

## **C.1. Attachment 1**

### **Data Collection Instrument**

Public reporting burden for this collection of information is estimated to vary from 15 to 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0499). Do not return this completed form to this address.

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**National Institutes of Health**  
**Department of Health & Human Services**

**Office of Extramural Research**

**NATIONAL SURVEY TO EVALUATE THE NIH SBIR PROGRAM**

**Thank you for participating in the National Survey to Evaluate the NIH SBIR Program.**

*This survey is implemented using SSL (Secure Socket Layer) encryption technology. After you access the survey, you will see a "lock" symbol in the lower right-hand corner indicating a secure connection. Please be aware that participation in this survey is voluntary. The information you provide will be kept confidential and will not be disclosed in identifiable form to anyone but the researchers conducting the survey or as provided by law. Your privacy and confidentiality will be protected.*

**Please enter your unique ID number in the box below:**

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**Click on Start to continue.**

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If you have forgotten your ID number or are having trouble logging in, please call us at 301/608-3290 x213 or email us at [SBIRSurveySupport@humanitas.com](mailto:SBIRSurveySupport@humanitas.com) for assistance.

*Throughout this survey, please make sure you only click the buttons on each page ONCE. Please do not click the same button twice in a row, or click another button while you are waiting. Doing so will cause an error in the survey.*

## SECOND NATIONAL SURVEY TO EVALUATE THE NIH SBIR PROGRAM

The following award was identified through the National Institutes of Health (NIH) databases as a Small Business Innovation Research (SBIR) Phase II award. Please keep this particular award in mind when responding to the survey questions.

Company:	Principal Investigator:
Award Number:	Company Contact:
Project Period:	NIH Sponsoring Institute:
Project Title:	

### SECTION A

The following questions ask for information about the company identified above that won the referenced SBIR award.

**1.** To the best of your knowledge, in what year was this company founded?

\_\_\_\_\_

**2.** Which of the following best describes this company's major field of business?

(PLEASE SELECT ONLY ONE.)

Biotechnology

Pharmaceuticals

Diagnostics

Medical devices

Healthcare

Medical education, health promotion

Instrumentation

Computer hardware, software

Informatics, research

Chemicals, reagents

Environmental

Engineering, fabrication

Other (please specify): \_\_\_\_\_

**3.** If the SBIR program were not available, would the project funded by the referenced award still have been pursued?

YES

NO

NOT SURE / DON'T KNOW

**4. Which one of the following most characterizes the product, process, or service that was planned under this project?**

*(PLEASE SELECT ONLY ONE.)*

A totally new product, process, or service

An improvement to an existing product, process, or service

A combination of products, processes, or services

A new use for an existing product, process, or service

Other (please specify): \_\_\_\_\_

**5. Has the company won any other SBIR Phase I or Phase II awards, in addition to the referenced award, for products, processes, or services that are related to this project? (The awards may have different principal investigators, and they may have come before or after the referenced SBIR award and from different NIH agencies.)**

YES → CONTINUE

NO  
NOT SURE → GO TO Q.8

**6. How many SBIR Phase I awards, that involve products, processes, or services related to the project supported by the SBIR award referenced earlier, has the company won?**

\_\_\_\_\_

**7. How many other SBIR Phase II awards, that involve products, processes, or services related to the project supported by the SBIR award referenced earlier, has the company won?**

\_\_\_\_\_

**8. How important overall has SBIR support been, or how important will it be, in research and development of this product, process, or service?**

Very important

Important

Somewhat important

Not important

Not very important

**9. Did the granting of one or more SBIR awards for this product, process, or service have an impact on any of the following activities....**

*(PLEASE SELECT ONE RESPONSE FOR EACH ACTIVITY.)*

	Yes	No	Not sure
Pursuing a high-risk idea or action that might not otherwise be undertaken			
Hiring additional personnel			
Raising additional capital			
Credibility or visibility for finding partners			

## SECTION B

The following questions ask about commercialization of the product, process, or service resulting from the project supported by the referenced SBIR award.

**10. When you applied for this SBIR award, what product, process, or service did you plan to commercialize?**

(PLEASE SELECT ONLY THE ONE MOST APPROPRIATE CATEGORY.)

- Drug
- Medical device
- Biologic
- Genomic
- Research tool
- Software or hardware
- Educational materials
- Diagnostic material or device
- Measurement or assessment tool
- Environmental, ergonomic, or assistive tool
- Chemical (non-drug) or chemical process
- Non-drug therapeutic
- Other (please specify): \_\_\_\_\_

**11. Was or is FDA approval (IND, NDA, IDE, PMA, 510(k), HUD, HDE) required for the product, process, or service selected above?**

- YES —————> CONTINUE
- NO —————> GO TO Q.14

**12. Has this product, process, or service been submitted for FDA review?**

- YES —————> CONTINUE
- NO, NOT YET —————> GO TO Q.14

**13. Currently, in what stage of the FDA approval process is this product, process, or service?**

- Applied for *clinical trial* approval (IND, IDE, HUD)
- Applied for *marketing* approval (NDA, PMA, 510(k), HDE)
- Review ongoing
- Obtained approval to use in clinical trials (IND, IDE, HUD, granted an exemption from IND or deemed nonsignificant risk)
- Obtained approval for marketing (NDA, PMA, 510(k), HDE)
- Given orphan drug status
- Not approved
- Other (please specify): \_\_\_\_\_

**14. Please give any applicable trade or commercial name, the generic name, and the model number for this product, process or service:**

Trade or Commercial Name (if any):

\_\_\_\_\_

None yet; not applicable

We are interested in the **precise** trade or commercial name of the product, process, or service resulting from this supported research. A trade or commercial name, which may or may not be registered as a trademark, uniquely identifies the commercial product. The trade name is also commonly called the **brand name**.

