

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**VULNERABILITIES IN THE
HHS SMALL BUSINESS
INNOVATION RESEARCH
PROGRAM**



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EXECUTIVE SUMMARY: VULNERABILITIES IN THE HHS SMALL BUSINESS INNOVATION RESEARCH PROGRAM, OEI-04-11-00530

WHY WE DID THIS STUDY

The Small Business Innovation Research (SBIR) program awards funds to small businesses to pursue innovative research and development ideas that have potential for commercial and that meet research and development needs of the Federal Government. Since the implementation of the SBIR program in 1982, the Department of Health and Human Services (HHS) has funded more than \$8 billion in awards to small businesses that self-certify that they meet program requirements. However, unlike most other SBIR awarding agencies, HHS does not have a single office responsible for overseeing its SBIR program. In 1999, the Office of Inspector General reported that HHS had not evaluated the success of the program. Further, other Federal agencies have identified fraud in their respective SBIR programs, including awardees that falsely certify eligibility and receive duplicative funding from multiple agencies.

HOW WE DID THIS STUDY

We reviewed fiscal year 2011 data from the four HHS Operating Divisions (OpDivs) that participate in the SBIR program to determine the extent to which they ensured that awardees were eligible and that awards were meeting program guidelines and goals. We also verified awardees' eligibility using data sources commonly used by other Federal agencies to identify potentially ineligible awardees.

WHAT WE FOUND

HHS awarded \$360 million in SBIR funds to nearly 1,000 awardees in 2011 and had the highest average SBIR award amount of any participating agency. Although it was not required to do so, HHS did not consistently collect information on or assess the commercial success of SBIR awards and therefore cannot determine whether the program is meeting one of its primary goals. Although all awardees self-certified that they intended to meet SBIR eligibility requirements, we found that 31 percent of awardees had questionable or unverified eligibility for at least one requirement. Although they are not required to do so, HHS OpDivs did not take any steps to independently verify that these awardees met eligibility requirements. Furthermore, although one OpDiv checked for duplicative funding within HHS, none of the four OpDivs completed a required check for duplicative awards across other Federal agencies.

WHAT WE RECOMMEND

Our findings raise concerns about vulnerabilities in the SBIR program. To address these vulnerabilities, HHS should create a central office to oversee the SBIR program. HHS OpDivs should track and assess the commercial success of SBIR projects, ensure compliance with eligibility requirements, and improve procedures to check for duplicative awards. The Office of the Assistant Secretary for Financial Resources (ASFR) did not indicate whether it concurred with each of our recommendations. However, ASFR concurred that additional coordination and oversight across participating OpDivs is warranted and agreed that HHS must ensure that applicants meet SBIR eligibility requirements.

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OBJECTIVES

1. To describe the Department of Health and Human Services (HHS) Operating Divisions' (OpDivs) expenditures on the Small Business Innovation Research (SBIR) program in 2011.
2. To determine the extent to which, in 2011, HHS OpDivs:
 - collected information on the commercial success of SBIR products and services;
 - ensured that SBIR awardees met eligibility requirements; and
 - performed required checks to ensure that SBIR awardees did not receive duplicative funding for grants and contracts (i.e., awards).

BACKGROUND

The SBIR program is a competitive awards program created by the Small Business Innovation Development Act of 1982.¹ These awards are intended to provide Federal funding to small businesses pursuing research and development ideas that have potential for commercialization and that meet research and development needs of the Federal Government.^{2,3}

Federal agencies with research and development budgets of over \$100 million for nongovernment groups are required to participate in the SBIR program and in 2011, were required to allocate 2.5 percent of their budgets to SBIR awards.⁴ SBA is the Federal agency that coordinates the

¹ P.L. 97-219, 96 Stat. 217 (1982), 15 U.S.C. § 638. Congress reauthorized this statute in 2011. This statute also created the Small Business Technology Transfer (STTR) program, which shares the goals of the SBIR program and also reserves a specific percentage of Federal research and development funding to award to small businesses.

² Small Business Administration (SBA), *Small Business Innovation Research Program: 2011 Policy Directive* (2011 SBIR Program Policy Directive), p. 3. Accessed at <http://documents.scribd.com/s3.amazonaws.com/docs/4nxkhp8hs11bk8f.pdf?t=1310401127> on August 9, 2011.

³ Commercialization is the process of developing marketable products or services and producing and delivering those products or services for sale to Government or commercial markets. SBIR awards can be distributed to awardees through grants or contracts.

⁴ This budget is known as an agency's extramural budget, or the sum of the total obligations minus amounts obligated for such activities by Government-owned, Government-operated facilities. 15 U.S.C. § 638(e)(1). The 2011 SBIR reauthorization specified that the percentage of the extramural research and development budget that agencies must allocate to SBIR awards would increase to 2.6 percent in 2012 and to 2.7 percent in 2013. 15 U.S.C. § 638(f)(1)(C-E).

SBIR program across the 11 participating Federal agencies.^{5,6} SBA issues Policy Directives to guide agency implementation of the program, monitors agency implementation of the program, and reports program results to Congress annually.⁷ Federal law and SBA establish general standards for the SBIR program, and agencies have flexibility in managing their individual programs within these standards.⁸

Since the implementation of the SBIR program in 1982, HHS has funded more than \$8 billion in awards to small businesses pursuing innovative research ideas. However, in 1999, the Office of Inspector General (OIG) reported that within HHS, the National Institutes of Health (NIH) did not evaluate the success of the program.⁹

If HHS does not properly oversee the SBIR program, it cannot evaluate the program's success or ensure that awardees are eligible and are appropriately using funds. Other Federal agencies have identified fraud in the SBIR program. Specifically, NASA has identified awardees that falsely certified eligibility, including a company that stated it was American-owned but was not and a company that stated it was a small business but was not.¹⁰ Further, the Government Accountability Office (GAO) stated in a 1995 report that SBIR awardees had received duplicative funds from at least three participating agencies.¹¹ One of these agencies was the National Science Foundation, which stated that duplicative funding is the most frequent violation in its SBIR program.¹²

⁵ 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 (NASA), and the National Science Foundation.

⁶ SBA, *What We Do*. Accessed at <http://www.sba.gov/about-sba-services/what-we-do> on December 5, 2011.

⁷ SBA, *2011 SBIR Program Policy Directive*, pp. 3, 4, 25. (See footnote 2 for URL information.)

⁸ SBA, *2011 SBIR Program Policy Directive*, p. 4. (See footnote 2 for URL information.)

⁹ OIG, *Review of the Effectiveness of the National Institutes of Health's Administration of the Small Business Innovation Research Program*, A-15-98-00031. This report focused solely on NIH because it makes the most SBIR awards in HHS.

¹⁰ NASA, *Review of NASA's Management of its Small Business Innovation Research Program*. Accessed at <http://oig.nasa.gov/audits/reports/FY11/IG-11-010-R.pdf> on July 10, 2013.

