

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

Justification

1.Circumstances Making the Collection of Information Necessary

HHS found that systematically, over a period of several years, 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 Bayh-Dole Act, 35 U.S.C. 200, et seq., 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 nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health. A copy of the section of the Bayh-Dole Act mandating use of DEC's is attached.

A decision was made to add two clauses to the HHS supplement to the FAR, the HHS Acquisition Regulation (HHSAR), to provide the additional legal protection required. These clauses would ensure that providers of proprietary material(s) to the government will retain all their preexisting 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" means any proprietary material, method, product, composition, compound or device, whether patented or unpatented.

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 in order to protect the contractor's rights to not disclose proprietary data and to insure that non-proprietary data developed with public funds is available to the public.

These two new 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**. These clauses prescribe policies, solicitation provisions, and contract clause pertaining to inventions made in the performance of work under a Government contract or subcontract for experimental, developmental or research work. This additionally supports the requirements of chapter 18 of title 35, U.S.C. (as implemented by 37 CFR part 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

Clause 352.227-11 contains the following information collections. All submissions are considered critical to the Government ensuring the patent rights of the Contractor, Government and third parties are protected appropriately.

- a) A request for a determination of whether the Contractor or the employer inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer;
- b) The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Office and to the Director, Division of Extramural Inventions and Technology Resources (DEITR) using the website at <http://www.iEdison.gov>;
- c) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: 1. Establish or confirm the rights the Government has throughout the world in Subject Inventions ... and 2. convey title to a Third party assignee ...and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention;
- d) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention made under contract;
- e) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none;
- f) The Contractor agrees to submit, on request, periodic reports no more frequently than annually 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 under subparagraph b.3. has been granted by the Agency; and

- g) All invention disclosures and requests for greater rights shall be sent to the Agency Contracting officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to <http://www.iEdison.gov>.

Clause 352.227-14 contains the following two collections of information. All submissions are considered critical to the Government ensuring the data rights of the Contractor, Government and third parties are protected appropriately.

- h) "Accordingly, the Contractor will provide the Contracting Officer a copy of any proposed publication or other public disclosure relating to the proposed publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure." This information collection is being done to insure that the Contractor does not prematurely publish information concerning possible inventions made under this contract so that the ability to obtain patent protection on such inventions is adversely affected.
- i) "The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings." This information collection is being done to preserve the Government's right to cancel or ignore the markings at any time after the stated period, making the data no longer subject to any disclosure prohibitions.

3. Use of Improved Information Technology and Burden Reduction

We use improved information technology 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 requirement is for written documents. Only the minimum information necessary for the purposes of the invention are being collected (such as only collecting the face page of the document when the complete document is not necessary). 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 government officials.

4. Efforts to Identify Duplication and Use of Similar Information

As these two HHSAR clauses 352.227-11 and 352.227-14 will be used in lieu of FAR clauses 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. No comments indicating duplication of information collection activities were received in response to the Federal Register notice for the proposed rule.

5. Impact on Small Businesses or Other Small Entities

An Initial Request for Regulatory Flexibility addressing anticipated impact of the requirements of these clauses on small businesses or entities was prepared and a copy is attached. 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 insures 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 appropriate. Agreement to the frequency of this collection of information will be obtained when the contractor signs the contract. Although requests for less frequent collection of this information are not anticipated, should they occur during the contract negotiation process, they would be considered and processed as a deviation to the cited HHSAR clause.

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. Collecting this information will not include any of the following circumstances:

- 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.
- 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 that 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 which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Requiring respondents to submit proprietary, trade secret, 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.

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

HHS vetted the notice to components of the National Institutes of Health, the Food and Drug Administration and the Office of General Counsel. A number of comments were received and resolved prior to submitting the notice for publication in the Federal Register. None of the comments were related to the information collection.

A notice of proposed rulemaking was published in the *Federal Register* on January 10, 2013, Volume 78, Number 7, pages 2229 - 2236. Although public comments were received, none of the comments were relative to the collection of information.

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 proposed 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 identifiers.

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 352.227-11 Patent Rights - Exceptional Circumstances and 6 hours per response under 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. Although these requirements are new to the HHSAR, collection of this information is not new as it has been collected through use of deviated FAR clauses 52.227-11 Patent Rights - Ownership and 52.227-14 Rights in Data - General in the past.

Data from Fiscal Years 2007 through 2012 contract awards using those approved FAR deviations was used to determine the burden. If this proposed reporting requirement had been in place during those Fiscal Years, it would have covered 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 1197 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 proposed 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)	2268
d)	Technical (8) Legal (4) Management (2)	63	3	14 (42)	2646
e)	Technical (6) Legal (2) Management (2)	63	1	10	630
f)	Technical (4) Legal (2) Management	63	1	8	504

	(2)				
g)	Administrative (8)	63	3	8 (24)	1512
h)	Administrative (2) Management (1)	63	3	3 (9)	567
i)	Technical (4) Legal (2) Management (2)	63	3	8 (24)	1512
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 99,351 hours x \$39.46/hour = \$3,920,390.40. The \$39.46, which is the hourly rate for a GS-12/4, 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	\$39.46/hour	\$315.68
b)	Technical (8) Legal (2) Management (2)	12	\$39.46/hour	\$473.52
c) 1	Technical (8) Legal (3) Management (1)	12	\$39.46/hour	\$473.52
c) 2	Technical (8) Legal (3) Management (1)	12	\$39.46/hour	\$473.52
c) 3	Technical (8) Legal (3) Management (1)	12	\$39.46/hour	\$473.52
d) 1	Technical (8) Legal (4) Management (2)	14	\$39.46/hour	\$552.44

d) 2	Technical (8) Legal (4) Management (2)	14	\$39.46/hour	\$552.44
d) 3	Technical (8) Legal (4) Management (2)	14	\$39.46/hour	\$552.44
e)	Technical (6) Legal (2) Management (2)	10	\$39.46/hour	\$394.60
f)	Technical (4) Legal (2) Management (2)	8	\$39.46/hour	\$315.68
g) 1	Administrative (8)	8	\$39.46/hour	\$315.68
g) 2	Administrative (8)	8	\$39.46/hour	\$315.68
g) 3	Administrative (8)	8	\$39.46/hour	\$315.68
h) 1	Administrative (2) Management (1)	3	\$39.46/hour	\$118.38
h) 2	Administrative (2) Management (1)	3	\$39.46/hour	\$118.38
h) 3	Administrative (2) Management (1)	3	\$39.46/hour	\$118.38
i) 1	Technical (4) Legal (2) Management (2)	8	\$39.46/hour	\$315.68
i) 2	Technical (4) Legal (2) Management (2)	8	\$39.46/hour	\$315.68
i) 3	Technical (4) Legal (2) Management (2)	8	\$39.46/hour	\$315.68
		173	\$39.46/hour	\$3275.18
	63 respondents x 19 responses = 1197 responses	173 total hours/19 responses = 9.15 average each response	1197 responses x 9.12 average hours per response = 10,899 hours x \$39.46/hour = \$430,074.54	\$430,074.54

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/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 are estimated to be a total of \$86,068.71 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 2 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-1102-13/3 of \$45.96, this would be a cost of \$34,745.76.

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 \$51,322.95. 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-14/3 of \$54.31, estimating an average of 5 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 \$17,107.65.

The government retained the right to request certain reports more often than annually. Using an hourly rate for a GS-14/3 of \$54.31, 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 \$13,686.12.

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-14/3 of \$54.31, 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 \$20,529.18.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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 a new 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.