

**Supporting Statement for Paperwork Reduction Act Submission
Health and Human Services Acquisition Regulation (HHSAR) Clause 352.227-11 -
Patent Rights - Exceptional Circumstances
and
HHSAR Clause 352.227-14 - Rights in Data - Exceptional Circumstances**

Justification

1. Circumstances Making the Collection of Information Necessary

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Financial Resources, Office of Acquisitions, Acquisition Policy Division, is requesting Office of Management and Budget (OMB), an extension on a previously approved information collection request, OMB number 0990-0419, titled Acquisition Regulation Clause Patent Rights and Rights in Data.

HHS found that when Determination of Exceptional Circumstances (DEC) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR 27.306 were necessary. A DEC is executed consistent with the policy and objectives of the Title 35 of the United States Code (U.S.C.) 200 *et seq.*, and commonly known as the “Bayh-Dole Act” and its implementing regulations, found at title 37 Code of Federal Regulations (CFR) parts 401 and 404. This is to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against non-use or unreasonable use of inventions; and in the case of fulfilling the mission of HHS, to ultimately benefit the public health.

To supplement these regulations, two HHS Acquisition Regulation (HHSAR) were created to request the detail necessary to ensure additional legal protections could exist. These clauses ensure that providers of proprietary material(s) to the government will retain all their pre-existing rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers), when a DEC has been executed. “Material”, as defined by the HHARS is any material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

Rights in data regulations concern the rights of the Government, and organizations with which

the Government contracts, to information developed under such contracts. The delineation of such rights is necessary to protect the contractor's rights to not disclose proprietary data and to ensure that non-proprietary data developed with public funds is available to the public.

These two HHSAR clauses maintain the current FAR coverage for this subject and provide additional coverage to address patent and data rights in lieu of using FAR clauses 52.227-11 and 52.227-14 as prescribed in FAR Part 27.

The clauses pertain to inventions made in the performance of work under a Government contract or subcontract for experimental, developmental or research work. Additionally, the information collection supports the requirements of chapter 18 of title 35, U.S.C. (as implemented by 37 CFR Section 401), Presidential Memorandum on Government Patent Policy to the Heads of Executive Departments and Agencies dated February 18, 1983, and Executive Order 12591, Facilitating Access to Science and Technology dated April 10, 1987, which also states that the policy and objective of the Government to -

- (1) Use the patent system to promote the use of inventions arising from federally supported Presidential Memorandum -- Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Businesses research or development;
- (2) Encourage maximum participation of industry in federally supported research and development efforts;
- (3) Ensure that these inventions are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;
- (4) Promote the commercialization and public availability of the inventions made in the United States by United States industry and labor;
- (5) Ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and
- (6) Minimize the costs of administering patent policies.-

2. Purpose and Use of Information Collection

- A. HHSAR 352.227-11 - Patent Rights - Exceptional Circumstances outlines the process for all Classes of Subject Inventions, the DEC, and Greater Rights Determinations. Requests for Greater Rights Determinations, and subsequent actions, require the following information to be submitted, at a minimum, to the Contracting Officer:
 - A written request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights to be submitted at the time of the first disclosure of the invention.
 - A written disclosure of each Subject Invention to be submitted to the Contracting

Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR). This will be a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

- An agreement to execute or to have executed all instruments necessary to:
 - Establish or confirm the rights the Government has throughout the world in Subject Inventions.
 - Convey title to a Third-party assignee.
 - Enable the Third-party assignee to obtain patent protection throughout the world in that Subject Invention.
- A written agreement by its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under contract.
- A final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none.
- An annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request has been granted. The report shall include:
 - Information regarding the status of development.
 - Date of first commercial sale or use.
 - Gross royalties received.
 - Other data and information as the Agency may reasonably specify.
- Any additional reports that may be requested in connection with any march-in proceedings undertaken by the agency.
- A copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications must be sent to <http://www.iEdison.gov>.

All submissions are considered critical to the Government ensuring the patent rights of the Contractor, Government, and third parties are protected.

- B. HHSAR 352.227-14 - Rights in Data - Exceptional Circumstances outlines what is required for the release, publications, and use of data . The Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely

published thereby adversely affecting the ability to obtain patent protection on such inventions.

- A copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure.
- As the request of the Contracting Officer, a written justification to substantiate the marking of proprietary data or the data contains any other restrictive or limiting markings not authorized by the contract.

All submissions are considered critical to the Government ensuring the data rights of the Contractor, Government and third parties are protected to ensure appropriate proprietary markings on data.