¹¹ GAO, *Federal Research: Interim Report on the Small Business Innovation Research Program*, GAO-RCD-95-59, March 1995. Accessed at <http://www.gao.gov/assets/160/154923.pdf> on December 16, 2013.

¹² Alison Lerner, Inspector General of the National Science Foundation, *Statement Before the Senate Committee of Science, Commerce, and Transportation*, August 6, 2009. Accessed at <http://www.nsf.gov/oig/SBIRtestimonyAugust6.pdf> on August 19, 2013.

Congress passed the SBIR/STTR Reauthorization Act of 2011 in December 2011.¹³ To incorporate changes from the reauthorization, SBA updated its 2011 SBIR Program Policy Directive in October 2012, after the May 2012 end of our data collection for this study. Throughout this report, we describe the SBIR program requirements that were in effect at the time of our review and note any changes resulting from the new Policy Directive. See Appendix A for a list of differences in the 2011 and 2012 SBIR Program Policy Directives relevant to our review.

The 2011 SBIR Reauthorization Act requires agency OIGs to cooperate in preventing fraud, waste, and abuse in the SBIR program by (1) establishing fraud detection indicators; (2) reviewing agency regulations and operating procedures; (3) coordinating information sharing between agencies; and (4) improving the education and training of SBIR administrators, applicants, and awardees.¹⁴ The 2011 SBIR Reauthorization Act also requires OIGs to submit annual reports to Congress describing actions taken and funds used to address fraud, waste, and abuse in each SBIR program.¹⁵ This report is not intended to fulfill HHS OIG's annual reporting requirement.

SBIR Program Eligibility and Phases

To be eligible for an SBIR award, an applicant must:

- have a Principal Investigator (i.e., the primary researcher who will conduct and oversee the research project) who is primarily employed by the small business;¹⁶
- have fewer than 500 total employees, including affiliates;¹⁷
- maintain a place of business in the United States and operate primarily within the United States;¹⁸ and

¹³ National Defense Authorization Act for Fiscal Year 2012, P.L. 112-81, 125 Stat. 1298, Section 5001 (2011).

¹⁴ 15 U.S.C 638b(a)(5). See also SBA, *2012 SBIR Program Policy Directive*. Accessed at <http://documents.scribd.com/s3.amazonaws.com/docs/6c90n43wxs1wmoxi.pdf?t=1351707349> on July 31, 2013.

¹⁵ 15 U.S.C. § 638b(c).

¹⁶ To be considered primarily employed by the company, the Principal Investigator must spend more than half of his or her time in the employ of the company at the time of award and during the proposed project. Occasionally, deviation from this requirement may occur; such deviation must be approved in writing. SBA, *2011 SBIR Program Policy Directive*, p. 13. (See footnote 2 for URL information.)

¹⁷ In determining whether affiliation exists, SBA considers such factors as ownership, management, previous relationships with or ties to another company, and contractual relationships. 13 CFR § 121.103 (a)(1-2).

¹⁸ Alternatively, applicants can make significant contributions to the U. S. economy through payment of taxes or use of American products, materials, or labor. SBA, *2011 SBIR Program Policy Directive*, p. 7. (See footnote 2 for URL information.)

- be organized as a for-profit entity.¹⁹

All SBIR applicants must certify that they meet all of the eligibility requirements before receiving an SBIR award.²⁰ Specifically, applicants must check a box on the electronic application indicating that they intend to meet all eligibility requirements at the time of the award.²¹ Although awarding agencies are not required to do so, they can conduct additional eligibility checks at their discretion.

The SBIR program consists of three phases.²² Applicants selected to receive SBIR funds, or awardees, must participate in Phase I of the program to participate in Phases II and III. The object of Phase I is for agencies to determine the scientific merit and feasibility of a proposal as well as the quality of an awardee's performance.²³ Generally, Phase I runs for 6 months, and awardees may receive up to \$150,000 in SBIR funds.²⁴

After completing Phase I, awardees must apply to receive additional funding in Phase II. In Phase II, awardees continue the research and development of the project.²⁵ Phase II applications must include a commercialization plan that may include market analyses, patent status, and/or plans to secure funding for Phase III.²⁶ Phase II generally runs for 2 years, and awardees may receive up to \$1 million in additional SBIR funds.²⁷ The SBIR program permits agencies to exceed the amount in the funding guidelines for Phases I and II if the additional amount is fully justified and scientifically appropriate.²⁸ Agencies must provide SBA with written justification for all awards that exceed the amounts in the funding guidelines. This justification must be included in the agency's annual report to SBA on the SBIR program.²⁹

¹⁹ Ibid., p. 7.

²⁰ HHS, *SBIR Application Guide*, p. III-27. Accessed at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_Adobe_VerB.pdf on October 26, 2011.

²¹ If an awardee becomes ineligible after receiving an award, the award may continue at the scientific discretion of OpDiv program officials. However, the awardees are not allowed to compete for new SBIR awards after becoming ineligible.

²² SBA, *2011 SBIR Program Policy Directive*, p. 8. (See footnote 2 for URL information.)

²³ Ibid., p. 9.

²⁴ Ibid., p. 17.

²⁵ Ibid., p. 9.

²⁶ Ibid., p. 14.

²⁷ Ibid., p. 17.

²⁸ NIH, *NIH Grants Policy Statement* (October 2010), p. IIB-254. Accessed at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on April 17, 2013.

²⁹ SBA, *2011 SBIR Program Policy Directive*, p. 17. (See footnote 2 for URL information.)

In Phase III, awardees do not apply for or receive SBIR funding but instead seek non-SBIR Federal funds or private funds to pursue commercialization of products or services resulting from Phase I and II research and development.^{30,31} Figure 1 illustrates the three phases of the SBIR program.

Figure 1: SBIR Program Phases



Source: OIG analysis of 2011 SBIR Program Policy Directive.

The SBIR Program Within HHS

Four HHS OpDivs issue SBIR awards: NIH, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Administration for Children and Families (ACF).

Unlike most other agencies that make awards under the SBIR program, HHS does not have a single office responsible for overseeing its OpDivs' respective SBIR programs.³² Because NIH makes most of HHS' SBIR awards, NIH solicits SBIR proposals for all participating HHS OpDivs, manages the scientific review of all HHS SBIR applications, and submits an annual HHS SBIR report to SBA on behalf of all four HHS OpDivs.³³

HHS uses grants and contracts to award SBIR funds and uses a different review process for the two types of awards. Once they have received all HHS SBIR grant applications, external peer reviewers in NIH's Center for

³⁰ Ibid., pp. 9–10. See also SBA, *SBIR*. Accessed at <http://www.sbir.gov/about/about-sbir> on April 22, 2013.

³¹ Phase I awardees may advance to Phase III and receive non-SBIR funds without participating in Phase II.

³² SBA's SBIR Policy Directive assumes that each participating agency has an SBIR program manager or coordinator and assigns several responsibilities to this office. See SBA, *2011 SBIR Program Policy Directive*, pp. 13, 26, 29, and 37. (See footnote 2 for URL information.) The Department of Defense, the Department of Education, the Department of Energy, the Department of Homeland Security, NASA, and the National Science Foundation each have an SBIR program manager or coordinator.

