

SUPPORTING STATEMENT
U.S. Department of Commerce
National Institute of Standards and Technology
iEdison
OMB Control No. 0693-0090

SUPPORTING STATEMENT PART A

Abstract

Patent Rights in Inventions Made with Federal Assistance, commonly referred to as “The Bayh-Dole Act” (35 USC § 200-212) and its implementing regulations (37 CFR 401) allow for recipients of federal research funding (Contractors) to retain ownership of inventions developed under federal funding agreements. In exchange, the government retains certain rights to the invention, including a world-wide right to use by or on behalf of the U.S. government. The law also requires the Contractor to obtain permission for certain actions and fulfill reporting requirements including:

- a. Initial reporting of invention;
- b. Decision to retain title to invention;
- c. Filing of patent protection;
- d. Evidence of government support clause within patents;
- e. Submission of a license confirming the government’s rights;
- f. Notice if the Contractor is going to discontinue the pursuit or continuance of patent protection;
- g. Information related to the development and utilization of invention;
- h. Permission to assign to a third party; and
- i. Permission to waive domestic manufacturing requirements.

This information is used for a variety of reasons. It allows the government to identify technologies to which the government has rights to use without additional payment or licensing. This acts as a time and cost-saving mechanism to avoid unnecessary negotiating and payment. It also provides data for calculation of return on investment (ROI) from federal funding and identifies successful research programs. Thirdly, it allows the government the opportunity to timely protect inventions which the Contractor declines title or discontinues patent protection.

Historically, NIH has collected this information via their on-line portal, iEdison. Although previously administered by NIH, NIST will take on these duties in the future. Agencies that do not register with iEdison are required to collect this information independently.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Bayh-Dole Act (35 USC § 200-212) and its implementing regulations (37 CFR 401) require Contractors to report information related to inventions and patents to the federal agency which awarded the relevant funding. The purpose of this legislation included promoting utilization of inventions resulting from federal R&D funding, encourage collaboration between non-profit and for-profit entities, increase commercialization and public availability of inventions made in the United States, and to ensure that the Government obtains sufficient rights in federally funded inventions to meet the needs of the Government and protect the public. To facilitate these and other objectives

as well as to track both compliance with and effectiveness of this legislation, collection of data is required. Initially when the legislation was passed, this information had to be reported manually via mail or fax. In the mid-90s, the NIH developed the iEdison web-portal which allowed Contractors to electronically report this information. To minimize burden on both Contractors and agencies, the NIH allowed other agencies to register to use this system as well, and eventually more than 30 federal agencies were using this system instead of traditional mail, fax, or email submission. Recently, there was a mutual decision to transfer management and upkeep of the iEdison system and its associated data from NIH to NIST.

The collection of this information allows the federal government to:

1. Ensure compliance with Bayh-Dole Act reporting and timing requirements to ensure that federally funded inventions are protected in a timely manner in accordance with patent laws, that federally funded inventions are being commercially developed, and ensure that preference is giving to US industry and small businesses.
2. Determine return on investment (ROI) of taxpayer dollars used on extramural federal research programs.
3. Identify technologies to which the government has rights to avoid unnecessary licensing and fees.

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 table below details the information/data fields being requested as well as the statute or regulation(s) authorizing the collection of this information and the needs or uses for collection of this piece of information. The information will be collected in one of three major record categories within iEdison: Invention, Patent, or Utilization Records. The majority of the information is already being collected by the current iEdison website hosted by the NIH. Any additional data fields and/or changes to data fields have been made to comply with updated regulations, to provide clarity, or at the justified request of federal agencies or Contractors who provide the information into the iEdison database. It should be noted that because the iEdison system is used by multiple agencies, the needs/uses listed represent the needs/uses for all agency iEdison users. If only certain agencies use or requested a particular piece of information, that is indicated within the chart. Because most of the information is not made public, but the Contractors who provide the information can use the iEdison database for their own reporting/tracking purposes, the Contractors own uses of the information are also included in the table below. Note on revisions: Utilization reports are due annually. If a user must submit a utilization report that was due before 2023 (applicant should have completed in a previous year but they are late), then the applicant will follow the Utilization Record outline in the below table. If an applicant submits a utilization report for 2023 or later, then they will follow the revised Utilization Records outlined in Question 15 of this supporting statement.

Item No.	Record Type where Requirement is Located	Requirement	Statute	Regulation	Needs/Uses
1	Invention Record	Invention Docket Number			- Used by Contractors to identify the specific invention within their own database by labeling it with their specific nomenclature.
2	Invention Record	Invention Title			- Used by both Contractors and agencies to quickly identify an invention. - Avoids duplicate records within the system by flagging entries with the same title.
3	Invention Record	Inventor(s) (First, Middle, Last Name)		37 CFR 401.14(c)(1)	- Used by Contractors to allow for compiling reports of all inventions