3. Use of Improved Information Technology and Burden Reduction

The use of information technology is being used to the maximum extent practicable. Where Contractors are capable of electronic interchange, the contractors may submit this information collection requirement electronically. Nothing in the HHSAR precludes the use of electronic interchange where the requirements are for written requests and documentation. Only the minimum information necessary for the purposes of the invention are being collected. To reduce the burden, a government website at <http://www.iEdison.gov> is provided to collect certain information so that the contractor does not have to send multiple hard copies to various Federal agencies and officials.

4. Efforts to Identify Duplication and Use of Similar Information

HHSAR 352.227-11 and 352.227-14 will be used as a supplement to FAR 52.227-11 and 52.227-14 when a DEC is in place; it is not believed that these information requirements duplicate any other information collection activities currently being done.

5. Impact on Small Businesses or Other Small Entities

There is no impact on Small Businesses by using these clauses. As this data collection would be part of a Federal contract, the burden could not be reduced or minimized for small businesses or entities. However, the information being requested has been held to the absolute minimum required for the intended use of the data. As many of the third parties whose legal rights this clause will insure are small businesses, it is generally believed that use of this clause and subsequent collection of the necessary information is to the benefit of small businesses.

6. Consequences of Collecting the Information Less Frequent Collection

This information collection will be included as part of a clause in a Federal contract to be used when it is applicable and deemed necessary. The frequency in the collection of information is also based on the minimum requirement that is outlined in the Code of Federal Regulations and

the Federal Acquisition Regulations. HHS is not requesting any additional information beyond what is required.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

All guidelines have been met and this request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

The 60 day was published in the *Federal Register* on April 20, 2023, Volume 88, page 24429. No public comments were received.

9. Explanation of any Payment/Gift to Respondents

There will be no remuneration, payment or gifts offered to the respondents for this collection of information. This collection of information will be part of the requirements of a Federal contract.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. The clauses concern patent and data rights and the collection of information will require submission of documents containing or referencing proprietary data. These documents will be used only for the purposes stated in the contract document and, with the proper markings, will not be made available to the public. It is not anticipated that the documents collected by the government will contain personal identifiable information.

11. Justification for Sensitive Questions

This information collection does not ask any questions of a sensitive nature, such as race/ethnicity, social security numbers, sexual behavior and attitudes, religious beliefs or other matters that are commonly considered private.

12. Estimates of Annualized Hour and Cost Burden

Public reporting burden for this collection of information is estimated to average 11 hours per response under HHSAR 352.227-11 Patent Rights – Exceptional Circumstances and six (6) hours per response under HHSAR 352.227-14 Rights in Data – Exceptional Circumstances, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed and completing and reviewing the collection of information. This represents a total average of 17 hours per response for this information collection. Collection of this information is not new as it has been collected through use of FAR clauses 52.227-11 Patent Rights – Ownership and 52.227-14 - Rights in Data – General in the past.

Data from previous fiscal years' contract awards using those approved FAR deviations were used to determine the burden. The proposed reporting requirement is estimated to cover 63 cost-reimbursement contracts above the simplified acquisition threshold. We estimate 19

responses will be required from each of the 63 respondents for a total of 1,197 responses. The total number of hours estimated for each response is 83, which is a total of 99,351 hours to prepare and submit reports for this information collection. Public reporting burdens indicated for submission of the data required includes the time for gathering the data needed, and completing and reviewing the collection of information.

Public comment was sought regarding whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of Information Technology. No comments were received.

12A. Estimated Annualized Burden Hours

Information Collection (see page 2-3 for legend)	Type of Respondent and hours for each	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden Hours
a)	Technical (4) Legal (2) Management (2)	63	1	8	504
b)	Technical (8) Legal (2) Management (2)	63	1	12	756
c)	Technical (8) Legal (3) Management (1)	63	3	12 (36)	2,268
d)	Technical (8) Legal (4) Management (2)	63	3	14 (42)	2,646
e)	Technical (6) Legal (2) Management (2)	63	1	10	630
f)	Technical (4) Legal (2) Management (2)	63	1	8	504
g)	Administrative (8)	63	3	8 (24)	1,512
h)	Administrative (2) Management (1)	63	3	3 (9)	567

i)	Technical (4) Legal (2) Management (2)	63	3	8 (24)	1,512
TOTAL		63	19	83 (173)	10,899

12.B Annualized cost to respondents for the hour burdens:

It is anticipated that the type of respondents required to respond to the information collection would be administrative, technical, legal and management personnel. The estimated annual cost would be 10,899 hours x \$49.65/hour = \$541,135.35. The \$49.65 which is the hourly rate for a GS-12 Step 4, is considered an average of the rates that would be paid for administrative, legal, management and technical personnel.

