U.S. Department of Health and Human Services
Public Health Service
Final Progress Report Instructions

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TABLE OF CONTENTS

A. Final Progress Report Requirement and Submission Information

A final progress report is required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. The report is due within 90 of the end of the project period. If a competitive renewal (Type 2) application has been submitted, whether funded or not, the progress report contained in that application may serve in lieu of a separate final progress report at the discretion of the funding Institute/Center (IC). Otherwise, a final progress report should be prepared in accordance with the requirements below and any specific requirements set forth in the terms and conditions of the award.

There is no form page for the final progress report. At the top of the first page provide the grant number, project title, name of grantee organization, project period (start and end dates), name of the PD/PI, and clearly indicate "Final Progress Report."

All grantees are strongly encouraged to submit the final progress report electronically through the eRA Commons at https://commons.era.nih.gov/commons/. See the eRA Commons User Guide, section 9.11 Closeout. Additional information on electronic submission of closeout documents is available at the NIH eRA Commons homepage or by contacting the eRA help desk at: http://ithelpdesk.nih.gov/eRA/ or Toll-free (866) 504-9552, Phone 301-402-7469, TTY 301-451-5939.

If not submitted electronically through the eRA Commons, the original final progress report should be submitted to the centralized mailing address at:

Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 594-6584

If submitted via paper to the centralized mailing address, the report should contain the signature of a Signing Official/Authorized Organization Representative.

Additional information on submitting closeout documents to AHRQ, CDC, FDA and IHS can be obtained from their websites.

Public reporting burden for this collection of information is estimated to average 1 hour 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 (0925-0002). Do not return the completed form to this address.

B. Instructions for All Final Progress Reports (exclusive of SBIR/STTR Phase II Final Progress Reports)

There is no form page for the final progress report. At the top of the first page provide the grant number, project title, name of grantee organization, project period (start and end dates), name of the PD/PI, and clearly indicate "Final Progress Report."

The final progress report should include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. Grantees should also

report additional information required by the awarding IC in program-specific final progress report instructions. The final progress report also should address the following when applicable:

1. Report on the final enrollment data for study subjects based on sex/gender, race, and ethnicity (use the Inclusion Enrollment Report).
2. If appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see Public Policy Requirements and Objectives—Inclusion of Children as Subjects in Clinical Research).
3. Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed. If the initial research plan addressed, or the terms of award require, a formal plan for sharing final research data, model organisms, Genome Wide Association Studies data, or other such project-specific data, provide a final statement on the implementation of that plan.
4. Publications that were authored or co-authored by the PD/PI and arose from the award must include the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.
5. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report.

C. Instructions for SBIR/STTR Phase II Final Progress Reports

Final reports serve as an important source of material for staff of the IC in preparing annual agency reports, for planning purposes, for tracking program outcomes, and in communicating scientific accomplishments achieved through the SBIR/STTR program. There is no form page for a final SBIR/STTR report, but the format below is strongly recommended and is available as a fillable MS Word file at: http://grants.nih.gov/grants/funding/finalprogressreport_SBIR_PhaseII.doc. All 15 items, plus requested attachments, should be provided. If uploaded through the Commons all documents must be combined into a single pdf.

1. Provide the grant number, project title, name of grantee organization, project period (start and end dates), and name of the PD/PI.
2. If the company has undergone a recent name change provide the new name.
3. Provide a summary of the specific aims and impact on public health of the Phase II grant. (limit 1,300 characters)
4. Provide a succinct account of published and unpublished results, indicating progress toward achievement of the originally stated aims.
5. List patents (U.S. and international), copyrights, trademarks, and invention reports, if any, that resulted from the award.

	# Filed (Enter Numeric Value)	# Approved (Enter Numeric Value)	Patent Numbers (separated by commas)
Patents			
Copyrights			
Trademarks			

	# Filed (Enter Numeric Value)	# Approved (Enter Numeric Value)	Patent Numbers (separated by commas)
Invention Reports			

Describe other printed materials or demonstration of IP protection, if any, that resulted from the award. (limit 500 characters)

6. Check all boxes below that best describe the technology developed from this SBIR/STTR.

☐ Small Molecules: The development or reformulation of drugs as chemical substances used in the treatment, cure, prevention, or diagnosis (*in vivo*, imaging agents, etc) of disease or used to otherwise enhance physical or mental well-being; includes so-called “naturopathic” or naturally-derived substances in alternative care regimes.

☐ Biologics: A medicinal product created by biologic processes, such as a vaccine, blood or blood component, allergenic, somatic cell, gene therapy, tissue, recombinant therapeutic protein, or living cells.

☐ Companion Product: A diagnostic, therapeutic, or device that must be used in combination with another diagnostic, therapeutic, or device type (e.g. companion diagnostic for a specific therapy; a small molecule that activates expression from a gene therapy vector; a device and imaging agent that work together). This does not include "drug cocktails." The Phase II project may include only one aspect of the companion product.

☐ Medical Devices: The development and/or use of instruments or machines, used in the diagnosis of disease or in the cure, mitigation, treatment, or prevention of disease or conditions associated with the deterioration of physiological function (e.g., prostheses); this would also include medical imaging devices and the use of innovative materials to construct new devices.