					<p>associated with a particular researcher.</p> <ul style="list-style-type: none"> - Used by agencies to identify all inventors in the event that the Contractor does not elect title and the agency decides to file for patent protection. This information and additional information from the inventors may be needed in the patenting process.
	Invention Record	Is this Inventor a US Federal Employee?		37 CFR 401.10(a)	<ul style="list-style-type: none"> - Used by agencies to identify when one or more of the inventors of an invention is a federal employee. The regulations require the funding agency to notify the agency employing the federal employee inventor and the funding agency is unable to fulfill this requirement if they do not if there is an inventor who is also a federal employee.
	Invention Record	US Federal Agency		37 CFR 401.10(a)	<ul style="list-style-type: none"> - Used by agencies to identify the federal agency employing an inventor(s) when one or more of the inventors is a federal employee. The regulations require the funding agency to notify the agency employing the federal employee inventor and the funding agency is unable to fulfill this requirement if they do not know which agency employs that inventor.
5	Invention Record	Date Invention Reported to Organization	35 USC 202(c)(1)	37 CFR 401.14(c)(1)	<ul style="list-style-type: none"> - Used by agencies to determine whether the invention was timely reported to the funding agency. In accordance with the regulations, the invention must be reported within 2 months of disclosure to the Contractor. This data point provides the date that the invention was reported so that it can be determined if it was timely reported.
6	Invention Record	Primary Funding Agency		37 CFR 401.13(a)	<ul style="list-style-type: none"> - Used by agencies to designate a funding agency to review and accept/reject submitted documentation. Without this information, it would be unclear which federal agency would take the lead in reviewing this technology and its associated compliance.
7	Invention Record	Funding Agency	35 USC 202(c)(1)	37 CFR 401.14(c)(1)	<ul style="list-style-type: none"> - Used by agencies to give full view and reporting access to records with their agency designated. - Used by Contractor to filter and report inventions, patents, and inventions by the agency that funded them.
8	Invention Record	Funding Agreement Grant/Contract Number	35 USC 202(c)(1)	37 CFR 401.14(c)(1)	<ul style="list-style-type: none"> - Used by agencies to tie the invention to the funding mechanism through which it was funded. - Used by agencies to assist in calculating ROI for specific funding agreements or programs. - Used by Contractors to search and report all activity related to a specific funding agreement.
	Invention Record	Start Date			<ul style="list-style-type: none"> - Used by agencies to identify when the

					terms and conditions of the award were last updated so that the agency can more accurately determine applicable award terms and regulations.
	Invention Record	Award Type			<ul style="list-style-type: none"> - Used by the agency to determine whether the funding agreement was awarded to the Contractor directly or subawarded by another organization. - If subaward is selected, Contractor would fill out the details in the subaward section (described below).
	Invention Record	Agreement Type			<ul style="list-style-type: none"> - Used by the agency to determine the type of funding agreement (for example, a contract, a grant, a cooperative agreement, etc.). This may determine certain internal federal processes for reporting.
9	Invention Record	Bayh-Dole Regulation Version Original/2018			<ul style="list-style-type: none"> - Used by both the Contractor and the agencies to identify which Bayh-Dole regulation applies – the original implementing regulations (1980) or the new regulations implemented in 2018. Making this indication affects certain obligations and reporting timelines on both the Contractor and the federal agency. - This field will default to select 2018 for all new records entered into iEdison, so the Contractor will only need to enter this field if they wish to change it from 2018 to the Original (earlier) Regulations.
10	Invention Record	Subcontract Number			<ul style="list-style-type: none"> - Used by Contractor to reflect that the federal funding flowed to their institution/organization through a sub-award. - Used by agency to identify why the party to the funding agreement is not an owner of the resulting invention/patent.
11	Invention Record	Prime Contractor Name			<ul style="list-style-type: none"> - Used by agency to confirm institution to which the funding agreement was originally granted, thus confirming correctness of award number.
12	Invention Record	Prime Contractor UEI/DUNS			<ul style="list-style-type: none"> - Used by agency to help identify Prime Contractor if there was an error, if there are similarly named institutions, etc.
13	Invention Record	Prime Contractor City			<ul style="list-style-type: none"> - Used by agency to help identify Prime Contractor if there was an error, if there are similarly named institutions, etc.
14	Invention Record	Prime Contractor State			<ul style="list-style-type: none"> - Used by agency to help identify Prime Contractor if there was an error, if there are similarly named institutions, etc.
15	Invention Record	Prime Contractor Country			<ul style="list-style-type: none"> - Used by agency to help identify Prime Contractor if there was an error, if there are similarly named institutions, etc.
16	Invention Record	Budget and Reporting Code(s)			<ul style="list-style-type: none"> - Used by agency to link inventions to the specific budgets from which their funding originated. <i>Specifically requested by DOE for use by only DOE labs that are government owned,</i>

					but contractor operated.
	Invention Record	Is this invention made under a funding agreement subject to a determination of exceptional circumstances? (Y/N)			- Used by agencies and contractors to identify when non-standard terms apply to one of the funding agreements and thus the resulting invention.
17	Invention Record	Title Election Status	35 USC 202(c)(2)	37 CFR 401.14(c)(2)	- Used by Contractors to notify the agencies whether they intend to elect or decline title. - Used by agencies to notify if they have the right to retain title and file for patent protection for the invention. If a Contractor declines title, the government has the opportunity to take ownership and pursue protection for the invention.
18	Invention Record	Does Not Retain Title Reason			- Used by agencies to provide insight as to why the Contractor decided not to elect title on an invention. For example, if the invention is not patentable, then the government agency may take time to research the invention's commercial viability. .
	Invention Record	Does Not Retain Title Other Reason			- Used by agencies to provide insight as to why the Contractor decided not to elect title on an invention. This field is only required with the Contractor selects "Other" as the "Not Elect Title Reason". This allows the Contractor to explain their reason for not electing title.
19	Invention Record	Parent Invention Report Number	N/A	N/A	- Used by Contractors to indicate that a single patent family is covering multiple inventions (because each patent can only be entered into the system once to avoid duplicated information). - Used by agencies to recognize that compliance obligations may have been fulfilled under another invention record (links the invention records within the database).
20	Invention Record	Date of First Publication/Sale/Public Use Date		37 CFR 401.14(c)(1)	- Used by agencies to identify timeframe during which patent protection must be filed. - Used by Contractors as a reminder of when they either need to file for patent protection or notify the agency of their decision not to file to preserve rights in case the government wants to file for patent protection.
21	Invention Record	Organization Code for Other Organizations to View Invention and Related Patents			- Used by agencies to identify when an invention is jointly owned. - Used by Contractors to allow joint-owners view only access to select invention and patent records.
22	Invention Record	Requests – Request Type	35 USC 202(c)(1-3); 35 USC 202(c)(7); 35 USC	37 CFR 401.14(c)(5); 37 CFR 401.14(k)(1); 37 CFR	- Used by Contractors to indicate what type of request they are submitting. - Used by agencies to identify the type of request being submitted. - Used by both agencies and Contractors

