SUPPORTING STATEMENT U.S. Department of Commerce Bureau of Economic Analysis 2017 Biomedical Research and Development Price Index Expenditure Survey OMB CONTROL Number 0608-0069

A. Justification

1. Explain the circumstances that make the collection of information necessary.

The Biomedical Research and Development Price Index (BRDPI) is developed and updated annually by the Bureau of Economic Analysis (BEA), Department of Commerce (DOC), under an interagency agreement with the National Institutes of Health (NIH).

The BRDPI measures changes in the weighted average of the prices of all the inputs (e.g. personnel services, supplies, and equipment) purchased with the NIH budget to conduct biomedical research. It is a vital tool for planning the NIH research budget. Annual changes in the BRDPI approximate how much the total NIH budget should be increased to compensate for price increases and to sustain the level of research effort supported during the previous year.

As with any price index, the BRDPI is derived each year on the basis of two variables: the price levels for different types of expenses (wages, supplies, energy costs, etc.) and the shares of those types of expenses, or "weights." For example, the largest proportion, or greatest weight, among these types of expenses is for the salaries of researchers, where the average wage rate would be the price level. The BRDPI combines price levels with expenditure weights, based on standard microeconomic price theory to derive the overall proportional change in the costs to NIH of funding biomedical R&D. The accuracy of the index thus depends on the accuracy of these two types of data.

Prior to the BRDPI survey, which was first implemented in 2005, the BRDPI estimates for FY 2003 were based on 1993 weights, which weakened the reliability of the information estimated. The survey modernized the BRDPI to account for the changing character of biomedical research, which would be better reflected by up-to-date information on prices and weights. This survey rebases the BRDPI each year because it provides annual updated expenditure weights.

BEA proposes to survey 150 organizations that receive NIH biomedical research awards. Because the top 100 organizations that received NIH awards accounted for about 77 percent of total NIH funding in FY 2015, each of these organizations will be included in the survey sample. An additional 50 organizations will be selected based on a random sample of the remaining organizations that receive NIH grants, in two groups depending on the character of the "Research and Development" that they perform. (See section B.1)

History of the BRDPI:

The BRDPI is developed and updated annually by BEA under an interagency agreement with NIH. Because BEA produces certain price indexes, and because NIH was seeking a reliable price index focused on the inputs used to perform biomedical research and development, NIH requested that BEA develop and update BRDPI estimates annually. These estimates have been, and will continue to be, used extensively by NIH in its budgetary analysis and planning. (Further

information on the BRDPI may be found at NIH's website at https://officeofbudget.od.nih.gov/pdfs/FY17/BRDPI final memo 02092016.pdf).

Legal Mandate:

This survey will be voluntary. The authority for NIH to collect information for the BRDPI is provided in 45 C.F.R. Subpart C, Post-Award Requirements, Section 74.21 which sets forth explicit standards for grantees in establishing and maintaining financial management systems and records and Section 74.53 which provides for the retention of such records as well as NIH access to such records.

BEA will administer the survey and analyze the survey results on behalf of NIH, through an interagency agreement between the two agencies. The authority for the NIH to contract with DOC to make this collection is the Economy Act (31 U.S.C. 1535 and 1536).

The "Special Studies Authority", 15 U.S.C. § 1525 (first paragraph), permits DOC to provide, upon the request of any person, firm or public or private organization (a) special studies on matters within the authority of DOC, including preparing from its records special compilations, lists, bulletins, or reports, and (b) furnishing transcripts or copies of its studies, compilations and other records.

NIH's support for this research is consistent with the Agency's duties and authority under 42 U.S.C. § 282.

2. How, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.

The information for each of the fiscal years 2017-19, collected each year through this proposed survey, will be used by BEA to develop, update, and rebase the weights used to prepare the BRDPI. Respondents to this proposed survey and future surveys will be the top 100 recipients of NIH biomedical research and development awards, according to the most recent data, plus additional institutions that will be selected randomly with probability of selection proportional to the institution's share of NIH awards. For the 2017-19 BRDPI survey, a total of 150 institutions will receive the letter and survey.