☐ Research Tools: The development of new or improved tools, devices, and sensors to enhance laboratory or field studies on humans, animals, or any model system. This includes tools to broaden the research knowledge base and for biomonitoring.

☐ Biotechnology: The use of microorganisms, such as bacteria or yeasts, to perform specific industrial or manufacturing processes.

☐ *In Vitro* and *Ex Vivo* Diagnostics: The use of tools (software, hardware or combinations) to identify or screen for medical conditions and determine whether specified diseases or disease processes are present in living organisms. Includes the use of these tools for non-clinical screenings and to provide insights in the work of clinicians, providers, manufacturers of equipment, and companies involved in therapies associated with disease.

☐ Healthcare IT: Approaches and tools derived from information technology that allow for the management of research, educational and medical information. Includes software, media, educational tools, and digital health.

☐ Other, please specify. (limit 500 characters)

Describe the technology’s intended commercial application, potential market size, and who will use it. (limit 500 characters)

7. Check the box that best describes the current R&D status of the product.

☐ Non-clinical technology in prototype development/testing stage

☐ Non-clinical technology in full development/testing stage

☐ Pre-clinical development

☐ Clinical development

☐ Commercially available

☐ Discontinued

☐ Other (limit 500 characters)

Describe the current status of this product and explain reasons if discontinued. (limit 500 characters)

8. Check the boxes that best describes the regulatory approval status for your product, process, or service.

(Check all that apply)

☐ Not applicable (no regulatory approval needed)

FDA approval:

PMA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
510(k)	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
IDE	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
BLA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
IND	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
NDA	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
FDA Facility Registrations	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected

EU/UK approval:

CE Mark	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected

☐ Other regulatory submissions and approvals. List all other planned and submitted regulatory applications, including any foreign submissions. (limit 500 characters)

9. Check the boxes that best describe the reimbursement approval status of the product, process, or service.

(Check all that apply)

☐ Not applicable

CMS Reimbursement	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected
Private Payer Reimbursement	☐ Not yet submitted	☐ Submitted	☐ Approved	☐ Rejected

10. Check the boxes that best describe the status of clinical trials for your product, process, or service.

(Check all that apply)

☐ Not applicable

Phase I clinical trial	☐ Ongoing	☐ Completed
Phase II clinical trial	☐ Ongoing	☐ Completed
Phase III clinical trial	☐ Ongoing	☐ Completed
Premarket approval (PMA) device trial	☐ Ongoing	☐ Completed
Phase IV Postmarketing study	☐ Ongoing	☐ Completed
Outside of the United States (OUS)	☐ Ongoing	☐ Completed

11. Describe company outcomes occurring, at least in part, as a result of this award.

(Check all that apply)

☐ Follow on funding — Total cumulative dollar amount $_____

(check all that apply and enter amount invested)

☐ Venture Capital (VC) — Total cumulative dollar amount_____

☐ Angel — Total cumulative dollar amount_____

☐ State/Local — Total cumulative dollar amount_____

☐ Strategic partnership — Total cumulative dollar amount_____

☐ Federal — Total cumulative dollar amount_____

☐ Internal SBC Funds — Total cumulative dollar amount_____

☐ Other (Foundations, bank loans, etc) — Total cumulative dollar amount_____

☐ Out-licensing agreements/sale of IP — Number _____

Total cumulative dollar amount_____

Nature of agreement _____

☐ In-licensing agreements — Number _____

Total cumulative dollar amount_____

Nature of agreement _____

☐ Strategic partnership/s that do not include funding

Name(s) _____

☐ Spin-off companies — Name(s) _____

☐ Public offering — Country _____

Year _____

Value _____

☐ Merger or acquisition of Awardee — Name of acquirer _____

Year _____

Total value _____

Further description of any economic, commercial or other outcomes attributable to the award, including any pending investments or strategic partnerships. List names and nature of significant partnerships, if available. (limit 1000 characters)

12. Describe the sales or revenues, if any, which resulted from this SBIR/STTR award (not including award funds).

☐ No sales or revenue to date.

Please provide projected date of first sale/commercial service launch in MM/DD/YYYY:_____

Sales or service to:

(check all that apply and enter the total cumulative dollar amount to date)

☐ Federal _____

☐ Private sector _____

☐ Other _____

List the generic and/or commercial name of the product(s), process(es), or service(s), if any, that resulted, at least in part, from this award. If applicable, indicate the number of products sold.

** If the SBIR/STTR-supported product is a component of a larger commercial product, please list the sales revenues of both the component and the commercial product*

Product or Service	Revenues Generated	Number Sold (if applicable)

13. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the Phase II award. When citing articles that fall under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.
14. Provide the current number of employees (total full time equivalents or FTEs): _____

    Provide the number of FTEs directly supported by this award: _____

    Provide an estimate of the total number of FTEs attributable to all previous and current SBIR/STTR funding received: _____
15. Attach the Inclusion Enrollment Report from the competing application instructions, with the final enrollment data for clinical research.