			204	401.14(i)	to report on how many of each type of request were submitted during a specified time period.
Invention Record	Requests – Assigning To		35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate whether they are seeking to assign to an individual inventor or a third party. - Used by agencies to determine factors to consider in whether to grant the assignment.
Invention Record	Requests – Inventor Name		35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the invention. - Used by agencies to inform to which of the inventors the Contractor is wanting to assign the invention. - Required only when Assignment is selected as “Request Type” and Inventor is selected as “Assigning To”.
Invention Record	Requests – Inventor’s Organization Code		35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the invention. - Used by agencies to confirm that this person has created their own iEdison account in order to continue reporting. Allows iEdison system to automatically transfer the record to the inventor’s account when the request is approved. - Required only when Assignment is selected as “Request Type” and Inventor is selected as “Assigning To”.
Invention Record	Requests – Third Party Name		35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the invention. - Used by agencies to inform to what company or organization the Contractor is wanting to assign the invention. - Required only when Assignment is selected as “Request Type” and Third Party is selected as “Assigning To”.
Invention Record	Requests – Third Party Organization Code		35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the invention. - Used by agencies to confirm that this third party has created their own iEdison account in order to continue reporting. Allows iEdison system to automatically transfer the record to the third party’s account when the request is approved. - Required only when Assignment is selected as “Request Type” and Third Party is selected as “Assigning To”.
Invention Record	Requests – Transfer to Organization				<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to transfer reporting responsibilities for the invention. - Used by agencies to inform to what company or organization the Contractor is wanting to transfer the invention and to confirm that they have created their

					<p>own iEdison account in order to continue reporting. Allows iEdison system to automatically transfer the record to the organization's account when the request is approved.</p> <ul style="list-style-type: none"> - Required only when Transfer is selected as "Request Type".
	Invention Record	Requests – Number of Months Extension			<ul style="list-style-type: none"> - Used by Contractors to indicate how long of an extension they are seeking. Gives Contractors flexibility in amount of time sought for extension. - Used by agencies to see how much time the Contractor is seeking and inform their decision. - Also allows iEdison system to automatically adjust timeframe and reminders for Contractors. - Required only if the Request Type is selected as "Election Extension", "Initial Patent Extension", or "Non-Provisional Patent Extension".
23	Invention Record	Requests – Support Document	35 USC 202(c)(1-3); 35 USC 202(c)(7); 35 USC 204	37 CFR 401.14(c)(5); 37 CFR 401.14(k)(1); 37 CFR 401.14(i)	<ul style="list-style-type: none"> - Used by Contractors (as needed) to provide additional information in the form of attachments to justify their request. - Used by agencies to receive documentation to assist in determining whether or not to approve a request.
24	Invention Record	Request – Request Reasons/Comments	35 USC 202(c)(6); 35 USC 202(c)(7);	37 CFR 401.14(c)(5); 37 CFR 401.14(k)(1);	<ul style="list-style-type: none"> - Used by Contractors to provide additional information, such as reasoning, to justify a request. - Used by agencies to receive justification or other relevant information to determine whether or not to grant a request. - Used for all requests except Domestic Manufacturing Waiver requests.
	Invention Record	Request – Domestic Waiver Reason	35 USC 204	37 CFR 401.14(i)	<ul style="list-style-type: none"> - Used by Contractors to indicate the statutory reason under which they are submitting this request. - Used by agencies to track and report on the statutory reason(s) that waivers are sought. Having this specific field (with drop-down options) makes reporting statistics easier for agencies. - Required for Domestic Manufacturing Waivers only.
25	Invention Record	Keywords			<ul style="list-style-type: none"> - Used by Contractors to categorize inventions to allow for specific searching or reporting of inventions. - Used by agencies to search for technologies of particular interest by topic or category.
26	Invention Record	Invention Disclosure Form File Upload		37 CFR 401.14(c)(1)	<ul style="list-style-type: none"> - Used by Contractors to fulfill requirement to disclose invention in sufficient detail by providing additional description of the technology. - Used by Contractors as evidence of accuracy of information reported into iEdison.