³³ NIH manages the review of SBIR grant applications on behalf of all OpDivs, but CDC independently evaluates its SBIR contract proposals. CDC awarded five contracts in 2011.

Scientific Review evaluate the scientific merits of the proposed projects.³⁴ After receiving reviewers' scores and comments on the strengths, weaknesses and budget of the proposed project, each OpDiv considers NIH's scientific assessment and the OpDiv's research and development needs to select which projects to fund.³⁵

A technical evaluation panel assesses SBIR contract proposals according to requirements in the Federal Acquisition Regulations and the HHS Acquisition Regulations.³⁶ The panel makes recommendations related to the proposed research and budget. Program staff then conduct a second level of review before awarding a contract.³⁷

To help SBIR awardees commercialize products or services, agencies may also use SBIR funds to provide technical assistance to awardees in drafting and executing a commercialization plan.³⁸ NIH has two technical assistance programs for SBIR awardees; for both, awardees must apply and be selected to participate. The Niche Assessment Program helps selected Phase I awardees identify the most appropriate market for their products or services.³⁹ The Commercialization Assistance Program is for selected Phase II awardees that may need help transitioning their innovations from the research and development phase to the marketplace.⁴⁰ NIH maintains a page on its Web site where SBIR awardees can self-report commercialization of products and services. Other HHS OpDivs do not participate in structured commercialization assistance plans, but awardees may request technical assistance from their respective awarding OpDivs.

HHS Oversight of the SBIR Program

Each HHS OpDiv is responsible for overseeing its awards. Oversight includes ensuring that awardees meet eligibility requirements and that awards are not duplicative.

³⁴ NIH, *NIH Grants Policy Statement* (October 2010), pp. I-49–I-53. Accessed at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on October 7, 2011.

³⁵ NIH, *Peer Review Process*. Accessed at http://grants.nih.gov/Grants/peer_review_process.htm on May 17, 2013.

³⁶ NIH and CDC are the only HHS OpDivs that award SBIR contracts. These OpDivs use a joint guidance document for reviewing SBIR contract proposals. HHS, *Solicitation of NIH and CDC for SBIR Contract Proposals, PHS 2013-1*. Accessed at <http://grants.nih.gov/grants/funding/SBIRContract/PHS2013-1.pdf> on November 25, 2013.

³⁷ *Ibid.*, pp. 25–26.

³⁸ SBA, *2011 SBIR Program Policy Directive*, p. 21. (See footnote 2 for URL information.)

³⁹ NIH, *Niche Assessment Program*. Accessed at <http://grants.nih.gov/grants/funding/nap.htm> on October 21, 2011.

⁴⁰ NIH, *Commercialization Assistance Program*. Accessed at <http://grants.nih.gov/grants/funding/cap/index.htm> on October 21, 2011.

Ensuring That Awardees Are Eligible. Before receiving an award, SBIR awardees must certify that they intend to meet all eligibility requirements at the time of the award. Although they are not required to do so, HHS OpDivs can conduct additional eligibility checks before funding an award. Further, if an HHS OpDiv is uncertain whether an applicant meets the SBIR eligibility requirements, it may request a “size determination” from SBA.⁴¹ SBA size determinations generally focus on the number of employees and size of affiliates, but SBA also collects information relevant to other eligibility requirements during this process.⁴²

Additionally, NIH uses what it calls “Just-in-Time” procedures to request additional information from applicants after an application has been peer reviewed and is being considered for funding. This information may include documents relevant to an applicant’s eligibility.⁴³ These procedures are specific to NIH grant awards.

If an SBIR applicant submits a false certification of eligibility, OpDivs follow standard procedures for reporting grant fraud and abuse that may include actions up to and including pursuing criminal charges with the Department of Justice.⁴⁴ If an entity knowingly submits a false claim and receives government funds, it is liable for three times the government’s damages plus civil penalties.⁴⁵

Ensuring That Awards Are Not Duplicative. Applicants may propose the same project to multiple agencies. However, agencies must avoid funding essentially equivalent, or duplicative, work under SBIR and other Federal programs.⁴⁶ If an applicant receives funding from one agency, the applicant must withdraw the application(s) from any other agencies to which it applied. If the applicant does not withdraw the other application(s), it may subsequently receive duplicative funding.

⁴¹ NIH, *NIH Grants Policy Statement* (October 2010), p. IIB-251. Accessed at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on October 7, 2011.

⁴² SBA, *Guide to Size Standards*. Accessed at <http://www.sba.gov/content/guide-size-standards> on April 24, 2013. See also SBA Form 355. Accessed at <http://www.sba.gov/sites/default/files/SBA%20%20Form%20355.pdf> on April 24, 2013.

⁴³ NIH, *NIH Grants Policy Statement* (October 2010), pp. I-54–I-55. Accessed at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on October 7, 2011. Information requested as part of the “Just-in-Time” procedures may also include approval from the Human Subjects Assurance and Institutional Review Board and/or approval from the Institutional Animal Care and Use Committee.

⁴⁴ *Ibid.*, p. I-44. See also False Statements, 18 U.S.C. 1001, Theft of Federal Funds, 18 U.S.C. § 641.

⁴⁵ False Claims Act, 31 U.S.C. §§ 3729-3733.

⁴⁶ SBA, *2011 SBIR Program Policy Directive*, p. 21. (See footnote 2 for URL information.)

Duplicative funding can also occur if an awardee receives funding for the same project in multiple years.

To manage awardee data, and in part to avoid duplicative funding, NIH stores data on HHS SBIR awardees and their projects in its IMPAC II and NIH Data Warehouse databases, which contain information for all HHS awards.⁴⁷ CDC, FDA, and ACF provide data on their SBIR awardees to NIH to be included in these databases and can search the databases to avoid funding duplicative work within HHS. NIH is responsible for providing all of HHS's SBIR data to SBA through the SBIR.gov database. Before granting an award, each OpDiv is also required to check SBIR.gov to ensure that applicants have not been previously funded by HHS or other Federal agencies for duplicative projects.⁴⁸ NIH requires applicants to self-disclose other active and pending financial support (e.g., other grants or contracts) as part of its "Just-in-Time" procedures.⁴⁹ NIH does not require applicants to provide information on past awards. Further, NIH does not independently verify that applicants disclosed all other active and pending financial support.

Previous OIG Work

In 1999, OIG determined that NIH did not track and assess awardees' commercialization of SBIR products and services. NIH generally agreed with OIG's recommendations to improve its tracking and assessment of SBIR commercialization data. NIH also stated that it was developing a methodology to link the significant investments that NIH has made in the SBIR program to specific and measurable outcomes.⁵⁰

METHODOLOGY

We used NIH's Research Portfolio Online Reporting Tools (RePORT) Web site and SBA's SBIR.gov database to obtain and assess information on SBIR-funded projects as of March 12, 2012, for fiscal year (FY)

⁴⁷ NIH, *Query, View, and Report*. Accessed at http://era.nih.gov/nih_and_grantor_agencies/other/query_view_and_report.cfm on October 22, 2013.

