CLOSEOUT GUIDANCE

For
Grants and Cooperative Agreements
Supported by National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
August 2016

Purpose of this Guidance

The National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC), Office of Financial Resources, Office of Grants Services (OFR/OGS) have developed this guidance for closing out completed grant awards. Instructions for preparing four required closeout documents are provided for use by the Principal Investigator (PI) and Business Officials.

Effective Date/Applicability

This version of the guidance will apply to all awards which end on, or after, December 31, 2015. These instructions replace the NIOSH closeout guidance version dated April 6, 2011. This guidance does not replace or supersede any Department of Health and Human Services (DHHS) or CDC policies.

Required Closeout Documents and Timeline

In most cases, the PI and the institution's business official will receive an advance reminder from their assigned OFR/OGS Grants Management Specialist (GMS) that the official project period end date is approaching. The official project period end date is specified in the most recent Notice of Award (NOA). It can also be obtained from the institution's business office. Closeout documents must be submitted no later than 90 days after the expiration of the project period. NIOSH will close out grants as soon as possible after their official end date or termination date as provided in 45 CFR 75.381. It is therefore essential that grantees are timely in following this guidance.

If the 90 day timeline cannot be met for submitting the required closeout documents, a prior approval request for an extension must be submitted to the GMS named in the most recent NOA with a written justification for the delay. The PI should follow-up with the GMS to verify that the request has been received and approved.

In some cases the grantee may need to request a no cost time extension (NCTE) to complete specific work on the grant beyond the existing project period end date. A sample template can be found at http://www.cdc.gov/grants/alreadyhavegrant/priorapprovalrequests.html, and the request must be submitted to the GMS 10 days or 30 days if additional cost are required.

With the exception of the two situations described above, grantees must submit the following documents as requested:

1. *Final Progress Report:* one signed PDF document and one editable electronic document, e.g. Microsoft Word file.
2. Federal Financial Report SF-425: electronic submission to eRA Commons
3. *Equipment and Inventory Report:* Tangible Personal Property Report SF-428-B*:* an original signed paper document an editable electronic file.
4. Final Invention Statement and Certification (Form HHS 568)*:* an original signed paper document.

Failure to submit timely and accurate final reports may affect future funding to the recipient institution or the PI. It is the institution's responsibility to be aware of and comply with all grant closeout procedures and timelines. For additional information, please refer to Section II of the HHS Grants Policy Statement.

Closeout of a grant does not automatically cancel any requirements for property accountability, record retention, or financial accountability. Following closeout, the recipient remains obligated to return funds due as a result of later refunds, corrections, or other transactions, and the federal government may recover amounts based on the results of an audit covering any part of the period of grant support.

Closeout Document 1: *The Final Progress Report* (submit as a 508 compliant PDF and an editable 508 compliant electronic document, e.g. Microsoft Word file)

The Final Progress Report likely represents the **most important** report which a PI prepares for a grant. It communicates the cumulative results and major accomplishments of the research, including accomplishments for each aim and whether all research aims were fully completed. NIOSH is tasked with exercising stewardship of public funds and providing evidence of the value of federally sponsored research on occupational safety and health issues. Documenting accomplishments and outcomes of the research project is critical.

NIOSH uses the content of Final Progress Reports to inform Congress, the Executive Branch, the CDC and NIOSH Divisions and Offices, and other stakeholders on successes and impacts of the NIOSH extramural research program in addressing occupational safety and health issues. It is essential the PI provide a clear, coherent, well-organized description of key findings.
The format for Final Progress Reports presented below is primarily for single project grant or cooperative agreement. R01, R03, R21, K01, R43, R44, and U01 awards typically support single component, single project awards.

Grantees should contact the NIOSH Scientific Program Official (SPO, or the CDC GMS assigned to their award (named in the most recent NOA) with any questions about the use of this guidance. For example, clarifications typically include centers and other complex awards

typically funded as T03, T42, U19, U24, U54, and U60 mechanism e.g., Ag Center, Total Worker Health Center, Education and Research Centers, and expanded state surveillance projects. For clarity, the final progress report and the annual report of accomplishments and impacts for the final year are not the same.

Title Page
The title page must contain the PI's name, affiliation and contact information (address, telephone, email); the institution to which the award was made (include full address); project title; date and number of report (if any); co-investigators, project director and sponsors; grant number(s); the project starting and ending dates; and the date the final report was completed.