					<ul style="list-style-type: none"> - Used by agencies to confirm information entered into iEdison. - Used by agencies to understand the characteristics of the technology to know what the technology is, what the government has non-exclusive rights to, and assist in determining (if applicable) whether to take title, march-in, or pursue patent protection if a Contractor does not.
27	Invention Record	Other Document Files			<ul style="list-style-type: none"> - Used by Contractors to upload and attach any additional documentation they wish to the invention record. - Used by agencies to review additional documentation related to the invention record either requested by the agency or voluntarily provided by the Contractor.
28	Invention Record	Explanatory Notes			<ul style="list-style-type: none"> - Used by Contractors to add relevant information that they wish to permanently include in the invention record. - Used by Contractors as a place to document anomalies associated with the invention.. - Used by agencies to add information they wish to permanently include in the invention record and make visible to the Contractor, such as temporary status changes, etc.
	Invention Record	Discussion Subject			<ul style="list-style-type: none"> - Used by Contractors and agencies to indicate and determine the subject of the discussion and also to differentiate between discussions when there are multiple discussions under one record.
29	Invention Record	Discussion Comments			<ul style="list-style-type: none"> - Used by Contractors to communicate directly with the primary funding agency for that invention and associated patents and utilization. - Used by Contractors to ask questions to the funding agency and document questions/responses in the invention record. - Used by Contractors to make certain requests that may not be included in the “request” section of the record, such as an explanation and request for the agency to re-review an invention disclosure for acceptance. - Used by agencies to communicate directly with Contractors about a specific invention and its associated patents and utilization. - Used by agencies to further explain rejections or requirements of the Contractor. - Used by agencies to document notice to Contractors of required information, documentation, action, etc.
30	Patent Record	Patent Docket Number			<ul style="list-style-type: none"> - Used by Contractors to identify the specific patent record within their own

					<p>database by labeling it with their specific nomenclature.</p> <ul style="list-style-type: none"> - Used by Contractors to link parent/child patents together to indicate continuity of patent protection. - Used by both agencies and Contractors to reference specific patent records within correspondence.
31	Patent Record	Patent Type			<ul style="list-style-type: none"> - Used by Contractors to indicate the type of patent which determines if certain regulatory requirements have been fulfilled or if other regulatory requirements are triggered. - Used by Contractors to quickly assist in identifying (in graphic view) if all patent records have been recorded. - Used by agencies to confirm if regulatory requirements have been met or triggered. - Used by agencies to determine if a new/additional confirmatory license is needed (in cases of CIP patent applications). - Used by both Contractors and agencies to run reports on total numbers of different patent types during specified time periods.
32	Patent Record	Patent Status		37 CFR 401.14(f)(3)	<ul style="list-style-type: none"> - Used by Contractors to communicate to the agencies when an application/patent is being allowed to go abandoned, lapse, or has expired. - Used by agencies as an indicator that a Contractor is discontinuing protection of a patent, allowing the government the option to continue protection. - Used by both Contractors and agencies to track/report active or inactive patents.
33	Patent Record	Patent Title			<ul style="list-style-type: none"> - Used by Contractors and agencies to identify the patent or patent application. - Used by Contractors to auto-populate information into Confirmatory License.
34	Patent Record	Patent Inventor(s) (First, Middle, Last Name)			<ul style="list-style-type: none"> - Used by Contractors to allow for compiling reports of all inventions associated with a particular researcher. - Used by agencies to identify all inventors in the event that the Contractor does not elect title and the agency decides to file for patent protection. This information and additional information from the inventors may be needed in the patenting process. Used by Contractors to auto-populate information into Confirmatory License.
35	Patent Record	Patent Application Number (Provisional Application Number, PCT Application Number, Non-Provisional Application Number)		37 CFR 401.5(f)(2)	<ul style="list-style-type: none"> - Used by Contractors and agencies to identify the patent or patent application. - Used to ensure that patent records are not duplicated within iEdison. - Used by Contractors to auto-populate

					<p>information into Confirmatory License.</p> <ul style="list-style-type: none"> - Used by agencies to locate publicly available information related to pending and issued patents.
36	Patent Record	Patent Application Filing Date (Provisional Application Date, PCT Application Date, Non-Provisional Application Date)	35 USC 202(c)(3)	37 CFR 401.14(c)(2)	<ul style="list-style-type: none"> - Used by Contractors and agencies to identify the patent or patent application. - Used to calculate application/patent expiration dates. - Used by Contractors to auto-populate information into Confirmatory License.
37	Patent Record	Issued Patent Number		37 CFR 401.5(f)(2)	<ul style="list-style-type: none"> - Used by Contractors and agencies to identify the patent or patent application. - Used by Contractors to auto-populate information into Confirmatory License.
38	Patent Record	Issued Patent Date		37 CFR 401.5(f)(2)	<ul style="list-style-type: none"> - Used by Contractors and agencies to identify the patent or patent application. - Used by Contractors to auto-populate information into Confirmatory License.
39	Patent Record	Expiration Date			<ul style="list-style-type: none"> - Used by Contractors and agencies to confirm when patent protection and certain reporting obligations cease.
	Patent Record	Organization Code for Other Organizations to View Patent			<ul style="list-style-type: none"> - Used by Contractors to allow joint-owners view only access when they want to limit to individual patent records but not the invention record.
41	Patent Record	Parent Patent(s)			<ul style="list-style-type: none"> - Used by Contractors to link patent records together, indicating continuity of protection and documenting patent family. - Used by agencies to confirm continuity of patent protection.
43	Patent Record	Foreign Filings (Country, Status, FilingDate)		37 CFR 401.5(f)(2)/ 37 CFR 401.5(f)(2)	<ul style="list-style-type: none"> - Used by Contractors to notify the government in which countries patent protection is filed. - Used by Contractors to indicate if they are discontinuing patent protection in foreign countries. - Used by agencies to identify which countries that Contractors are not filing so that they can decide if the government would like to pursue protection in those countries. - Used by agencies to know when foreign patent protection is being discontinued so that they can choose whether to assume ownership/cost of those patents.
	Patent Record	Confirmatory License Execution Date			<ul style="list-style-type: none"> - Used by contractors to indicate when the Confirmatory License was executed. - Allows agencies to more easily file Confirmatory Licenses with the USPTO.
44	Patent Record	Confirmatory License Document Upload		37 CFR 401.14(f)(1)	<ul style="list-style-type: none"> - Used by agencies as documented evidence of non-exclusive right to use patented invention or have used on their behalf.
45	Patent Record	Government Support Clause Document Upload	35 USC 202(c)(6)	37 CFR 401.14(f)(4)	<ul style="list-style-type: none"> - Used by agencies to confirm that required government support language is included in the application/patent.