⁴⁸ SBA, *2011 SBIR Program Policy Directive*, p. 21. (See footnote 46 for URL information.) The 2011 SBIR Program Policy Directive instructs agencies to use a database called Tech-Net to check for duplicative funding. However, OpDivs review information on SBIR.gov, which contains all Tech-Net data. The 2012 SBIR Program Policy Directive requires agencies to develop policies and procedures to avoid funding duplicative work, which could include searching Tech-Net or SBIR.gov. SBA, *2012 SBIR Program Policy Directive*. Accessed at <http://documents.scribd.com/s3.amazonaws.com/docs/6c90n43wxs1wmoxi.pdf?t=1351707349> on July 31, 2013.

⁴⁹ NIH, *NIH Grants Policy Statement* (October 2010), pp. I-54–I-55. Accessed at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_2010.pdf on October 7, 2011.

⁵⁰ OIG, *Review of the Effectiveness of the National Institutes of Health's Administration of the Small Business Innovation Research Program*, A-15-98-00031, November 1999.

2011.⁵¹ We selected a sample of Phase I and II awardees from each HHS OpDiv. We also collected SBIR award data from each of the four participating HHS OpDivs and requested documents (e.g., internal policies or procedures) to determine the extent to which each of these OpDivs oversees its SBIR awards. We report data HHS-wide and for specific OpDivs, as appropriate.

The SBIR program was reauthorized in December 2011. To incorporate changes from the reauthorization, SBA issued a new Policy Directive in October 2012, after our data collection concluded in May 2012. For this report, we reviewed SBIR awards administered under SBA's previous Policy Directive. Changes in the 2012 Policy Directive do not affect the results of our review.

Data Collection and Analysis

We collected and analyzed data to describe HHS SBIR expenditures in 2011 and to determine the extent to which HHS OpDivs tracked and assessed the commercialization of SBIR products and services. We also determined the extent to which HHS OpDivs ensured that awardees were eligible and that awards were not duplicative.

Determining the Extent to Which HHS OpDivs Tracked and Assessed the Commercialization of SBIR Products or Services. We analyzed the responses to our requests for information and supporting documentation to determine the extent to which each HHS OpDiv evaluated the commercialization of SBIR awardees' products and services. We reviewed NIH's Niche Assessment and Commercialization Assistance Program data to determine the number of participants for which commercialization data was collected. We also determined how many SBIR awardees have self-reported success stories on NIH's Web site since 2001.

Determining the Extent to Which HHS Ensured That SBIR Awardees Were Eligible. Using the data we received in response to our requests, we determined the extent to which HHS OpDivs verified and had written procedures to verify applicant eligibility beyond self-certification. We also asked SBA whether any HHS OpDivs had requested its assistance in determining eligibility.

To determine the extent to which HHS OpDivs ensured that SBIR awardees met eligibility requirements, we selected a random sample of

⁵¹ RePORT is a publically available site that provides access to reports, data, and analyses of NIH research activities, including information on NIH awards. NIH, *The ReSource*, Issue 1 (no date; circa 2010–2011). Accessed at <http://report.nih.gov/resource/issue1/> on December 5, 2013.

137 SBIR awards, stratified by OpDiv. The number of awards that CDC and FDA granted in 2011 was small in comparison to that of NIH.⁵² Therefore, we included all awards from CDC and FDA to ensure that awards from these OpDivs were included in our sample. Table 1 shows the sample of awards used to analyze eligibility by stratum and the population of 2011 awards. This stratified random sample is projectable to all 2011 HHS SBIR awards.⁵³

Table 1: Sample and Population of 2011 SBIR Awards

Stratum	Awards in Sample	Award Amount in Sample	Awards in Population	Award Amount in Population
NIH	100	\$40,768,573	957	\$353,529,688
CDC	26	\$4,889,690	26	\$4,889,690
FDA	11	\$1,479,428	11	\$1,479,428
Total	137	\$47,137,691	994	\$359,898,806

Source: OIG analysis of SBIR awardees reported by HHS OpDivs.

See Appendix B for a detailed methodology of our process for verifying awardee eligibility.

Determining the Extent to Which HHS OpDivs Ensured That SBIR Awards Were Not Duplicative. We used the responses to our information requests to determine the extent to which HHS reviewed SBIR awards for duplicative funding. We used the stratified random sample of 137 HHS SBIR awards described in Table 1 to determine whether any projects were listed multiple times in NIH databases using RePORT.

All estimates in this report are projected to the specified population or subpopulation of 2011 SBIR awards, at the 95-percent confidence level. Appendix C shows the sample size, point estimates, and 95-percent confidence intervals for all statistics in this report.

Limitations

We did not independently verify data reported by HHS and SBA. Additionally, some Web sites used to verify awardees' eligibility contained self-reported data submitted voluntarily. We did not independently verify information reported on these Web sites, and we did not attempt to verify awardees' eligibility through other means if they had no information on these Web sites.

⁵² ACF allowed NIH to award ACF's 2011 SBIR funds, totaling \$395,770. NIH, *SBIR Program Annual Report to the U.S. Small Business Administration*.

⁵³ To project our findings, we weighted each sample statistic by the total number of awards from each stratum, or OpDiv.

Standards

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

FINDINGS

HHS awarded \$360 million in SBIR funds to nearly 1,000 awardees in 2011

In 2011, HHS funded 994 Phase I and II SBIR awards for a total of \$360 million, second to only the Department of Defense in the amount of SBIR funding among Federal agencies.⁵⁴ This amount does not reflect HHS' total SBIR expenditures in 2011 because it does not include SBIR funds used in 2011 for awards funded in previous years. According to its annual report to SBA, HHS obligated \$617 million for all SBIR expenditures in 2011.⁵⁵ NIH awarded 957 of HHS' 994 SBIR awards in 2011, which amounted to \$353.5 million, or 98 percent of all HHS SBIR dollars.

Agencies are permitted to exceed SBIR funding guidelines if they submit written justification in their annual report to SBA. In 2011, 528 (53 percent) of HHS' SBIR awards exceeded the amounts in the funding guidelines, totaling nearly \$170 million in funds over the guideline amounts.⁵⁶ In its annual report to SBA, HHS included one general justification for all awards that exceeded the amounts in the funding guidelines.

On average, HHS Phase I awards exceeded funding guidelines by \$111,819, ranging from \$43 to \$1.6 million in excess. Phase II awards exceeded guidelines by an average of \$301,584, ranging from \$7,031 to \$2 million in excess. Further, for FYs 2009–2011, HHS' average award amounts for Phase I and II awards exceeded the average SBIR award amount across the Federal Government by \$121,000 and \$568,000, respectively.⁵⁷ HHS had the highest average award amount for Phase I and II awards during this period.