Table of Contents
Format the table using the headings, sections and sub sections listed below.

List of Terms and Abbreviations

Abstract (500 words or less)
The abstract is a brief summary that informs others about the key findings and importance of the project. It must provide a concise overview of the occupational safety and health issues that were addressed, worker group(s) or setting(s) studied, the approaches used, and key findings or conclusions. The abstract should also clearly state how the results of the study relate or translate to improvements for worker safety and health.

Project title, PI(s) and contact information for the PI who will receive correspondence about the study should be listed at the top of the abstract. The abstract should be 'stand-alone' and suitable for dissemination to a wide audience. It should be written in a style that can be understood by general readers interested in science issues (for example, the style used by *Scientific American or Public Health Reports*). Technical terms, jargon or acronyms in the abstract should be minimal. The 500 word limit applies to the body of the abstract. Abstracts far in excess of 500 words will be returned to the PI for revision and resubmission to OGS and NIOSH.

NIOSH may provide the abstract to members of Congress, the Secretary of HHS, the NIOSH Director or the CDC Director, other government agencies or organizations, and interested individuals. Once approved by CDC/ NIOSH, the Final Progress Report abstracts will be used without subsequent editing. The PI may be contacted if clarifications are needed.

Section 1 of the Final Progress Report (2-page limit)
Please provide a concise, cogent Section 1 *using the headings below* that can be understood by a broad audience. PIs for Centers of Excellence and other complex awards with more than one project or component must contact the NIOSH SPO named in the NOA for specific instructions as to page limits.

Significant or Key Findings. These are the most important results of the project, and should address the project aims. Use a separate paragraph for each key finding. Describe major or significant research products (stated anticipated outputs in the application) whenever possible. It may be useful to identify whether and why the completed research yielded basic/applied, translational, or intervention related contributions (outputs) and for what worker populations or area of occupational safety and health. The PI is encouraged to review the NIOSH program portfolio webpage, as appropriate. Details may be elaborated in the Scientific Report.

Translation of Findings. Provide a description and/or interpretation of how the significant findings can be used to prevent workplace diseases and injuries, or modify contributing or risk factors, or improve safety practices or programs. Highlight to what degree and types of translation and dissemination was achieved i.e., type of research transfer. If specific recommendations are made for reducing hazards on the job, the language should be as non-technical as possible to communicate to employers or employees. It is important the PI identify how these findings have been, or may be, adopted or adapted in the workplace. If the findings cannot yet be applied to the workplace, this section should address how they can be used to guide future planning or decision-making (e.g., intervention development). The PI is encouraged to review the CDC Knowledge for Action Framework, especially the translation phase, at http://www.cdc.gov/pcd/issues/2011/mar/10_0012.htm and research to practice at NIOSH website resources at http://www.cdc.gov/niosh/r2p/.

Research Outcomes/Impact. The primary goal is to answer questions such as "How did this project lead to improvements in occupational safety and health?" or "How can the findings of this study guide or make improvement in future investigations and research?" Address how your project relates to occupational safety and health with regard to improved practices, prevention or intervention techniques, scientific assessment or surveillance, safety communication, economic or commercial, legislation, policy or use of technology. Outcomes should be explained and classified in one of the following ways:

1) potential outcomes, i.e., findings, results, or recommendations that could impact workplace risk if used;
2) intermediate outcomes, i.e., how findings, results, or recommendations have been used by others to influence practices, legislation, product design, safety management program and training and so forth; and
3) end outcomes, i.e., how findings, results, or recommendations have contributed to documented reductions in work-related morbidity, mortality, and/or exposure.

Section 2 of the Final Progress Report

Scientific Report. This section should contain the following: background for the project, specific aims, methodology, results and discussion, and conclusions. More detail should be provided in this section than in the Section 1 "Significant or Key Findings." **This section can be as technical as the author would like, although PIs are encouraged to limit the Scientific Report to less than 50 pages.** Each of the specific aims originally planned or added during the project must be

addressed in terms of what was accomplished or what barriers and obstacles impeded progress. In this way there will be a complete documentation of the efforts for the grant.