46	Patent Record	Other Document Upload			<ul style="list-style-type: none"> - Used by Contractors to upload and attached any additional documentation they wish to the patent record. - Used by agencies to review additional documentation related to the patent record either requested by the agency or voluntarily provided by Contractors.
47	Patent Record	Patent Requests – Request Type		37 CFR 401.14(c)(5)	<ul style="list-style-type: none"> - Used by Contractors to indicate what type of patent request they are submitting. - Used by agencies to identify the type of patent request being submitted. - Used by both agencies and Contractors to report on how many of each type of patent request were submitted during a specified time period.
	Patent Record	Requests – Assigning To	35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate whether they are seeking to assign to an individual inventor or a third party. - Used by agencies to determine factors to consider in whether to grant the assignment.
	Patent Record	Requests – Inventor Name	35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the patent. - Used by agencies to inform to which of the inventors the Contractors is wanting to assign the patent. - Required only when Assignment is selected as “Request Type” and Inventor is selected as “Assigning To”.
	Patent Record	Requests – Inventor’s Organization Code	35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the patent. - Used by agencies to confirm that this person has created their own iEdison account in order to continue reporting. Allows iEdison system to automatically transfer the record to the inventor’s account when the request is approved. - Required only when Assignment is selected as “Request Type” and Inventor is selected as “Assigning To”.
	Patent Record	Requests – Third Party Name	35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the patent. - Used by agencies to inform to what company or organization the Contractor is wanting to assign the patent. - Required only when Assignment is selected as “Request Type” and Third Party is selected as “Assigning To”.
	Patent Record	Requests – Third Party Organization Code	35 USC 202(c)(7)	37 CFR 401.14(k)(1)	<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to assign the patent. - Used by agencies to confirm that this third party has created their own iEdison account in order to continue reporting. Allows iEdison system to

					<p>automatically transfer the record to the third party's account when the request is approved.</p> <ul style="list-style-type: none"> - Required only when Assignment is selected as "Request Type" and Third Party is selected as "Assigning To".
	Patent Record	Requests – Transfer to Organization			<ul style="list-style-type: none"> - Used by Contractors to indicate to whom they are seeking to transfer reporting responsibilities for the patent. - Used by agencies to inform to what company or organization the Contractor is wanting to transfer the patent and to confirm that they have created their own iEdison account in order to continue reporting. Allows iEdison system to automatically transfer the record to the organization's account when the request is approved. - Required only when Transfer is selected as "Request Type".
48	Patent Record	Patent Requests – Support Document		37 CFR 401.14(c)(5)	<ul style="list-style-type: none"> - Used by Contractors (as needed) to provide additional information in the form of attachments to justify their patent request. - Used by agencies to receive documentation to assist in determining whether or not to grant a patent request.
49	Patent Record	Patent Request – Request Reasons/Comments		37 CFR 401.14(c)(5)	<ul style="list-style-type: none"> - Used by Contractors to provide additional information, such as reasoning, to justify a patent request. - Used by agencies to receive justification or other relevant information to determine whether or not to grant a patent request.
50	Patent Record	Patent Explanatory Notes			<ul style="list-style-type: none"> - Used by Contractors to add relevant information that they wish to permanently include in the patent record. - Used by Contractors as a place to document anomalies associated with the patent, such as finding out about additional funding or removing funding during the prosecution process, etc. - Used by agencies to add information they wish to permanently include in the patent record and make visible to Contractors, such as temporary status changes, etc.
51	Utilization Report	Reporting Year*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to designate the year (usually fiscal) for which they are calculating the information requested in the Utilization Report Questions. - Used by agencies to assist in reporting utilization information by sorting data by years.
52	Utilization Report	Indicate the latest stage of development of any product arising from this invention, according to the following categories*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to run reports on which inventions have been licensed to companies or developed into a commercialized product. - Used by agencies to identify

					<p>development of federally funded technologies.</p> <ul style="list-style-type: none"> - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
53	Utilization Report	If any product arising from this invention has reached the market, what was the calendar year of the first commercial sale*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to run reports on which of their federally funded inventions have resulted in a sale. - Used by agencies to identify how many federally funded inventions have made it into the marketplace. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
54	Utilization Report	In the designated reporting period, what was the total income received as a result of license or option agreements? Do not include specific patent costs reimbursement. *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to run reports on how much revenue resulted from the licensing of federally funded inventions. - Used by agencies to aid in calculation of ROI from federal research dollars.
55	Utilization Report	Did the grantee organization/contractor or any of the exclusive licensees request a waiver of the U.S. manufacturing requirements in the designated reporting period? *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies as a mechanism to have Contractors confirm how many U.S. manufacturing waivers were requested during a specific time period.
56	Utilization Report	If yes, how many such waivers were obtained? *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies as a mechanism to have Contractors confirm how many U.S. manufacturing waivers were requested during a specific time period.
57	Utilization Report	Commercial Product Name (of FDA-Approved Product) *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to link federal funding to FDA approved products. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
58	Utilization Report	FDA Approved Number*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to link federal funding to FDA approved products.
59	Utilization Report	FDA Approval Type*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to determine the type of FDA approval that product received.
60	Utilization Report	Public (Yes/No)*	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to indicate that they want FDA information to not be published by agencies. - Used by agencies to obtain consent from the Contractor so that this part of the Utilization Data can be posted publicly.
61	Utilization Report	In the designated reporting period, how many exclusive licenses and/or Options are active? *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to run reports on how many federally funded inventions are exclusively licensed. - Used by agencies to calculate the number of federally funded inventions that are exclusively licensed. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. - Used by agencies to identify how many technologies (once commercialized) should be substantially manufactured within the United States or have an