Section 515 of the Information Quality Guidelines applies to the information collected from this survey. The information is collected according to documented procedures in a manner that reflects standard practices accepted by the relevant economic/statistical communities. BEA conducts a thorough review of the survey input data using sound statistical techniques to ensure the quality of the data before the final estimates are released.

The data are collected and reviewed according to documented procedures including the use of checklists, procedures manuals, and on-going review by the appropriate supervisor or team leader. The quality of the data is validated using a battery of computerized edit checks to detect potential errors and to otherwise ensure that the data are accurate, reliable, and relevant for the estimates being made. Data are routinely revised as more complete source data become available.

3. <u>Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of</u>

information technology.

The survey will be distributed to the respondents by email. Respondents will be given the option of submitting a completed paper survey by postal (ordinary) mail, attachment to electronic mail, or the Internet to complete and submit the survey. BEA hopes to collect most of the survey data via the Internet. BEA will place the survey form, reporting instructions, and reporting requirements on its Internet Website (https://www.bea.gov/brdpi/) that is controlled by secure usernames and passwords. The website will provide an alternative, and for some, a more convenient way to transmit, access, and/or retrieve information about the BRDPI survey.

4. Describe efforts to identify duplication.

BEA is the only Federal agency that collects and develops information on biomedical research and development expenditures for purposes of developing a price index. The only other information comparable to this survey was information acquired by a similar test survey of nine institutions previously administered by Joel Popkin and Associates, under a contract with NIH. The survey experience demonstrated feasibility, but a survey of only nine institutions does not provide sufficient reliability to support an annual rebasing of the BRDPI. It is for this reason that BEA has proposed a suitable and dependable survey that will produce statistically reliable data based on a much larger sample of institutions or organizations that receive NIH biomedical research or development grants.

5. <u>If collection of information involves small businesses or other small entities, describe</u> the methods used to minimize burden.

This collection of information does not impose a significant impact on small business or other small entities.

6. <u>Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.</u>

The BRDPI is a vital tool for planning the NIH research budget. Annual changes in the BRDPI approximate how much the total NIH budget should be increased to compensate for price increases and to sustain the level of research effort supported during the previous year. The weights used to construct the index reflect the pattern of NIH expenditures in a designated base year. All price indexes, like the BRDPI, benefit by updating the weights used, which would be achieved in this case by conducting the BRDPI survey.

If the collection were not conducted or conducted less frequently, then the weights applied would be those of the most recent year for which the collection was actually made. The longer the gap in time between the current year and the survey-data collection year, the more likely it is that the true weights could have changed significantly during that interval. If the true weights change significantly, and the old weights continue to be used, then the BRDPI would be less accurate.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the OMB guidelines.

There are no special circumstances that would require information collection to be conducted in a manner inconsistent with OMB guidelines.

8. Provide the information of the PRA Federal Register notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record-keeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

The Federal Register Notice to solicit public comment was published on July 25, 2017 (Vol. 82, pages 24290-24291). No comments were received.

In 2004, seven out of nine potential respondents expressed interest in participating or willingness to support the survey. These seven organizations said that either they will be able to complete the survey form based on available information within their institutions, or they will try to support the survey. There have been no comments since that time, therefore these methods still apply.

9. Explain any decision to provide any payments or gifts to respondents, other than remuneration of contractors or grantees.

No payments or gifts are provided under this program.