Generic Name or Description:

\_\_\_\_\_

None yet; not applicable

The generic name is a **general** name for the product, process, or service. It is typically descriptive of an entire group or class of products.

Model Number:

\_\_\_\_\_

None yet; not applicable

The model number **uniquely** identifies one specific product, process, or service.

**15. A. From the following list, please select the categories that best describe the medical, societal, or technological outcome(s) that relate to the product, process, or service supported by the above referenced SBIR award.**



*(PLEASE SELECT ONLY APPROPRIATE OUTCOME(S).)*

**B. Next, select the single category that is the most important medical, societal, or technological outcome.**



**Q.15A: SELECT ONE OR MORE OUTCOMES**



**Q.15B: SELECT THE MOST IMPORTANT**



	<b>Outcomes</b>	<b>Most important outcome</b>
Preventing disease or disability		
Detecting disease or disability		
Diagnosing disease or disability		
Treating disease or disability		
Reducing the cost of medical care		
Developing information for health care professionals		
Developing health information for the general public		
Fostering new research collaborations		
Improving research tools		
Training research investigators		
Other (please specify): _____		

**16. A. From the following list, please select those population(s) who are currently using, or are likely to use, the product, process, or service developed under this project?**

**B. Next, select the single population that is the most important population.**

*(PLEASE SELECT ONLY APPROPRIATE POPULATION(S).)*

**Q.16A: SELECT ONE OR MORE POPULATIONS**

**Q.16B: SELECT THE MOST IMPORTANT**

	▼ <b>Populations</b>	▼ <b>Most important population</b>
<b>Hospitals, patients:</b>		
Outpatients		
Inpatients		
Hospital personnel		
<b>Laboratories:</b>		
Research laboratories		
Diagnostic laboratories		
<b>Healthcare providers:</b>		
Medical practitioners		
Homecare providers		
Emergency medical services		
Military medical services		
Other health services		
<b>Other populations:</b>		
General public		
Educators		
Worksites		
Schools, universities		
Police, fire, other municipal workers		
Other companies, other technologies		
<b>Other</b> (please specify): _____		



**17. Within the next few years, what is the anticipated size of the total target populations that would benefit from or use the product, process, or service being developed under this project?**

- Under 10,000 persons
- 10,000 – 49,999
- 50,000 – 199,999
- 200,000 – 499,999
- 500,000 or more
- Not sure

**18. What is the current status of the project funded by the referenced SBIR award?**

*(PLEASE SELECT ONLY ONE.)*

- Under development (project being improved, refocused, evaluated, or in clinical trials)
  - Commercialization stage
  - In use by target population (project completed, commercially available, or in use)
  - Discontinued (project ended without commercialization or without significant sales)
- > CONTINUE
- On hold (project currently inactive or awaiting funding)
  - Other (please specify): \_\_\_\_\_

GO TO Q.20

GO TO Q.20

**19. Did the reasons for discontinuing this project include any of the following....**

*(PLEASE SELECT YES OR NO FOR EACH REASON.)*

	Yes	No
Idea failed		
Market demand too small		
Level of risk too high		
Not enough funding		
Company shifted priorities		
Principal investigator left		
No FDA approval		
Licensed to another company		
Product, process, or service not competitive		
Other (please specify): _____		

▶ GO TO Q.24

**20. Which of the following describes the status of marketing activities by your company and/or your licensee for this project....**

*(PLEASE SELECT ONE RESPONSE FOR EACH ACTIVITY.)*

	Not yet planned	Planned	Ongoing	Complete	Need assistance	Not applicable
Preparation of marketing plan						
Hiring of marketing staff						
Publicity and advertising						
Test marketing						

**SECTION C**

The next group of questions asks about the economic impact of the product, process, or service resulting from the project supported by the SBIR award referenced earlier.

**21. Upon completion of the project, were (or are) sales expected? (Include both sales and sales of licenses.)**

YES —————> CONTINUE  
 NO —————> GO TO Q.24

**22. With regard to sales, which of the following resulted?**  
*(PLEASE SELECT ONLY ONE RESPONSE.)*

Sales were realized —————> CONTINUE  
 Sales are anticipated —————> GO TO Q.24  
 Other (please specify):

\_\_\_\_\_ —————> GO TO Q.24

**23. What is the dollar range of cumulative sales to date—that is, total cumulative sales through December, 2006, related to the product, process, or service developed under this project? (Please do not give incremental sales, but indicate total cumulative sales from the first sales through the most recent sales.)**

- Less than \$50,000
- \$50,000 - \$99,999
- \$100,000 - \$499,999
- \$500,000 - \$999,999
- \$1,000,000- \$4,999,999
- \$5,000,000- \$24,999,999
- \$25,000,000 - \$49,999,999
- \$50,000,000 or more

**24. What is the current number of total employees (full-time equivalents) in your company?**

\_\_\_\_\_

**SECTION D**

The following questions ask about any additional funding that your company may have received for the project supported by the referenced SBIR award.