					accepted U.S. Manufacturing Waiver.
62	Utilization Report	In the designated reporting period, how many non-exclusive licenses and/or options are active? *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by Contractors to run reports on how many federally funded inventions are non-exclusively licensed. - Used by agencies to calculate the number of federally funded inventions that are non-exclusively licensed. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
63	Utilization Report	How many licenses and/or options of any type to small businesses (<500 employees are active in the designated reporting period? *	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. - Used by agencies to track fulfillment of legislative objective to benefit small businesses.
64	Utilization Report	Approx. Number of US-based Jobs Created Because of Commercialization Efforts During Reporting Period ⁺	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. Provides a key indicator of commercial success of an invention; an objective way to measure the benefit to the US economy of DOE's investment in supporting the R&D of a particular energy technology, and helps verify that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
65	Utilization Report	Number of new US-based Companies Created from Commercialization Efforts During Reporting Period ⁺	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. Provides a key indicator of commercial success of a particular invention; an objective way to measure the benefit to the US economy of DOE's investment in supporting the R&D of a particular energy technology and helps verify that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements. This information also aids the Department in tracking how inventions licensed by awardees to third parties eventually make their way to the marketplace.
66	Utilization Report	Unique Commercial Products made (with NAICS code if applicable) ⁺	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to link federal funding to products in the marketplace. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. Used to quantify the commercial success of an invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
67	Utilization Report	Manufacturing Country ⁺	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to determine if Contractors are enforcing applicable

					<p>domestic manufacturing requirements.</p> <ul style="list-style-type: none"> - Used to quantify the commercial success of an invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
	Utilization Report	Manufacturing State	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars to states. - Used to quantify the commercial success of an invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
	Utilization Report	First Date of Manufacturing	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used to quantify the commercial success of an invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
	Utilization Report	Manufacturing Type	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used to quantify the commercial success of an invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.
	Utilization Report	Manufacturing Product Quantity	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to determine if Contractors are enforcing applicable domestic manufacturing requirements. This information is needed to quantify the commercial success of a particular invention and verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements
69	Utilization Report	Describe how development complies with US manufacturing requirements (e.g., U.S. Preference, a U.S. Competitive Clause, U.S. Manufacturing Plan, etc.) ⁺	35 USC 202(c)(5)	37 CFR 401.14(h)	<ul style="list-style-type: none"> - Used by agencies to determine if Contractors are enforcing requirement that exclusive licensees are manufacturing products substantially within the United States (or obtaining a waiver for this requirement). This information is needed to verify 1) qualitative statements by awardees regarding their commercialization efforts and 2) that subject inventions are being utilized in a manner consistent with DOE's US manufacturing requirements.

* Information only required for NIH and/or DOE funded technologies

⁺ Information only required for DOE funded technologies

The information detailed above will be collected from recipients of federal funding with resulting inventions, including universities, research institutions, hospitals, non-profit organizations, for-profit businesses, etc. Information will also be collected from individual inventors who, with federal agency approval in accordance with the Bayh-Dole Act and associated regulations, had patent rights assigned back to them by the organization that received federal funding. Although there may be rare occasions where information may need to be collected via email, by phone, or by paper mail, the information will be primarily collected via the iEdison website to allow for an easily centralized location for reporting information to all of the agencies who have registered with iEdison. The information will be provided to all federal agencies who have registered iEdison accounts. Agencies registered with iEdison will have full read access to records to which they are associated as a funding agency (the primary funding agency will have edit access).

Because of the volume of information, the implication of publication on the availability of patent protection, and the legislative and regulatory timeline requirements, the information provided will be reported and used constantly and on an on-going basis.

Overall, the information collected is either required by the Bayh-Dole Act and its regulations or they help advance, track compliance and/or measure impact related to the Act's purpose and objectives. Agreement to provide the information is essentially a requirement to receive the benefit of federal research dollars. The information is used by federal agencies in the following ways:

- a. To ensure that federal agencies are made of aware of the inventions and patents, and the utilization thereof, associated with its funding programs and to which the government has certain rights;
- b. To tie inventions and patents to their associated federal funding programs;
- c. To allow inventions resulting from federal research the opportunity to be protected and commercialized either by the Contractor or (if the Contractor does not pursue or continue to pursue protection) the government;
- d. To track compliance with the Bayh-Dole Act and its implementing regulations;
- e. To track ROI from federal research funding in a number of ways, including inventions, patents, revenue, licenses, products, jobs, etc.

In general, we only anticipate that limited data derived from the information entered into the system will be made public, specifically the number of subject inventions, patent applications, issued patents, requests, and conveyances to the government. However, the specifics of the information in general is not anticipated to be released publicly. Certain information is subject to confidentiality requirements (see answer to question 10), but might be released to individuals under a FOIA request if certain requirements are met. The exception to this statement is NIH-funded FDA-approved products. These products are routinely published on a public website by the NIH to inform the public which FDA-approved products were developed with NIH funding.

