

SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a hard copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information, or you may provide a valid URL link or paste the applicable section¹. Specify the review type of the collection (new, revision, extension, reinstatement with change, reinstatement without change). If revised, briefly specify the changes. If a rulemaking is involved, make note of the sections or changed sections, if applicable.

P.L. 106-554, the "Small Business Reauthorization Act of 2000, H.R. 5567" (the "Act") was enacted on December 21, 2000. The Act requires certain agencies, including the Department of Health and Human Services (HHS), to establish a Small Business Innovation Research (SBIR) program by reserving a statutory percentage of their extramural research and development budgets to be awarded to small business concerns for research or research and development (R/R&D) through a uniform, highly competitive, three-phase process each fiscal year. The Act further requires the Small Business Administration (SBA) to issue policy directives for the general conduct of the SBIR programs within the Federal Government.

Awards are made on the basis of competitively reviewed applications. The Department is requesting approval of this grant application package for the information used to apply for grants under the Small Business Innovation Research (SBIR) Phase II program. Phase I is intended to determine, insofar as possible, the scientific or technical merit and feasibility of ideas. Phase II is intended to expand on the results of and to further pursue the development of a Phase I project. Phase II is the principal research and research and development effort. It requires a more comprehensive application, outlining the effort in detail including the commercial potential. Phase II applications must be Phase I grantees with findings that appear sufficiently promising as a result of Phase I. Applications are evaluated based on published criteria by panels of experts.

The purpose of this program is to stimulate technological Innovation in the private sector, strengthen the role of small business in meeting Federal research and research and development needs, increase the commercial application of Department of Health and Human Services (HHS) supported research results, and improve the return on investment from Federally-funded research for economic and social benefits to the Nation.

This grant application package is being extended for three years from the approval date with minimal changes to reflect the move of the program from the Department of Education to the

¹ Please limit pasted text to no longer than 3 paragraphs.

Department of Health and Human Services (as mandated by the passage of the Workforce Innovation Opportunity Act (WIOA) effective July 22, 2014).

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The grant application package is necessary to standardize applications for the SBIR program across participating program offices within the Department of Health and Human Services and to ensure that the information required by SBIR program directives is collected efficiently and with the least amount of burden to the applicants. Without the information contained in this application package, the Department would not be able to comply effectively with the legislative mandate and conduct expert peer reviews to make Phase II SBIR funding decisions. Information related to the number of applicants and applicant demographics is compiled by each agency and reported to the SBA.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision of adopting this means of collection. Also describe any consideration given to using technology to reduce burden.

The Department provides electronic access to forms and instructions for SF-424, and ED 524a to record much of the information required by P.L. 106-554 and the SBA Policy Directive. Some required information items are outside the scope of these forms. The Department uses Grants.gov APPLY and the Grants Solutions of the U.S. Department of Health and Human Services processes for this program to expedite the application review and project awards. Concurrently, this electronic process is intended to reduce applicant burden.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

As stated in Item 3, the Department uses HHS standard forms to collect basic descriptive applicant information. In addition, this package seeks to reduce burden and duplication by addressing SBA Policy Directive collection mandates in a consolidated SBIR grant application package.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden. A small entity may be (1) a small business which is deemed to be one that is independently owned and operated and that is not dominant in its field of operation; (2) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; or (3) a small government jurisdiction, which is a government of a city, county, town, township, school district, or special district with a population of less than 50,000.

The SBIR competition by definition is aimed at improving the opportunity of small businesses to seek funding for development of technology that improves the lives of individuals with disabilities. By definition the SBIR program aims to increase the role of small businesses in bolstering technological improvements. To support this effort, NIDILRR has accepted only

electronic applications, submitted to grants.gov for a number of years. This decision reflected our interest in streamlining and standardizing the application process by reducing the use of paper. We conduct preapplication meetings at which we describe the program, its requirements, and the application process and answer questions from potential applicants in an effort to encourage participation in the program.