See Figure 2 for a comparison of average HHS awards and average awards for the 10 other participating agencies.

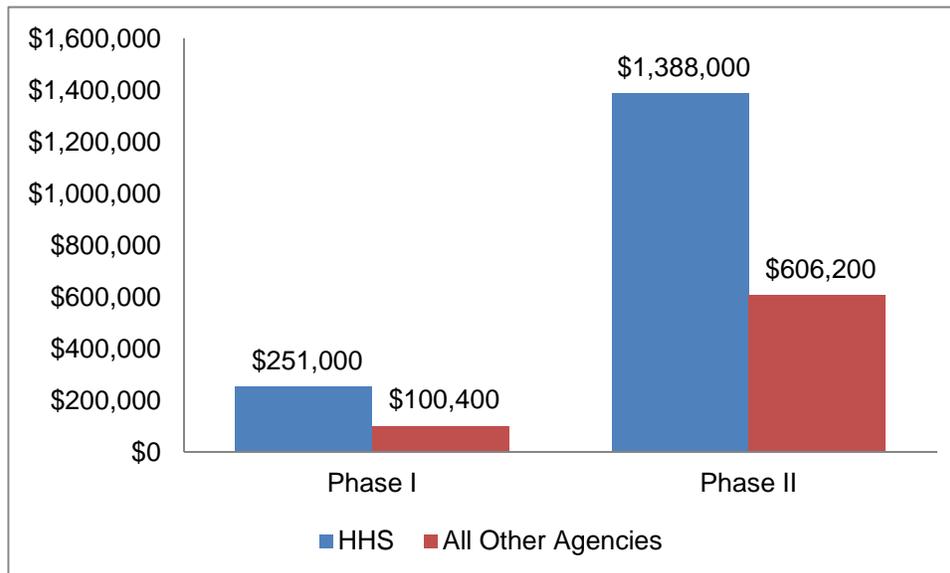
⁵⁴ The Department of Defense awarded 2,754 awards for a total of \$1.04 billion in 2011. Department of Defense, *Department of Defense SBIR Annual Summary Report*. Accessed at <http://www.dodsbir.net/annualreport/annrpt.html> on April 8, 2013.

⁵⁵ HHS, *SBIR Program Annual Report to the U.S. Small Business Administration*.

⁵⁶ Phase II awards span 2 or more years. For this portion of our data analysis, we included the Phase II amount awarded for FY 2011.

⁵⁷ SBA, *SBIR and STTR Annual Report, FY-2009–2011*, p. 7.

Figure 2: Average Award Amounts for HHS and All Other Participating Agencies, FY 2011



Source: OIG analysis of SBA's SBIR and STTR Annual Report for FY 2009-2011

Although HHS OpDivs are not required to collect information on the commercial success of SBIR awards, one of the four OpDivs did so

One goal of the SBIR program is to increase the commercialization of federally funded research. However, SBA does not require agencies to track the commercial success of SBIR projects. Further, at the time of this review, SBIR awardees were not required to report commercialization data (e.g., patents acquired, products and services developed and sold to companies or the general public) to OpDivs.⁵⁸ Without consistent tracking or an assessment of commercial success, HHS cannot determine whether the SBIR program is meeting its commercialization goal. Although NIH—which awards the bulk of HHS's SBIR funds—collects information on the commercial success of awards, the other three HHS OpDivs that made SBIR awards did not. Furthermore, the information that NIH collects is limited in scope.

⁵⁸ SBA's 2012 Policy Directive establishes a Commercialization Database to store information reported by awardees on the commercial activity resulting from their past SBIR awards. SBIR awardees are required to update information on their prior Phase II awards in the Commercialization Database when submitting an application for a SBIR Phase II award and upon completion of the last deliverable for that award. However, awardees are not required to update this information if they do not apply for a second Phase II award. SBA, *2012 Policy Directive*, pp. 44–45. Accessed at <http://documents.scribd.com/s3.amazonaws.com/docs/6c90n43wxs1wmxo.pdf?t=1351707349> on July 31, 2013.

None of the HHS OpDivs had a comprehensive, standardized data collection system to track the commercialization of products and services resulting from SBIR awards. NIH collects limited information on the commercial success of SBIR awards. Specifically, it uses survey data stored in the Performance Outcomes Database System (PODS) to assess commercial outcomes. However, the information in PODS is based solely on two surveys (conducted in 2002 and 2008) of Phase II NIH SBIR awardees.⁵⁹ Further, responses to the surveys were voluntary.⁶⁰ NIH also uses PODS to store Commercialization Assistance Program outcome data (e.g., estimated cumulative sales, number of awardees receiving additional non-SBIR funding) that it collects throughout an awardee's time in the program.⁶¹ However, providing data is voluntary and limited to the relatively low number of Commercialization Assistance Program participants (39 of 203 Phase II awardees in 2011).⁶² Because NIH received only limited and inconsistent data from program participants, it does not use PODS data as a metric to judge the commercial success of SBIR projects.

As of 2011, NIH did not collect commercialization data from Niche Assessment Program Participants. Of the 12,836 SBIR awards funded since 2002, 99 awardees (less than 1 percent) reported commercialization of products and services on the NIH Web site.⁶³

Although all SBIR awardees certified their eligibility, 31 percent of awardees had questionable or unverified eligibility for at least one requirement

Applicants are required to check a box on the electronic SBIR application certifying that they intend to meet all of the SBIR program's eligibility

⁵⁹ In 2004, 2005 and 2007, NIH followed up with awardees selected to participate in the original 2002 survey and updated the information stored in PODS. NIH, *Report on the 2007 Outcome Measures Update*, p. 1. Accessed at http://grants.nih.gov/grants/funding/sbir_pods_final_rpt_2007.pdf on September 4, 2013.

⁶⁰ NIH, *National Survey to Evaluate the NIH SBIR Program* (January 2009), p. I-3. Accessed at http://grants.nih.gov/grants/funding/sbir_2008surveyreport.pdf on April 22, 2013.

⁶¹ Sally J. Rockey, Ph. D., Deputy Director for Extramural Research, NIH, *SBIR: Defining Metrics and Outcomes of Success*. July 2012. Accessed at http://smrb.od.nih.gov/documents/presentations/2012/rokey_07112012.pdf on April 17, 2013.

⁶² SBIR awardees that received Phase II awards before 2006 were not eligible to participate in the Commercialization Assistance Program. NIH, *Commercialization Assistance Program for Phase II Awardees*. Accessed at http://grants.nih.gov/grants/funding/cap/more_on_cap.htm on January 7, 2013.

⁶³ The NIH Web site includes self-reported data from SBIR and STTR awardees. When we reviewed the self-reported data, we were unable to determine in which of the two programs the awardees were participating.

requirements at the time of the award. If an OpDiv is uncertain whether an applicant's certification is accurate, it may, but is not required to, independently verify the applicant's eligibility or request that SBA assist with determining eligibility.

