



NIH SCIENTIFIC MANAGEMENT REVIEW BOARD



SBIR/STTR Background and Charge to SMRB

**SBIR/STTR Working Group
October 3, 2012**

A series of five horizontal bars of different colors (green, red, blue, purple, and yellow) stacked vertically, with each bar slightly offset to the right from the one above it.

Gail Cassell, PhD

Visiting Professor, Department of Global Health and Social
Medicine – Harvard Medical School

Overview

- **Charge to the SMRB**
- **Process for Considering Change**
- **Preliminary Findings**
- **Goals of Today's Meeting**

Impetus for SMRB Charge

- With a total budget of nearly \$32 billion, NIH funds one of the largest SBIR/STTR programs (FY12 = \$717 million)
- 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.**

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

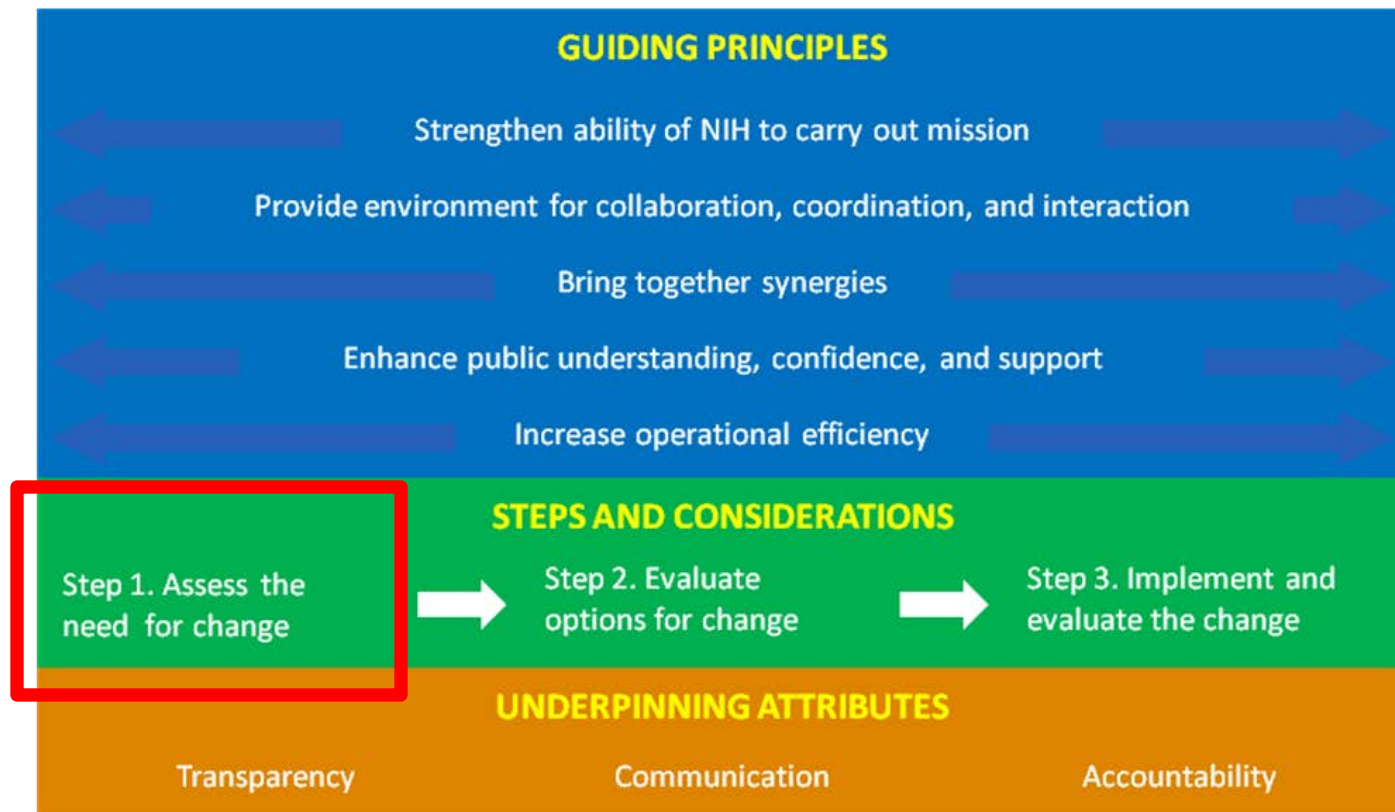
Roderic Pettigrew, PhD, MD

**Susan B. Shurin, MD
(*ad hoc*)**

**Harold Varmus, MD/Michael
Weingarten (*ad hoc*)**

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



GAO-06-565

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

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

Copyright © National Academy of Sciences. All rights reserved.