Publications

**List publications in calendar year order by most recent year first; if the publications aren't completed in this order the Section 2 will be returned to the PI for reformatting.*

List the published or "in press" articles resulting from the grant support. NIOSH support should be acknowledged in each article. A copy of reprints or publications not previously submitted should accompany the Final Progress Report. For publications resulting after the Final Progress Report is completed, please inform the NIOSH Scientific Program Official (SPO). Grantees are reminded that they are required to acknowledge federally funded research support from CDC/NIOSH in publications and all other information or media disseminations.

It is important that only publications and other documents resulting directly from the most recent competitive segment (usually 1 to years) be included. Publications and other documents that are attributable to prior project periods should not be included.

Citation Format Examples

Journal Article

Clark WW, Popelka GR: [1989] Hearing Levels of Railroad Trainmen. Laryngoscope 99:1151-1157.

Gomes M, Santella RM: [1990] Immunologic Methods for the Detection of Benzo(a)pyrene Metabolites in Urine. Chemical Research in Toxicology, in press.

Book

Trush MA, Thompson DC: [1989] Enhancement of Chemical Activation Via Radical- Dependent Mechanisms: An Emerging Concept in Chemical-Chemical Interactions. In: 2 Oxygen Radicals in Biology and Medicine, (eds. MG Simic, KA Taylor, JF Ward, CV Sonntag), Plenum Publishing Corporation, pp 739-744.

Murlas CG: [1989] Environmental Airway of Mucosal and Changes in Hyperreactivity. In Airway Epithelium: Structure and Function in Health and Disease, (eds. S Farmer, D Hay), Marcel Decker Inc., in press.

Proceedings

Park MY, Casali JG: [1989] A Laboratory Simulation of Selected In-field Influences on Hearing Protector Performance. Proc of 1989 Human Factors Society 33rd Annual Conference, Denver, Colorado, 946-950, October 16-20.

Dissertation/Thesis
Holton PM: [1986] Particle Size-Dependent leakage through the Face seal of Negative Pressure Half-Mask Respirators, Ph.D. Thesis, University of Cincinnati.

In addition to the final report and publications please include the following:

1. Include the Cumulative Inclusion Enrollment Table: for non-exempt human subject research (form and instructions can be found at (http://grants.nih.gov/grants/funding/2590/2590.htm). Studies involving a foreign research component should report enrollment separately from that of USA (domestic) enrollment. Note: For complex or multi-component awards (e.g., Center award), project specific inclusion enrollment is required. Information that is considered proprietary for commercial purposes should be clearly noted as such in case a Freedom of Information Act (FOIA) request is received. Otherwise, the entire report may be released.

2. Inclusion of gender and minority study subjects. When applicable, use the gender and minority inclusion table provided in the PHS 2590 (http://grants.nih.gov/grants/funding/2590/2590.htm).

3. Inclusion of Children. When applicable, indicate if children (a child is defined as an individual under the age of 21 years) were involved in the study *and* how the study was relevant for conditions affecting children.

4. Materials available for other investigators. List and describe any data, research materials (such as animal models), sensors or technologies, methods or protocols, data collection instruments, software programs, education or training curriculum, or other information resulting from the research that are available to be shared with other investigators/public *and* how it may be accessed. Regarding data, describe the nature of the micro data (while still preserving confidentiality) for open and machine readable format, whenever possible. For three or more materials available, the recommended format is a table. If the initial research plan addressed, or the terms of award require, a formal plan for sharing final research data or other project-specific data, provide a final statement on the implementation of that plan (exclusive of SBIR/STTR Phase II Final Progress Reports). For addressing plan implementation and availability, the following items should be considered:

   Digital scientific data:
   - maximize access by the general public, without charge, to digital scientific data
   - protect privacy, proprietary interests, and preserve the balance between the benefits of access/preservation and the costs

   Other elements:
   - descriptions of data
   - any standards to be used for metadata
   - mechanisms for providing access to and sharing of the data
   - provisions for reuse and redistribution of the data
   - milestones and timelines for making the data publicly accessible

- plans for archiving and long-term preservation of the data
- tools, including software, which may be needed to access and interpret the data
- any other specific requirements

Additional closeout guidance for specific type of awards:

- For **Small Business Innovation Research (SBIR) Phase I** Final Progress Report, Scientific Report: use this guidance and format recommendations to the best fit possible. In some cases, sub section may be omitted or labeled "Not Applicable." e.g., Inclusion Enrollment Table.