In 2011, all SBIR awardees self-certified that they intended to meet eligibility requirements at the time of the award. Using data sources commonly used by other Federal agencies to identify potentially ineligible SBIR awardees, we found that 31 percent of awardees had questionable eligibility for at least one requirement (16 percent of awardees) or unverified eligibility for at least one requirement (20 percent of awardees). Six percent of SBIR awardees in 2011 had questionable eligibility for at least one requirement and unverified eligibility for at least one other requirement.⁶⁴ Although they are not required to do so, HHS OpDivs did not take any steps to independently verify that these awardees met eligibility requirements.⁶⁵

Sixteen percent of awardees had questionable eligibility for at least one requirement

We found information indicating that 16 percent of SBIR awardees in 2011 may not have met at least one eligibility requirement. Therefore, we considered the eligibility of these awardees to be questionable. Table 2 shows the number of awardees in our sample that had questionable eligibility for each requirement.

⁶⁴ The percentage of awardees with questionable eligibility for at least one requirement, unverified eligibility for at least one requirement, and both questionable and unverified eligibility does not sum to 31 because of rounding.

⁶⁵ NIH requested SBA assistance with determining eligibility for 4 of the nearly 1,000 awardees in 2011. However, none of these four awardees were in our sample of 2011 SBIR awards.

Table 2: Eligibility Requirements and Corresponding Numbers of Awardees in Our Sample With Questionable Eligibility, 2011

Eligibility Requirement	Number of Awardees in Our Sample With Questionable Eligibility
Principal Investigator's primary employer was the SBIR awardee	21
SBIR awardee had fewer than 500 employees	4
SBIR awardee had a place of business and operated primarily in the United States	2
SBIR company was for-profit	0

Source: OIG analysis of HHS SBIR awardees, 2012

The eligibility of 21 awardees in our sample was questionable because we found information indicating that the awardee was not the Principal Investigators' primary employer. For example, one Principal Investigator for an award in our sample listed three positions on his LinkedIn profile at the time the SBIR award was made, including a full-time position at a university. This Principal Investigator was associated with one SBIR award in 2011 totaling \$575,303. Another Principal Investigator for an award in our sample stated in her LinkedIn profile that she was the president of two companies and head of business development for a third company at the time of the SBIR award. This Principal Investigator was also listed as an employee on the three organizations' Web sites. This Principal Investigator was associated with one SBIR award in 2011 totaling \$143,301.

The eligibility of 4 awardees in our sample was questionable because we found information indicating that the awardees, or their affiliate(s), had more than 500 employees. One awardee in our sample was owned by a larger company with 7,200 employees and was awarded \$582,698 in SBIR funds in 2011.

The eligibility of two awardees in our sample was questionable because we found information indicating that the awardees did not maintain a U.S. place of business and/or did not operate primarily in the United States. One awardee's Web site stated that many of its devices are made in the company's location in Canada. This company received two awards for a total of \$399,938 in SBIR funds in 2011.

We did not find information indicating that any awardee in our sample was not organized as a for-profit entity.

Challenges exist in verifying the eligibility of 20 percent of SBIR awardees

Twenty percent of SBIR awardees in 2011 had unverified eligibility for one or more of the four eligibility requirements—i.e., we could not find information in any of our searches to verify the awardee’s eligibility for the requirement(s). Two awardees in our sample had unverified eligibility for three requirements. There was one awardee in our sample for which we were unable to verify any of the four eligibility requirements. Table 3 shows each eligibility requirement and the corresponding number of awardees in our sample with unverified eligibility.

Table 3: Eligibility Requirements and Corresponding Numbers of Awardees in Our Sample With Unverified Eligibility, 2011

Eligibility Requirement	Number of Awardees in Our Sample With Unverified Eligibility
Principal Investigator’s primary employer was the SBIR awardee	13
SBIR awardee had fewer than 500 employees	14
SBIR awardee had a place of business and operated primarily in the United States	6
SBIR company was for-profit	3

Source: OIG analysis of HHS SBIR awardees, 2012

For 13 awardees in our sample, we were unable to verify that the awardee was the Principal Investigator’s primary employer. For these awardees, we were unable to find documentation confirming that the Principal Investigator was employed by the awardee.

For 14 of the awardees in our sample in 2011, we were unable to verify that the company had fewer than 500 employees. For these awardees, we were unable to find documentation on LinkedIn, Manta, or other Web sites confirming the number of employees at the company or its affiliate(s).

Further, we were unable to verify that six awardees in our sample had a place of business and operated primarily in the United States. For these awardees, we found documentation that the companies operated in foreign business locations and could not find documentation that the company operated primarily in the United States.

Finally, we were unable to verify whether three awardees in our sample were for-profit companies. For these awardees, we were unable to find documentation confirming that the awarded company was a for-profit business.

HHS OpDivs did not perform a required check for duplicative awards across other Federal agencies

Each Federal agency is required to check SBIR.gov for duplicative awards within the agency and across other Federal agencies before granting an SBIR award. Other agencies have identified awardees that committed fraud by not disclosing that they had received awards from other agencies for the same work.⁶⁶ While NIH checks for duplicative funding within HHS, none of the four HHS OpDivs checked SBIR.gov for duplicative awards across Federal agencies in 2011.

To check for duplicative funding within HHS, NIH reported that it compares SBIR applications to existing SBIR awards within HHS by searching IMPAC II, which contains information on HHS awards only.⁶⁷ NIH reported that no duplication within HHS occurred in 2011. We also did not identify any cases of duplicative awards within HHS. No other HHS OpDivs had procedures for performing checks for duplicative funding within HHS.

None of the HHS OpDivs checked SBIR.gov for duplicative awards across Federal agencies, as required. NIH has procedures to perform limited checks for duplicative funding across Federal agencies. These checks, known as “Just-in-Time” procedures, require applicants to self-disclose information on other active and pending financial resources, including other grants and contracts, before receiving an award. However, the procedures do not include steps to independently verify the information reported by applicants. No other HHS OpDivs had procedures for performing checks for duplicative funding across Federal agencies.

⁶⁶ Alison Lerner, Inspector General of the National Science Foundation, *Statement Before the Senate Committee of Science, Commerce, and Transportation*, August 6, 2009. Accessed at <http://www.nsf.gov/oig/SBIRtestimonyAugust6.pdf> on August 19, 2013. See also, NASA, *Review of NASA’s Management of its Small Business Innovation Research Program*. Accessed at <http://oig.nasa.gov/audits/reports/FY11/IG-11-010-R.pdf> on July 10, 2013.

⁶⁷ IMPAC II is also available to CDC, but the OpDiv reported that it relies on applicants to disclose duplicate SBIR funding.

CONCLUSION AND RECOMMENDATIONS

Since the implementation of the SBIR program in 1982, HHS has funded more than \$8 billion in awards to small businesses pursuing innovative research ideas. Furthermore, the reauthorization of the SBIR program in December 2011 increased the percentage of SBIR funds awarded by participating agencies from 2.5 percent of their annual extramural research budgets in 2012 to 3.2 percent by 2017.

