



NIH SCIENTIFIC MANAGEMENT REVIEW BOARD



SBIR/STTR Background and Charge to SMRB

**SBIR/STTR Working Group
May 29, 2012**

Four horizontal bars of different colors (green, red, blue, purple) and one yellow bar, all of varying lengths, stacked vertically.

Solomon Snyder, MD

Professor of Neuroscience, Pharmacology and Molecular Sciences, and Psychiatry - Johns Hopkins University

Overview

- **Background and Role for SMRB**
- **Charge to the NIH SBIR/STTR Working Group**
- **Process for Considering Change**
- **Next Steps**

Working Group Roster

Non-Federal

Solomon Snyder, MD (*Chair*)

William Brody, MD, PhD

Gail Cassell, PhD

Hon. Daniel Goldin

Arthur Rubenstein, MBBCh

Norman Augustine
(*ad hoc*)

Federal

Josephine Briggs, MD

Richard Hodes, MD

Roderic Pettigrew, PhD, MD

Susan B. Shurin, MD

Harold Varmus, MD

SBIR/STTR Legislative History

Small Business Innovation Development Act of 1982 (PL 97-219)

Federal agencies with extramural R&D budgets > \$100 million allocate 2.5% to an agency SBIR program

Small Business Technology Transfer Act of 1992 (PL 102-564)

Federal agencies with extramural R&D budgets > \$1 billion allocate 0.3% to an agency STTR program

Mission of the SBIR/STTR Programs

SBIR/STTR

SMALL BUSINESS INNOVATION RESEARCH
SMALL BUSINESS TECHNOLOGY TRANSFER

To support scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy.

Goals of the SBIR/STTR Programs

- Stimulate technological innovation;
- Meet Federal R&D needs; (*not an STTR priority)
- Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons; and
- Increase private-sector commercialization of innovations derived from Federal R&D funding.

*STTR program requires small businesses to formally collaborate with research institutions.

Defined by the US Government

Impetus for SMRB Charge

- With a budget of nearly \$32 billion, NIH funds one of the largest SBIR/STTR programs.
- The mission of NIH – to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability – makes the NIH SBIR/STTR programs unique in that:
 - The NIH mission is not focused on developing products and technologies for use by NIH; and
 - Identifying what has potential “commercial value” that aligns with the NIH mission can be both challenging and complex.

Impetus for SMRB Charge *(cont.)*

- Reauthorization of the SBIR/STTR* programs requires increasing the set-aside percentages over the course of the next 6 years despite the projection of flat budgets

Fiscal Year	SBIR Set-Aside	STTR Set-Aside
2012	2.6%	0.35%
2013	2.7%	0.35%
2014	2.8%	0.40%
2015	2.9%	0.40%
2016	3.0%	0.45%
2017	3.2%	0.45%

*P.L. 112-81

Charge to the SMRB

**Recommend strategies for how NIH
can optimize its utilization of the
SBIR/STTR programs in keeping with
the NIH mission.**