- For **Small Business Innovation Research (SBIR) Phase II** Final Progress Report: address the 15 items to the extent appropriate found at http://grants.nih.gov/grants/funding/finalprogressreport.pdf.

- **Conference Grant Award** Final Progress Report, Scientific Report (R13 & U13): the format may be somewhat different depending on the awarded application. For the entire project period including each meeting, the following format may be used: meeting goals and/or aims, major accomplishments for meeting plan, target worker population, collaborations and partnerships, dissemination and translation of meeting accomplishments, and public health impact. Inclusion tables(s) may not be applicable.

- For Academic and Non-academic **Training Project Grants** (TPGs T03):
    - The inclusion tables for enrollment (gender and minority study subjects and children) are not applicable.

Closeout Document 2: *Federal Financial Report (FFR) (SF-425)*

The final cumulative FFR is due 90 days after the project period end date. The final FFR should be submitted electronically through eRA Commons.

The FFR should only include those funds authorized and actually expended during the timeframe covered by the report. Handwritten forms will not be accepted. Although the sf-425 is available via eRA Commons, an electronic version of the form can also be downloaded into Adobe Acrobat and completed on-line by visiting:
http://www.whitehouse.gov/sites/default/files/omb/assets/grants_forms/SF-425.pdf

This report must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. In the event that the FFR does not match with the final expenditures reported to the Health and Human Services Payment Management System (PMS), the grantee or institution will be required to update the reports to PMS accordingly. The unobligated funds will be removed from the grant via the close out process.

If the final FFR and the Final Progress/Closeout Report cannot be submitted by the deadline, the grantee must provide a letter requesting an extension that includes the reason(s) for the delay and state the date to the GMS. Send the required documents via U.S. Postal Service or FEDEX to the GMS identified in the most recent Notice of Award. Alternatively, a co-signed electronic copy of the letter may be submitted to the GMS.

Closeout Document 3: *Equipment Inventory Report*

The Equipment Inventory Report is due 90 days after the project period end date. A signed original and two copies of the signed complete inventory must be submitted for all major equipment acquired or furnished under this project with a unit acquisition cost of $5,000 or more.

The inventory list must include the description of the item, manufacturer serial and/or identification number, acquisition date and cost, percentage of Federal funds used in the acquisition of the item. The Grantee or Institution should also identify each item of equipment that the institution wishes to retain for continued use in accordance with 45 CFR Part 75 for State and Local Governments. These requirements do apply to equipment purchased with non-federal funds for this program. The awarding agency may exercise its rights to require the transfer of equipment purchased under the assistance award referenced in the cover letter in 45 CFR 75 for State and Local Governments. We will notify the grantee or institution if transfer to title will be required and provide disposition instruction on all major equipment.

Equipment with a unit acquisition cost of less than $5,000 that is no longer to be used in projects or programs currently or previously sponsored by the Federal Government may be retained, sold, or otherwise disposed of, with no further obligation to the Federal Government. If no equipment was acquired under this award, a negative report is required.

Closeout Document 4: *Final Invention Statement and Certification*

A signed original and two copies of the signed Final Invention Statement are required. Electronic versions of the form can be downloaded by visiting http://www.hhs.gov/forms/hhs568.pdf.

The grantee must submit a Final Invention Statement and Certification (HHS-568), whether or not an invention(s) results from work under the grant. The final invention statement/certification is due 90 days after the project period end date, and must be signed by institution's Authorized Business Official.

This document must list all inventions that were conceived or first actually reduced to practice during the course of work under the project, from the original effective date of support through the date of expiration or termination, whether or not previously reported. If there were no inventions, the statement should indicate "None". If no inventions were conceived under this assistance award, a negative report is required. This statement may be included in a cover letter.

CONTACTS FOR FINAL REPORTS

Send an original and two hard copies of all report components (Final Progress Report, Final Cumulative FFR, Equipment Inventory Report, and Final Invention Statement and Certification) by email or US Postal Service or FedEx to the OFR/OGS Grants Management Specialist/Official listed in the most recent notice of award.

Email **editable electronic copies** of all final report components to both the GMS/Official and CDC/NIOSH SPO. For questions, contact the GMS or the NIOSH SPO.