In 1999, OIG reported that HHS had not evaluated the success of the SBIR program. Further, other Federal agencies have identified SBIR awardees that falsely certified that they met eligibility requirements and received duplicative funding.

In 2011, HHS awarded \$360 million in SBIR funds to nearly 1,000 awardees and had the highest average SBIR award amount of any participating agency. However, HHS does not have a central office for overseeing the SBIR program.

HHS did not consistently collect information on the commercial success of awards and therefore cannot determine whether the program is increasing the commercialization of federally funded research, one of the primary goals of the program. Additionally, all awardees in 2011 self-certified that they intended to meet SBIR eligibility requirements at the time of the award. However, using data sources commonly used by other Federal agencies to identify potentially ineligible SBIR awardees, we found that 31 percent of awardees had questionable or unverified eligibility for at least one requirement. Although they are not required to do so, HHS OpDivs did not take any steps to independently verify the eligibility of these awardees. Furthermore, while one OpDiv checked for duplicative funding within HHS, none of the four OpDivs completed a required check for duplicative awards across other Federal agencies.

Our findings raise 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 are eligible and are not receiving duplicative funding from other Federal agencies.

Therefore, we recommend that HHS:

Create a central office to oversee the SBIR program

Unlike most other participating agencies, HHS does not have a central office responsible for overseeing the SBIR program. Each OpDiv is separately responsible for awarding SBIR funds and overseeing these awards. The 2012 SBIR Program Policy Directive requires HHS to increase its coordination with other participating agencies and with HHS's

OIG to prevent fraud, waste, and abuse in the SBIR program. HHS should create a central office to facilitate this coordination and to ensure consistent oversight among OpDivs. Central office functions could include coordinating with OIG, developing agencywide policies and procedures, increasing oversight, and fulfilling agency reporting requirements. A central office would also facilitate the consistent implementation of our remaining recommendations.

Collect information to track and assess SBIR-funded projects' commercialization

SBA's new Policy Directive requires awardees to report commercialization data to a central Commercialization Database. The implementation of this requirement is ongoing; however, while these data are unavailable, HHS OpDivs should develop processes to track commercialization of SBIR awardees. These processes should be consistent among OpDivs. OpDivs should use this information to determine whether the SBIR program is meeting its goal of increasing private-sector commercialization of Federal research and development innovations.

Ensure compliance with SBIR eligibility requirements

The 2012 SBIR Program Policy Directive requires agencies to ensure compliance with SBIR eligibility requirements. SBA requires that awardees meet eligibility requirements at the time of the award. HHS OpDivs should take actions to ensure that awardees will meet requirements before they receive SBIR funds. These actions could include implementing a standardized process for verifying that a random or risk-based sample of awardees meets all eligibility requirements at the time of the award and during the life cycle of the award. OpDivs could also require applicants to provide proof that they will meet eligibility requirements at the time of the award and request SBA assistance to verify awardee eligibility.

Improve procedures to check for duplicative awards

The 2012 SBIR Program Policy Directive requires agencies to develop policies and procedures to avoid funding duplicative work. HHS should develop procedures beyond the "Just-in-Time" procedures used by NIH. "Just-in-Time" procedures rely on self-reported information that does not allow HHS to determine whether awardees have completed similar projects in the past or whether multiple awardees are completing similar projects. The new procedures should be consistent across HHS OpDivs to ensure that all SBIR applicants receive the same scrutiny regarding duplicative awards.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

The Office of the Assistant Secretary for Financial Resources (ASFR) provides advice and guidance to the Secretary of HHS on grants and acquisition management and provided comments on behalf of HHS. ASFR stated that it is committed to the successful implementation and oversight of the SBIR program. ASFR did not indicate whether it concurred with each of our recommendations. However, ASFR agreed that additional coordination and oversight across the participating OpDivs is appropriate and warranted. ASFR further noted that it is working with the respective OpDivs to determine the most effective and efficient use of resources to accomplish this coordination.

ASFR also agreed that HHS must ensure that applicants are in compliance with all SBIR eligibility requirements, noting that it will work with OpDivs to determine whether additional eligibility checks are required. However, ASFR stated that it has concerns about the official use of social media networking sites to verify applicant eligibility, and does not believe such sites are reliable sources of information for the purposes of confirming or questioning program eligibility. While we understand ASFR's concern, these are tools commonly used by other Federal agencies to identify potentially ineligible SBIR awardees.

We support ASFR's efforts to address these issues and encourage it to continue making progress in these areas. We ask that, in its final management decision, ASFR clearly indicate whether it concurs with each of our recommendations and what steps, if any, it will take to implement them. For the full text of ASFR's comments, see Appendix D. We made minor corrections to the report on the basis of ASFR's technical comments.

APPENDIX A

Table A-1: Differences in the 2011 and 2012 Small Business Innovation and Research Program Policy Directives

Requirement	2011 SBIR Program Policy Directive	2012 SBIR Program Policy Directive
Eligibility	Majority-owned by multiple venture capital operating companies, hedge funds and/or private equity firms are not eligible.	Majority-owned by multiple venture capital operating companies, hedge funds, and/or private equity firms are eligible, if agencies opt to include this provision.
Eligibility Certification	Awardees certify their eligibility at the time of the award.	Awardees certify their eligibility throughout the life cycle of the award.
Exceeding Funding Guidelines	<p>Agencies may exceed funding guidelines if the additional amount is fully justified and scientifically appropriate.</p> <p>Agencies must submit written justification of the excess funds with their Annual Reports to SBA.</p>	<p>Agencies may not exceed funding guidelines by more than 50 percent. Agencies must request a waiver to exceed funding guidelines by more than 50 percent for a specific topic.</p> <p>Agencies must maintain information on awards that exceed funding guidelines, including the amount of the award, justification for exceeding the guidelines for each award, the identity and location of the awardee, whether the awardee has received any venture capital, hedge fund, or private equity firm investment, and whether the awardee is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms.</p>
Commercialization Data	Agencies are not required to collect or track commercialization data. Awardees may voluntarily submit and update commercialization data.	Agencies and awardees must maintain commercialization data in the Commercialization Database. Awardees are required to update commercialization data for prior Phase II awards when applying for a subsequent Phase II award.

Source: OIG analysis of 2011 and 2012 SBIR Program Policy Directives.