10. <u>Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.</u>

The following confidentiality assurance information is provided in the letter sent to the respondents:

The information provided by the respondents will be held confidential and be used for exclusively statistical purposes. This pledge of confidentiality is made under the Confidential Information Protection provisions of Title V, Subtitle A, Public Law 107-347. Title V is the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA). Section 512 (on Limitations on Use and Disclosure of Data and Information) of the Act, provides that "data or information acquired by an agency under a pledge of confidentiality and for exclusively statistical purposes shall be used by officers, employees, or agents of the agency exclusively for statistical purposes. Data or information acquired by an agency under a pledge of confidentiality for exclusively statistical purposes shall not be disclosed by an agency in identifiable form, for any use other than an exclusively statistical purpose, except with the informed consent of the respondent."

Responses will be kept confidential and will not be disclosed in identifiable form to anyone other than employees or agents of BEA and agents of NIH, without prior written permission from the business or organization filing the data. By law, each employee as well as each agent is subject to a jail term of up to 5 years, a fine of up to \$250,000, or both if he or she makes public ANY identifiable information that is reported about a business or institution responding to the survey.

11. <u>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.</u>

No questions of a sensitive nature are asked.

12. Provide an estimate in hours of burden of the collection of information.

An estimated 120 institutions are expected to respond to the survey. Based on feedback gathered from respondents, an average burden of 16 hours per respondent was derived, producing an annual reporting burden of 1,920 hours. The burden estimate includes time for reviewing instructions, searching existing data sources, gathering or collecting the information from existing databases or records, completing the survey form, and management review of the completed survey form. The actual burden may vary from institution to institution, depending upon the number and variety of the respondent's transactions and the ease of assembling the data.

The burden of the survey will decrease as the respondents become familiar with the survey and develop routine database reports to respond. This is especially the case for the top 100 respondents that are surveyed each year.

Cost to the Respondents:

The total estimated annual cost of the survey's burden to the public is \$77,400. This estimate is based on the assumption of the hourly burden and corresponding direct monetary costs (average wage or salary compensation) to the respondent. Based on the feedback gathered from potential NIH award recipients, this survey will be prepared by a professional employee with an average hourly wage of \$31.00. Assuming the employee completing the survey is entitled to fringe benefits, the total cost (wages plus fringe benefits) to the respondent would be \$40.30 per hour. (Benefits were assumed to be 30 percent of wages, based on the latest available Bureau of Labor Statistics report on Employer Costs for Employee Compensation.) Given the estimated average burden of 16 hours per respondent, for the 120 respondents who complete the survey, and the \$40.30 average hourly compensation rate for these individuals, the total average cost per response per institution would be approximately \$645.

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in # 12 above).

Aside from the estimated hour burden and monetary costs of gathering the data for the survey, and filling out the survey form, the additional annual cost burden to respondents is expected to be negligible. Total capital and start-up costs are insignificant, because new technology or capital equipment would not be needed by respondents to prepare their responses to the survey. Consequently, the total cost of operating and maintaining the technology or capital equipment will also be insignificant. Purchases of services to complete the survey are also expected to be very small.

14. Provide estimates of annualized cost to the Federal government.

The estimated cost to the Federal Government is approximately \$80,000 per year—about 50 percent of the payment for the existing interagency agreement between NIH and BEA to prepare the BRDPI estimates. The estimate includes salaries, overhead, computer processing, and the cost of developing and administering an Internet-based survey tailored to the requirements of the BRDPI survey.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB 83-I.

There are no program changes or adjustments.

16. For collections whose results will be published, outline the plans for tabulation and publication.

Survey distribution is expected to be August of 2017, 2018 and 2019. Data collection, estimation and tabulation will be done from October through early December of the same year. The final results, analysis and report will be submitted to NIH in December. The BRDPI and some supporting details and analysis are expected to be published by January of the same fiscal year.

Publication of survey results or data will be governed by CIPSEA. (See Section A.10 on Assurance of Confidentiality.)

17. <u>If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.</u>

No request has been made to seek approval to not display the expiration date for OMB approval of the information collection.

18. Explain each exception to the certification statement identified in Item 19 of the OMB 83-I.

There are no exceptions.