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=11264

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
Policy and Global Affairs
Charles W. Wessner, Editor

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

Copyright National Academy of Sciences. All rights reserved.
This summary plus thousands more available at <http://www.nap.edu>

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

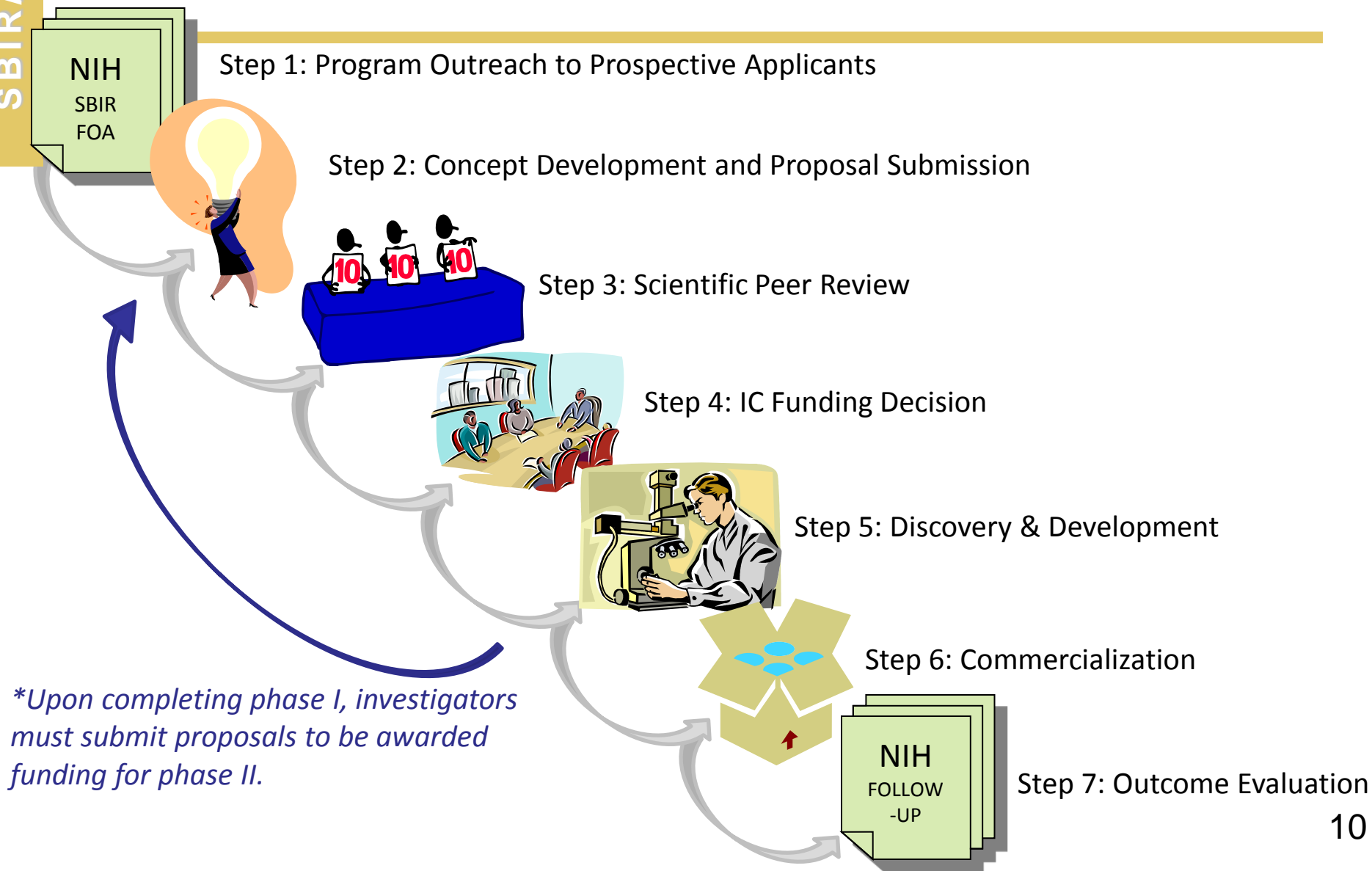
U.S. Government Accountability Office

GAO 90 YEARS 1921-2011
ACCOUNTABILITY • INTEGRITY • RELIABILITY

9

GAO-11-658

Data Collection: SBIR/STTR Lifecycle



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**

Meeting Goals

PANEL PRESENTATION I

Discussion with Representatives of the Small Business Community

Session Goals

- Solicit input from cutting-edge innovators about their experiences in commercializing biomedical products and with the NIH SBIR/STTR programs (if applicable)
- Identify ways in which SBIR/STTR programs could be strengthened, taking into consideration each step of the SBIR/STTR lifecycle
- Discuss the role of SBIR/STTR programs in the commercialization process and consider metrics for evaluating grantees success

Meeting Goals

PANEL PRESENTATION II

Discussion with Investors in Biomedical Research

Session Goals

- Solicit input from entrepreneurs regarding their experiences investing in biomedical products developed by small businesses
- Describe characteristics of projects that tend to achieve success in commercializing products and identify associated milestones for predicting this success
- Discuss the role of SBIR/STTR programs in the commercialization process and identify ways in which these programs could be strengthened

Meeting Goals

PANEL PRESENTATION III

Strategies for Increasing Commercialization

Session Goals

- Identify challenges faced in moving promising biomedical products through the discovery and investment cycles
- Discuss strategies and best practices for increasing the commercialization of biomedical products
- Deliberate the role of NIH SBIR/STTR programs in the commercialization pipeline for biomedical products