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

Information will be primarily entered electronically via NIST's iEdison website. NIST has also implemented a number of technological features to minimize the burden on users. NIST has made an Application Programming Interface (API) available for users to connect the system to their own internal intellectual property database. The API allows certain information to be reported automatically from the Contractor's database into the iEdison system without having to manually enter the information via the iEdison website. NIST is also utilizing drag and drop technology to allow for easier and more efficient upload of documentation into the iEdison records. Additionally, when associated patent records are generated, certain information is auto-populated from existing records. If this information is not accurate, the Contractor can correct the information, but the auto-population feature saves time for the Contractor by avoiding the manual entry of similar information. Finally, NIST has implemented API integrations with other government websites, such as the USPTO and sam.gov, so that if certain information is available for a patent application (such as

the Title, Inventors, Issued Patent Number, and Issued Patent Date) or for a company (such as the Company Name and Address), this information can be auto-populated and/or updated in the iEdison records.

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.

Pursuant to the regulations and federal funding agreements, each agency that provides federal funding contributing to the conception or first actual reduction to practice of an invention must have inventions, associated patents, and other information reported to them. Utilizing iEdison, if multiple funding agreements supported one invention, each agency and funding agreement would be entered into the single invention record to avoid having to send a separate report to each agency. However, participation by each federal agency in iEdison is not mandatory, so there may be instances where an invention, its associated patents, and other information may need to be reported within iEdison to a participating agency and outside of iEdison to a federal agency (or agencies) that does not participate with iEdison. To limit this reporting duplication, significant effort has been made to register as many funding agencies in iEdison as possible. Currently, more than 30 federal agencies are either enrolled in the current iEdison system or intend to participate in the redesigned iEdison system.

To avoid duplication with the iEdison system itself, the system recognizes if a contractor tries to enter an invention record with the same title as a previously submitted record and notifies that contractor that this could be a duplicate record and they should confirm that this record was not previously entered. Additionally, each patent serial number can only be entered into the system once (across all contractors). If a contractor tries to enter a patent serial number that has already been entered, they are given an error and told that the serial number already exists in the system.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Small businesses and entities normally do not have the same volume of information to enter into the database as larger institutions, such as universities. However, we have implemented time-saving features by building in the capabilities discussed in Question 3 above. NIST has programmed portions of the database to auto-populate basic information.

6. Describe the consequence 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.

If this information is not collected by Federal funding agencies in a timely manner, then the agencies would be out of compliance with requirements under the Bayh-Dole Act (35 USC § 200-212). Additional information not specifically required under the Bayh-Dole Act and its implementing regulations at 37 CFR 401, is allowed as additional information which can be collected under 37 CFR 401.5(f), which permits requiring certain additional information to be entered into grants or contracts terms and conditions, and 401.14(h), which allows agencies to require information related to utilization of inventions up to annually. In addition to being out of compliance, the consequences of not receiving this information in a timely manner include:

- a. Loss of intellectual property rights of interest to the government;
- b. Inability to calculate ROI from federally funded research programs;
- c. Unnecessary government spending as a result of government licensing and paying for rights to inventions in which they already have a government use license.

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 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 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.

- a. Respondents required to report information to the agency more often than quarterly: In accordance with the regulation and due to foreign and domestic patent laws that require the filing of patent protection before publication or within a specified timeframe afterward, it is necessary for respondents to notify the federal funding agency of inventions and patent filings on an ongoing basis. As such, respondents will likely be required to report information more than quarterly in order to adhere to the regulations and to ensure that patent applications are filed before they are legally barred from doing so.
- b. Respondents required to submit proprietary information: Because the Bayh-Dole Act and its regulations require the disclosure of inventions that are most often pre-patent application and/or patents that are pre-publication, the information contained therein is inevitably proprietary. However, the iEdison system is built to only provide this information to the federal government and is held in confidence. Pursuant to U.S. law, this information cannot be made public until a reasonable amount of time has passed in which to file a patent. Furthermore, the agencies are not required to produce copies of documents included in patent applications. Finally, in accordance with these laws, the Bayh-Dole regulations specifically exempt these documents from FOIA requests for reasonable time periods and only allow disclosure of this information under certain circumstances. As such, proprietary information obtained is kept confidential.

The remaining scenarios described do not apply.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, 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. 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.

A 60-day Federal Register Notice soliciting public comment was published on Thursday, May 4, 2023 (Vol. 88, pg. 28516-28517). No comments were received.

A 30-day Federal Register Notice soliciting public comment was published on Thursday, August 24, 2023 (Vol. 88, pg. 57941-57942).

NIST has been discussing these standardized utilization questions with the interagency working group for Bayh-Dole on a monthly basis since December of 2021. This group consists of members from agencies across the federal government. The questions went through several rounds of edits and changes due to agency suggestions as well as

Executive Order 14104. The interagency working group continues to discuss these questions as we work to create a guidance document to help users know how to answer the utilization questions.

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

There are no plans to provide payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

Because information submitted by the respondents often contains unpatented technical information, it is of the highest importance that the information is held in confidence. This fact is routinely communicated to the users through the database's user manual and training. Pursuant to 35 USC 205, the government can withhold information disclosing any invention in which it has an interest for "a reasonable time in order for a patent application to be filed" and is not required to disclose documents which are part of a patent application.

A Privacy Impact Assessment is not currently needed for this system. The information is deemed a Privacy Act System and is covered under the System of Records Notice COMMERCE/DEPT-23: Information Collected Electronically in Connection with Department of Commerce Activities, Events, and Programs.

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. This 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.