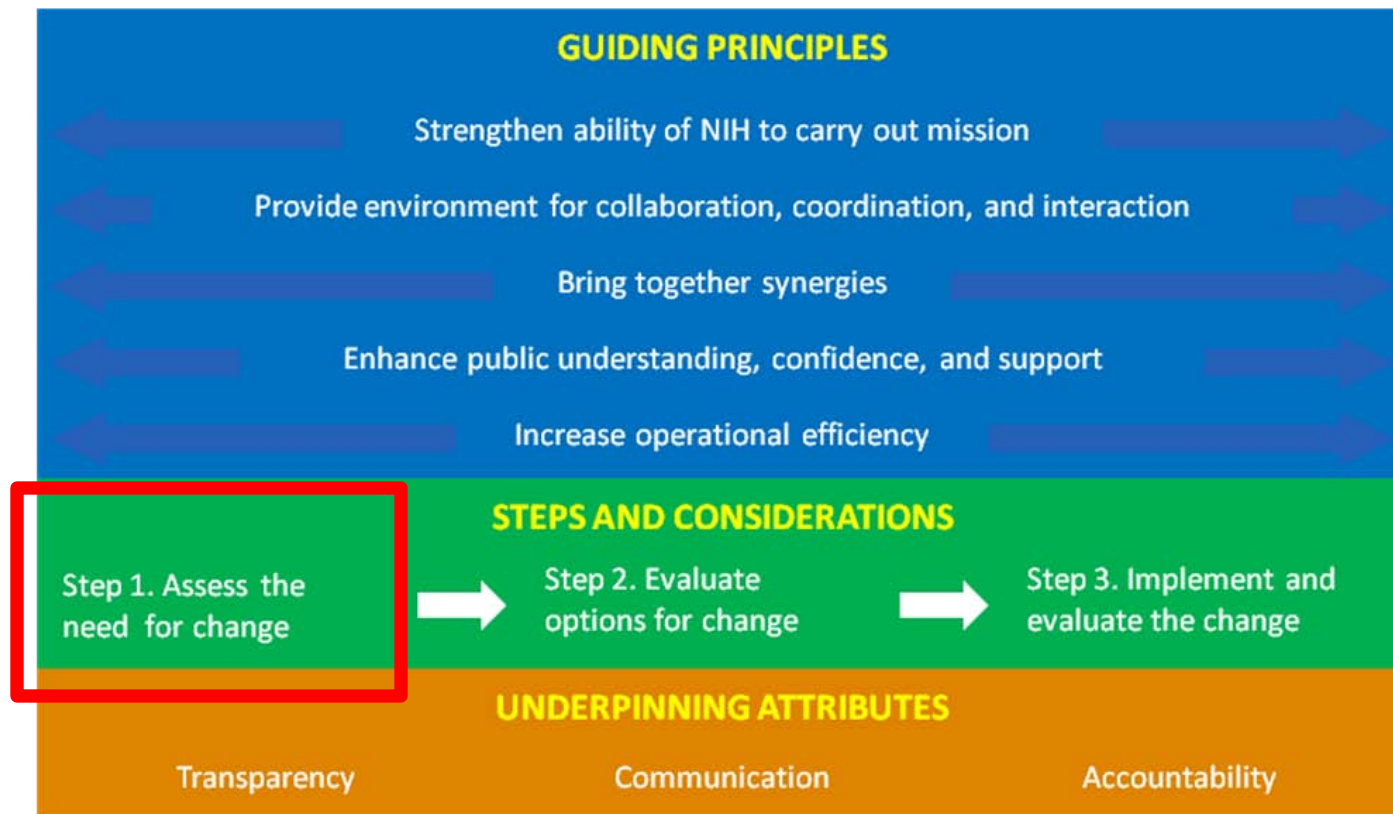
Charge Considerations

How can NIH support the SBIR/STTR programs in ways that:

- **Foster innovation within small businesses that aligns with the priorities of the NIH ICs;**
- **Fund quality proposals yielding the greatest potential for successful commercialization; and**
- **Leverage existing resources and expertise to enable the success of its grantees.**

Framework for Deliberating Organizational Change and Effectiveness

- Apply framework and process for considering change, as outlined by the Deliberating Organizational Change and Effectiveness (DOCE) Working Group:





Data Collection: Prior Recommendations

GAO

 United States Government Accountability Office
Report to Congressional Requesters

NRC, 2009a

SMALL BUSINESS INNOVATION RESEARCH

 Information on
Awards Made by NIH
and DoD in Fiscal
Years 2001 through
2004

The electronic version of this report was reprinted April 23, 2006, to report cover title displayed in the previous version. The time period "Years 2002 through 2004" has now been corrected to read "Fiscal Years 2001 through 2004."



GAO-06-345

GAO, 2006

VENTURE FUNDING AND THE NIH SBIR PROGRAM

 Committee for
Capitalizing on Science, Technology, and Innovation
An Assessment of the Small Business Innovation Research
Program
Policy and Global Affairs
Charles W. Wessner, Editor

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NRC, 2009b

 An Assessment of the Small Business Innovation Research Program at the National Institutes of Health
http://www.nap.edu/catalog.php?record_id=11964

AN ASSESSMENT OF THE SBIR PROGRAM AT THE NATIONAL INSTITUTE OF HEALTH

 Committee for
Capitalizing on Science, Technology, and Innovation
An Assessment of the Small Business Innovation Research Program
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NIH, 2009

National Survey to Evaluate the NIH SBIR Program

Final Report

 National Institutes of Health
Office of Extramural Research

January 23, 2009



GAO, 2011

GAO

 United States Government Accountability Office
Report to Congressional Requesters

August 2011

SMALL BUSINESS INNOVATION RESEARCH

 SBA Should Work with
Agencies to Improve
the Data Available for
Program Evaluation