APPENDIX B

Detailed Methodology for Verifying Awardee Eligibility

For our sample of 137 SBIR program awards, we verified awardee eligibility using the Lexis/Nexis Accurint for Government (Accurint) database, State Business Registration Web sites, and awardee Web sites.⁶⁸ We used additional Web sites (e.g., Manta, LinkedIn) to collect information not available from the sources referenced above.^{69, 70} We chose these sources to verify awardee eligibility because these are tools commonly used by other Federal agencies to identify potentially ineligible SBIR awardees.⁷¹ We classified awardees as having “verified” eligibility if we could determine—using these data sources—that the awardees met all four eligibility requirements. If at least one data source indicated that an awardee met a given eligibility requirement, we considered that requirement to be verified. We classified awardees as having “questionable” eligibility if we found information indicating that they may not meet one or more of the four eligibility requirements. We classified awardees as having “unverified” eligibility if we could not find information in any of our data sources indicating that awardees met one or more of the four eligibility requirements.⁷²

To verify awardee eligibility, we searched for the following information indicating that the awardee:

- 1) *Was the Principal Investigator’s primary employment.* We used Accurint, Principal Investigators’ profiles on LinkedIn, and other Internet searches to verify that the Principal Investigator was primarily employed by the awardee and did not have additional full-time

⁶⁸ Accurint is a database that collects a broad array of public records on businesses and individuals. For personal searches, Accurint contains information on Social Security numbers, driver’s licenses, and professional licenses. Accurint can also reveal connections between people, businesses, assets, and locations that are not available in public records. For business searches, Accurint draws from corporate filings, property information, phone listings, professional licenses, and Securities and Exchange Commission filings, among other data. Information on property assets and court proceedings is also available both for individuals and businesses.

⁶⁹ Manta is an online community for promoting and connecting small businesses that contains approximately 87 million company profiles. Company profiles include information on company size, type, and location collected from multiple sources (e.g., public company financial and trade records, business registrations, government registries, and representatives of the company).

⁷⁰ LinkedIn is an online professional networking tool. Registered members create individual profiles containing information about current and past employment, education, and other professional interests, or company profiles containing general information about the business. We used only public information on the LinkedIn site.

⁷¹ National Science Foundation, *Fraud Indicators*.

⁷² Occasionally, deviation from some eligibility requirements may occur and must be approved in writing by the SBA. We did not request documentation of SBA-approved deviations from eligibility requirements.

employment at the time of the award. We considered whether the dates of employment on LinkedIn were during the award period. We considered an awardee's eligibility questionable if we found information indicating that the Principal Investigator was primarily employed at another company or institution at the time of the award. We determined that we could not verify whether an awardee met this requirement if we could not find information indicating that he or she was employed by the awardee.

- 2) *Had fewer than 500 total employees, including affiliates.* We used awardee profiles on LinkedIn and Manta and other Internet searches to verify that awardees had fewer than 500 employees. We considered an awardee's eligibility to be questionable if we found information indicating that the awardee had more than 500 employees or was affiliated with an entity with more than 500 employees.⁷³ We determined that we could not verify whether an awardee met this eligibility requirement if we could not find any information on an awardee's and/or affiliate's number of employees.
- 3) *Has a place of business and operates primarily in the U.S.* We used Accurint, company profiles on LinkedIn and Manta, State Business Registration Web sites, and additional Internet searches to verify that awardees had U.S. locations and/or operated primarily in the United States. We considered an awardee's eligibility questionable if we found information indicating that the awardee operated primarily in a foreign location. We determined that we could not verify that awardees met this requirement if we found information indicating that the awardee had foreign locations and we could not verify that it operated primarily in the United States. We did not consider contributions to the U.S. economy in this analysis.
- 4) *Was a for-profit entity.* We used the Accurint and State Business Registration Web sites to verify that awardees were for-profit entities. We considered an awardee's eligibility questionable if we found information indicating that the awardee was not organized as a for-profit entity at the time of the award. We determined that we could not verify that awardees were for-profit entities if we could not find information to confirm the type of entity.

⁷³ In determining whether affiliation exists, SBA considers factors such as ownership, management, previous relationships with or ties to another concern, and contractual relationships. However, we considered an awardee to be affiliated with an entity only if we found information explicitly stating that the awardee was owned and/or operated by the entity.

APPENDIX C

Table C-1: Estimate Descriptions, Sample Sizes, Point Estimates, and Confidence Intervals

Estimate Description	Sample Size	Point Estimate*	Confidence Interval
Awardees With Verified Eligibility (i.e., we determined that the awardee was meeting all four eligibility requirements)	137	69%	55.6%--83.2%
Awardees With Questionable Eligibility (i.e., we found information indicating that the awardee was not meeting one or more of the following eligibility requirements)	137	16%	5.4%--27.1%
Awardees With Unverified Eligibility (i.e., we could not determine whether the awardee was meeting one or more of the following eligibility requirements)	137	20%	8.6%--31.3%
Awardees with both a questionable and unverified eligibility requirement	137	6%	0.3%--11.1%

* Weighted point estimates are provided rather than point estimates and confidence intervals because of small sample sizes. Each sample statistic is weighted by the size of each stratum's population from which our sample was selected.
 Source: OIG analysis of HHS SBIR Program data, 2011.

APPENDIX D

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAR 10 2014

TO: Daniel R. Levinson
Inspector General

FROM: Ellen G. Murray */S/*
Assistant Secretary for Financial Resources and Chief Financial Officer

SUBJECT: HHS Comments on OIG Draft Report: *Vulnerabilities in the HHS Small Business Innovation and Research Program*, OEI-04-11-00530

The Department of Health and Human Services' Office of the Assistant Secretary for Financial Resources (ASFR) appreciates the opportunity to review and comment on the Office of Inspector General's draft report on *Vulnerabilities in the HHS Small Business Innovation and Research Program*, OEI-04-11-00530.

ASFR values the Small Business Innovation and Research Program (SBIR) and is committed to the successful implementation and oversight of the program. As reported, the National Institutes of Health (NIH) awards the vast majority of the SBIR awards. NIH also serves an important function of coordinating much of the program with the other participating Operating Divisions. This approach has been successful in ensuring that the Operating Divisions work together to implement the requirements of the SBIR Program Policy Directive and the Small Business Act.

ASFR concurs with the OIG that additional coordination and oversight across the participating Operating Divisions is appropriate and warranted. ASFR is currently working with the respective Operating Divisions to determine the most effective and efficient use of resources to accomplish this coordination. We will provide the OIG with an update on these efforts as they progress.

ASFR also agrees that we must ensure that applicants are in compliance with all SBIR eligibility requirements. However, ASFR has concerns about the official use of websites such as Manta and LinkedIn and other similar sites to verify applicant eligibility. These sites, in particular, are social media networking sites; they are not government owned or controlled. The accuracy, completeness, and currency of the content are at the discretion of the user. There is no validation or quality control of any of the data at these sites. Therefore, ASFR believes that such sites are not reliable sources of information for the purposes of the government confirming or questioning eligibility for its programs. ASFR will work with the respective Operating Divisions to determine if additional, appropriate checks are required on eligibility. We will provide the OIG with an update on these efforts as they progress.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office, and Jaime Durley, Deputy Regional Inspector General.

Sarah Langford served as lead analyst. Office of Evaluation and Inspections staff from the Atlanta regional office who conducted this study include Sarah McLaulin. Central office staff who provided support include Clarence Arnold, Christine Moritz, and Talisha Searcy.

Office of Inspector General

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