The SBIR program is purposefully targeted for small business concerns. In keeping with the legislative and regulatory intent of the SBIR program, the Department has developed this uniform and consolidated grant application package.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The Department would not comply with the legislative mandate (P.L. 106-554) if this collection was not conducted each year in which its extramural research and research and development budget exceeds \$100 million.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- in connection with a statistical survey, that is not designed to produce valid and reliable results than can be generalized to the universe of study;
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or that unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

At the discretion of the applicant, proprietary information may be included in an application. This would be for the purpose of explaining the proposed research and/or research and development activity. Confidentiality assurances and information protection mechanisms are explained in item 9.

8. As applicable, state that the Department has published the 60 and 30 Federal Register notices as required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instruction and record keeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years – even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

In 2014,, the ACL/NIDILRR staff consulted with the SBIR Program Manager (Dr. Matt Portnoy) at the National Institutes of Health regarding the agency's implementation of the SBIR program to solicit comment and review on the ACL/NIDILRR SBIR grant process and application package. There are many similarities between the two programs, driven by the SBA requirements which apply to all applicants. ACL/NIDILRR uses the same instructions as NIH for applicants to use in the development of a succinct "commercialization Plan" as required by the SBA's SBIR Policy Directive (see Section E – Grant Application Preparation Instructions and Requirements of the Application Package.).

A 60-day notice was published in the Federal Register for public comment. Only one comment, which was non-germane was received.

A 30-day notice has been prepared for review by OMB.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees with meaningful justification.

There are no payments or gifts to respondents other than the remuneration of grantees.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If personally identifiable information (PII) is being collected, a Privacy Act statement should be included on the instrument. Please provide a citation for the Systems of Record Notice and the date a Privacy Impact Assessment was completed as indicated on the IC Data Form. A confidentiality statement with a legal citation that authorizes the pledge of confidentiality should be provided.² If the collection is subject to the

² Requests for this information are in accordance with the following HHS and OMB policies: Privacy Act of 1974, OMB Circular A-108 – Privacy Act Implementation – Guidelines and Responsibilities, OMB Circular A-130 Appendix I – Federal Agency Responsibilities for Maintaining Records About Individuals, OMB M-03-22 – OMB

Privacy Act, the Privacy Act statement is deemed sufficient with respect to confidentiality. If there is no expectation of confidentiality, simply state that the Department makes no pledge about the confidentiality of the data.

There are assurances of confidentiality provided to applicants using this data collection. These respond to requirements contained in the SBIR Policy Directive (Appendix – Instructions for SBIR Program Solicitation Preparation) “Proposal Cover Sheet” {Section 3 (b) }, page 54}; and, “Considerations – Proprietary Information” {Section 5 (k) (1) (i), page 57}.

The assurances in the HHS grant application package are contained on:

- *Page 27 - (D) “Legend for Proprietary Information;” and*
- *Page 28 – (C) (1) “Rights in Data Developed Under SBIR Funding Agreements.”*

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. The justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- Indicate the number of respondents by affected public type (federal government, individuals or households, private sector – businesses or other for-profit, private sector – not-for-profit institutions, farms, state, local or tribal governments), frequency of response, annual hour burden, and an explanation of how the burden was estimated, including identification of burden type: recordkeeping, reporting or third party disclosure. All narrative should be included in item 12. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.
- If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in the ROCIS IC Burden Analysis Table. (The table should at minimum include Respondent types, IC activity, Respondent and Responses, Hours/Response, and Total Hours)
- Provide estimates of annualized cost to respondents of the hour burdens for collections of information, identifying and using appropriate wage rate categories.

Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002, OMB M-06-15 – Safeguarding Personally Identifiable Information, OM:6-104 – Privacy Act of 1974 (Collection, Use and Protection of Personally Identifiable Information)

The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Number of Applications/Respondents: 16
Hours Needed to Complete: 220
Total Burden Hours: 3,520

Estimates of Annual Cost Burden to Respondents for this Information Collection:
Preparation of Application (\$35 per hour x 3,520 burden hours) = \$123,200
Total Cost Burden = \$123,200

**Please note that this estimate was adjusted to reflect the average number of applications received in recent years. We maintain information on the number of applications received for this competition. We recently, with the approval of the Small Business Administration, agreed to give Phase I applicants up to two years to apply for the Phase II awards. That has resulted in an increase in applications in our most recent competitions. We also increased the hourly wage rate to reflect information received from discussion with our most recent applicants. This number is an average of hourly rates of senior scientists moderated by the cost of clerical and other support staff. It is an estimate as costs vary across the region of the county. All applicants are required to submit their grant applications electronically.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14.)

