ SBA, *SBIR 2014 Policy Directive*, p. 50.

²¹ The number of awards that CDC and FDA granted in 2011 was small in comparison to that of NIH, so our review included all awards from CDC and FDA. Further, ACF did not fund any awards during our period of review. OIG, *Vulnerabilities in the HHS Small Business Innovation Research Program*, OEI-04-11-00530, April 2014.

²² OIG, *Vulnerabilities in the HHS Small Business Innovation Research Program*, OEI-04-11-00530, April 2014.

²³ SBA, *SBIR 2014 Policy Directive*, p. 30.

²⁴ Ibid.

²⁵ A list of pre-award fraud indicators can be found on the NIH website. NIH, Office of Management, *Fraud Indicators*. Accessed at <https://oma.od.nih.gov/DPI/Pages/Fraud-Indicators.aspx> on December 21, 2017.

²⁶ SBA, *SBIR 2014 Policy Directive*, p. 30.

²⁷ OIG, *Vulnerabilities in the HHS Small Business Innovation Research Program*, OEI-04-11-00530, April 2014.

²⁸ GAO, *Small Business Research Programs: Additional Actions Needed to Implement Fraud, Waste, and Abuse Prevention Requirements*, GAO-17-337, April 2017.

²⁹ Ibid.

³⁰ If an awardee has accurately disclosed a residential address, the awardee may use that address as a place of performance to carry out the work of SBIR award without violating SBIR requirements. However, the use of a residential address is still considered an HHS SBIR fraud indicator.

³¹ National Institutes of Health, *NIH Grants Policy Statement*, November 2016, p. 360.

³² GAO, *Small Business Research Programs: Additional Actions Needed to Implement Fraud, Waste, and Abuse Prevention Requirements*, GAO-17-337, April 2017.

³³ These changes were in response to a GAO recommendation. GAO closed this recommendation as having been implemented. NIH, *Revised Process for SBIR/STTR Life Cycle Certifications*, October 29, 2018. Accessed at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-025.html> on November 11, 2018.

³⁴ NIH stated that it provides additional guidance to staff on the review of lifecycle certifications; however, NIH did not provide documentation of this guidance. Further, NIH did not state what staff should do if they identify eligibility concerns during the review of lifecycle certifications, and NIH did not provide any documentation that offered such guidance.

³⁵ One of these awardees has been receiving HHS SBIR awards since 1985.