	Type of Respondent and hours for each response	Average Burden per Response (hours)	Hourly Wage Rate (Average)	Per Response Cost
a)	Technical (4) Legal (2) Management (2)	8	\$49.65	\$397.20
b)	Technical (8) Legal (2) Management (2)	12	\$49.65	\$595.80
c) 1	Technical (8) Legal (3) Management (1)	12	\$49.65	\$595.80
c) 2	Technical (8) Legal (3) Management (1)	12	\$49.65	\$595.80
c) 3	Technical (8) Legal (3) Management (1)	12	\$49.65	\$595.80
d) 1	Technical (8) Legal (4) Management (2)	14	\$49.65	\$695.10
d) 2	Technical (8) Legal (4) Management (2)	14	\$49.65	\$695.10
d) 3	Technical (8) Legal (4) Management (2)	14	\$49.65	\$695.10
e)	Technical (6) Legal (2)	10	\$49.65	\$496.50

	Management (2)			
f)	Technical (4) Legal (2) Management (2)	8	\$49.65	\$397.20
g) 1	Administrative (8)	8	\$49.65	\$397.20
g) 2	Administrative (8)	8	\$49.65	\$397.20
g) 3	Administrative (8)	8	\$49.65	\$397.20
h) 1	Administrative (2) Management (1)	3	\$49.65	\$148.95
h) 2	Administrative (2) Management (1)	3	\$49.65	\$148.95
h) 3	Administrative (2) Management (1)	3	\$49.65	\$148.95
i) 1	Technical (4) Legal (2) Management (2)	8	\$49.65	\$397.20
i) 2	Technical (4) Legal (2) Management (2)	8	\$49.65	\$397.20
i) 3	Technical (4) Legal (2) Management (2)	8	\$49.65	\$397.20
		173	\$49.65	\$8,589.45
	63 respondents x 19 responses = 1,197 responses	173 total hours/19 responses = 9.105 average each response		\$541,135.35

13. Estimates of other Total Annual Cost Burden to Respondents or Record-keepers/Capital Costs

No capital cost of maintaining or start-up costs are associated with this information collection.

14. Annualized Cost to Federal Government

The total annual cost to the Government of conducting normal business in relation to this collection of information is estimated to be a total of \$97,382.25 is calculated as follows:

Six of the nine information collections involved require action on the part of the prime

contractor, but copies of the information collected must be submitted to the Government. This will require receipt and filing in the appropriate places by the Government Contracting Officer (CO) or Contract Specialist (CS). Estimating two hours each year for receipt and appropriate disposition of the information per each of the six collections of data and continuing to use 63 contracts based on available historical data, we estimate this would be 756 hours of Government time. Using an average (CO at GS-14 and CS at GS-12) hourly rate for a GS-13, Step 3 of \$57.25, this would be a cost of \$43,281.00.

Three of the nine information collections require action on the part of the Government in addition to receipt and filing of data and total 945 hours and a cost of \$54,101.25. Details on calculations for each of the three collections are shown below.

The prime contractor must submit a request for a determination of whether the Contractor or the employer inventor is entitled to retain greater rights to the CO; in turn, the CO must make that determination. Using an hourly rate for a GS-14, Step 3 of \$67.65, estimating an average of five hours to make and write the determination, continuing to use 63 contracts based on available historical data, this would be an estimated 315 hours and a cost of \$21,309.75.

The government retained the right to request certain reports more often than annually. Using an hourly rate for a GS-14, Step 3 of \$67.65, estimating an average of 4 hours for the CO to make the decision to request the report in consultation with the project manager and COR, write the request, and issue the request, and continuing to use 63 contracts based on available historical data, this would be an estimated 252 hours and a cost of \$17,047.80.

The CO must make a written inquiry to the contractor giving them 60 days to provide written justification to substantiate the propriety of markings. Using an hourly rate for a GS-14, Step 3 of \$67.65, estimating an average of 6 hours for the CO to make the request in consultation with the project manager, write and issue the request, and then to respond if necessary to the justification provided, and continuing to use 63 contracts based on available historical data, this would be an estimated 378 hours and a cost of \$25,571.70.

15. Explanation for Program Changes or Adjustments

This is a request for an extension with no program changes or adjustments to the collection. Dollar values have been adjusted based on current hourly rates.

16. Plans for Tabulation and Publication and Project Time Schedule

There is no possibility that these information requirements will be published, tabulated, or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

This is an existing information collection, and we will be displaying the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This information collection does not include any exceptions to the certification.