- The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and acquiring and maintaining record storage facilities.
- If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.

- Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government or (4) as part of customary and usual business or private practices. Also, these estimates should not include the hourly costs (i.e., the monetization of the hours) captured above in Item 12

Total Annualized Capital/Startup Cost :
Total Annual Costs (O&M) :

Total Annualized Costs Requested : _____

There are no other respondent costs beyond these provided under Item 12.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

Estimates of Annualized Cost to the Federal Government:
Work of Program Staff (\$49.00 per hour x 1,000) = \$49,000
Reviews by outside reviewers (10 reviewers working 4 days x \$200/day) = \$8,000
Total Estimated Cost to the Federal Government = \$57,000.

Please note that we corrected the time estimate for outside reviewers to reflect current practice and increased average hourly rate for program staff to reflect current salaries. It is NIDILRR's practice across all its competitions to have five reviewers on each panel. Our statutory authority is broad, and our target populations range in age from birth to death, covering all disabilities, and many areas of focus, including employment, health and function, and community living and participation. As a consequence, the SBIR competitions result in a wide variety of topics and require a broad array of expertise. We determined some years ago that having five panelists afforded us the opportunity to obtain a sufficient representation of expertise to conduct informed and fair panels. The panels typically meet three-four days depending on the number of applications received. Program staff for this program who work on this program have included GS 12, 13, and 14s, including the program lead and the grants management and other support staff who work on the competition and awarding of the grant. The \$49/hour is an estimate of the average cost for staff who work on this program. Please note, however, that in reviewing this material, [we realized that an incorrect dollar amount for reviewer reimbursement was entered into the document](#) previous documents. NIDILRR pays its reviewers \$200/day. We have adjusted this calculation to correct the typo that resulted in an inflated estimate of the cost.

15. Explain the reasons for any program changes or adjustments. Generally, adjustments in burden result from re-estimating burden and/or from economic phenomenon outside of an agency's control (e.g., correcting a burden estimate or an organic increase in the size of the reporting universe). Program changes result from a deliberate action that materially changes a collection of information and generally are result of new statute or an agency action (e.g.,

changing a form, revising regulations, redefining the respondent universe, etc.). Burden changes should be disaggregated by type of change (i.e., adjustment, program change due to new statute, and/or program change due to agency discretion), type of collection (new, revision, extension, reinstatement with change, reinstatement without change) and include totals for changes in burden hours, responses and costs (if applicable).

There are no program changes. The number of respondents has changed to 16 due to Small Business Administration rules in which applicants are required to have successfully completed SBIR Phase I. Because of this the applicant pool has been limited thus reducing the number of eligible applicants.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Some information that is collected from the applicants is reported to the SBA in order to comply with the requirements of the legislative mandate (P.L. 106-554) and the SBA Policy Directive ("Federal Register/Vol. 67, No. 185 / Tuesday September 24, 2002; "See Section 10 – Annual Report to the Small Business Administration," page 60090.)

In addition, the Department of Health and Human Services will publishes selected information about recipients of grant awards on the HHS/ACL/NIDILRR website (firm name, address, phone number, email address, award amount, Principal Investigator, project title and abstract.)

All publications generated by SBIR grantees are submitted and publicly available via the National Rehabilitation Information Center (NARIC) (www.naric.com). Results for the SBIR Phase II program are included in the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) Government Performance and Results Act (GPRA) measures and are available for public review on the Department of Health and Human Services website at website at: <http://www.acl.gov/programs/NIDILRR/>

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

OMB approval of this collection with the expiration date will be displayed.

18. Explain each exception to the certification statement identified in the Certification of Paperwork Reduction Act.

There are no exceptions to the Certification Statement.