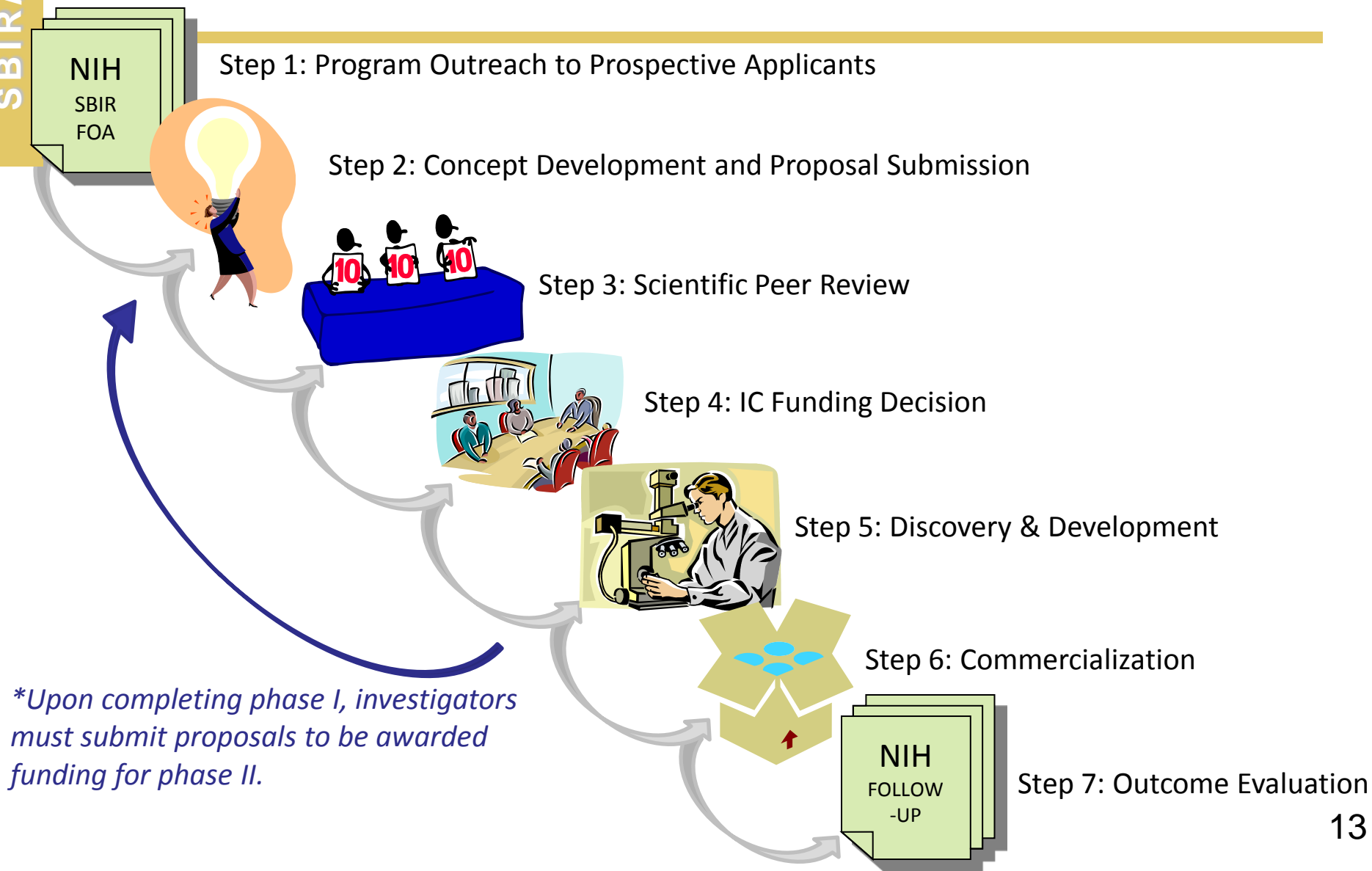
U.S. Government Accountability Office

GAO 90 YEARS 1921-2011

12

GAO-11-658

Data Collection: SBIR/STTR Lifecycle



Data Collection: Consultations

- **May – June**
 - NIH IC Directors
 - SBIR/STTR staff
- **June – July**
 - SBIR/STTR staff at other Federal agencies
 - Representatives of the Small Business Administration
- **August – October**
 - Representatives of the small business community
 - SBIR/STTR grantees
 - Representatives from Angel/Venture Capital Investors
 - Academic inventors

Preliminary Findings: From Good to Great

- **NIH SBIR/STTR programs are meeting their statutory objectives**
- **Flexibility in IC program management is a considerable strength**
- **ICs vary considerably in terms of degree of program management, size of budget, implementation of pilot initiatives, assessment of success, etc., creating a unique opportunity to leverage lessons learned**

Preliminary Findings: From Good to Great (cont.)

- **Recommendations to date are “designed to improve the operation of an already effective SBIR program at NIH” (NRC, 2009) and relate to:**
 - **Establishing reliable metrics and outcomes that can be used to assess the program’s impact on supporting small businesses and advancing human health**
 - **Strengthening the application process to save small businesses both time and effort**
 - **Enhancing scientific peer review and the criteria by which applications are judged**
 - **Defining and tracking success, in considering the public’s investment in these programs**

Next Steps

- **Continue consultations and data analyses**
- **Draft agenda for first stakeholder meeting – July 11**
- **Draft preliminary findings and recommendations**
- **Draft agenda for second stakeholder meeting (~October)**