**25.** Since the receipt of this Phase II SBIR award, has your company received any additional non-SBIR funding or capital for this project?

YES —————> CONTINUE  
 NO —————> GO TO Q.29

**26.** Do you believe that this additional funding or capital is a result of the NIH SBIR funding for the product, process, or service developed under this project?

YES  
 NO  
 NOT SURE

**27.** Thinking now about the sources of additional funding or capital for this project and its outcome (product, service, or process), were or are any of the following sources important?

*(PLEASE SELECT YES OR NO FOR EACH SOURCE.)*

Q.27: SELECT YES OR NO FOR EACH

Q 28: SELECT THE MOST IMPORTANT

	Important sources		Most important
	Yes	No	
Non-SBIR federal funds			
Your own company			
Other private company			
U.S. venture capital institution			
Foreign venture capital institution			
Private individual investor			
Personal funds			
State or local government funds			
College or university			
Other (please specify): _____			

**28.** Which source has been or is the most important source of additional funding or capital?

▶ PLEASE SELECT ONE IN THE RIGHTMOST COLUMN ABOVE.)

**29. Which, if any, of the following has your company experienced because of the product, process, or service developed during this project?**

*(PLEASE SELECT YES, NO, OR NOT SURE FOR EACH ACTIVITY.)*

	Yes	No	Not sure
Debt financing			
Private placement (angels, VC, relatives)			
Public offering			
Set up one or more spin-off companies			
Joint venture (academic or commercial)			
Strategic partnership or alliance			
Sold company			
Merged company			
Licensed agreement			

► IF YES ON Q.29, PUBLIC OFFERING, CONTINUE. OTHERWISE GO TO Q.31.

**30. A. On which stock exchange is your company listed?**

New York Stock Exchange (NYSE)

NASDAQ

American Stock Exchange (AMEX)

Other (please specify): \_\_\_\_\_

**B. What is its ticker symbol?**

\_\_\_\_\_

**SECTION E**

The next questions ask about possible contributions to the intellectual property and knowledge base resulting from support for this project by the SBIR award referenced earlier.

**31.** Which of the following items, associated with the product, process, or service developed under the project supported by the SBIR award referenced earlier, have you or your company received or achieved?

(PLEASE SELECT YES OR NO FOR EACH ITEM.)

Q.31: SELECT YES OR NO FOR EACH ITEM

Q.32: GIVE THE NUMBER FOR EACH "YES" ITEM

	You or company received or achieved		Number received or achieved
	Yes	No	
Patents			
Pending patents			
Copyrights			
Trademarks			
Manuscripts accepted for publication and publications			
Conference presentations			
Awards (such as Tibbetts or state)			
Other (please specify): _____			

**32.** For each of the items above that you or your company received or achieved, please indicate how many items were received or achieved.

▶ PLEASE USE THE RIGHTMOST COLUMN ABOVE

**SECTION F**

The last few questions ask about you and your experiences with the NIH SBIR award process.

**33. Thinking now just about the referenced award, how satisfied were you with your experiences going through the SBIR application, review, and award process?**

*(PLEASE SELECT ONE IN EACH ROW.)*

	Completely Satisfied	Mostly Satisfied	Mixed	Mostly Dissatisfied	Completely Dissatisfied	Not Applicable
Obtaining information about the SBIR program						
Instructions for preparing applications						
Review process						
Award process						
Post-award administration						
Other (please specify): _____						

**34. Were you aware that you could contact NIH staff for additional information or assistance about any aspects of the SBIR grant review, award, and management process?**

YES  
NO

**35. Based on your experiences with this and other SBIR awards, do you have any suggestions, comments, or criticisms to offer about both the strengths and weaknesses of the SBIR program? (Your advice will be valued greatly.)**

**36. Which of the following best describes your role in the SBIR award referenced earlier?**

*(PLEASE SELECT ONLY ONE.)*

- Initial principal investigator
- Subsequent principal or other investigator (full-time, part-time, or consultant)
- Business official on the SBIR application
- Other business official (company officer, board member, owner, or other official)
- Other (please specify): \_\_\_\_\_

**37. Which of the following characterize your current relationship with this company?**

*(PLEASE SELECT YES OR NO FOR EACH RELATIONSHIP.)*

	Yes	No
An employee		
An owner		
Part of management		
A shareholder		
Other (please specify): _____		

**38. How well do you feel you were able to recall the information that this survey requested about the referenced SBIR award?**

- Very well
- Well
- Somewhat well
- Not well
- Not very well

*Thank you very much for your time and effort spent in completing this questionnaire. NIH is extremely appreciative and will use the information to enhance the administration of the SBIR Program.*