Collection of gender is possibly a question of a sensitive nature and may be considered private. This field will be voluntarily given by the participant and is not required. NIST wishes to collect this information as we believe it can provide information to understand whether agency programs are achieving equity in program participation, specifically as it relates to the innovation process, and promoting the collection of information that has been shown to raise awareness and promote equity.

12. Provide estimates of the hour burden of the collection of information.

Providing burden estimates for this particular collection is difficult because not all record types (discussed in the answer to question 2 above) and not all fields will be applicable to each case and the frequency of entering information by users varies drastically based on the volume of their federal funding and how often that funding results in inventions. However, in order to most accurately estimate the burden, we have broken the hour burden down by record type (invention, patent, and utilization) and calculated the average number of each type of record which have been recorded in the current iEdison system for the last 5 years (Table 1 below). We then divided the total burden by the current number of Organizations with iEdison accounts (Table 2 below). However, it should be noted that some users, such as a small business, may only need to report 1 technology into iEdison ever, whereas other users, such as large research universities, may need to report hundreds or even thousands of inventions, patents, and utilization reports every year.

Annual Burden

Record Type	Number of respondents	Time to complete	Burden Hours
Invention Records	3063	75 minutes (5 times /year)	19,144 hours
Patent Records	3063	45 minutes (5 times / year)	11,486 hours
Utilization Records	3063	25 minutes (30 times / year)	38, 288 hours

* Utilization Records are the only record type to undergo a burden change in this revision.

13. Provide an estimate for 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 already reflected on the burden worksheet).

There are no capital/start-up or ongoing operation/maintenance costs associated with this information collection.

14. Provide estimates of annualized costs 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 may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

Type	Annual Budget
OISM Personnel (2 programmers, one data manager)	\$68,000
Contractor Support	\$505,000
TPO Personnel (1 manager, 1 data manager)	\$400,000
Software and Hosting Fees (iEdison.gov domain cost, login.gov service fee, AWS service fee, Salesforce service fee)	\$120,000
TOTAL	\$1,705,000

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

The Bayh-Dole Act (35 USC 18) and its implementing regulations (37 CFR 401) allow agencies to ask Contractors for periodic reports on the utilization of a subject invention or on efforts at obtaining such utilization. Under the regulations, these reports shall include “information regarding the status of development, date of first commercial sale or use, gross royalties received by the contractor, and such other data and information as the agency may reasonably specify. These new questions are deemed reasonable to request for a number of reasons. The new questions include a follow-up question to provide details when an invention is not licensed or commercialized to ensure that practical application is being timely achieved and additional information regarding product manufacturing to ensure that contractors, assignees, and licensees are compliant with any domestic manufacturing requirements.

Executive Order 14104 directs funding agencies to require Contractors to annually report to the funding agency the names of licensees and manufacturing locations of subject inventions (EO 14104, Section 4(c)). Executive Order 13985 directs agencies to assess whether their programs perpetuate systemic barriers to opportunities and benefits. In order to conduct these assessments, data is needed. The addition of the gender data field is a first step for agencies to be able to analyze participation and disparities by gender in the federally funded innovation process.

Additionally, under the regulations Contractors are required to identify inventors when reporting subject inventions to the funding agency(ies). Gender disparity in the innovation process has been of particular interest over the last several years. This amendment adds a gender data field to inventor information so that contractors and agencies can track participation by gender in inventing, patenting, and licensing and identify if there are any disparities by gender.

The table below details the information/data fields being requested as well as the statute or regulation(s) authorizing the collection of this information and the needs or uses for collection of this piece of information. The information will be collected in one of three major record categories within iEdison: Invention, Patent, or Utilization Records. Some of the data collected are questions already being asked by the current iEdison system, though some questions have been amended and several questions have been added to provide additional data to the funding agencies on the impact of their research programs and to comply with EOs 14104 and 13985. It should be noted that because the iEdison system is used by multiple agencies, the needs/uses listed represent the needs/uses for all agency iEdison users. If only certain agencies use or requested a particular piece of information, that is indicated within the chart. Because most of the information is not made public, but the Contractors who provide the information can use the iEdison database for their own reporting/tracking purposes, the Contractors own uses of the information are also included in the table below.

Item No.	Record Type where Requirement is Locate	Requirement	Statute	Regulation	Needs/Uses
1	Invention Record	Inventor Gender †			- Used by Contractors and agencies to to prepare simple reports in an effort to gauge the innovation process by gender, specifically to identify where and if gender disparity exists.
2	Utilization Report	Utilization Report (UR) Year	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to designate the year (usually fiscal) for which they are calculating the information requested in the Utilization Report Questions.
3	Utilization Report	Please indicate the latest stage of development of any product arising from this invention, according to the following categories: Not Licensed or Commercialized; Licensed; Commercialized	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to run reports on which inventions have been licensed to companies or developed into a commercialized product. - Used by agencies to identify development of federally funded technologies. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
4	Utilization Report	What are your current commercialization plans for this invention?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to track compliance with requirement to take steps to achieve practical application when a subject invention's stage of development is listed as "Not Licensed or Commercialized".
5	Utilization Report	In the designated reporting period, how many exclusive licenses and/or options are or were active?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to run reports on how many federally funded inventions are exclusively licensed. - Used by agencies to calculate the number of federally funded inventions that are exclusively licensed. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. - Used by agencies to identify how

					many technologies (once commercialized) should be substantially manufactured within the United States or have an accepted U.S. Manufacturing Waiver.
6	Utilization Report	Name of each exclusive licensee	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to identify number and names of companies or individuals that that are licensing inventions resulting from federal research dollars.
7	Utilization Report	In the designated reporting period, how many non-exclusive licenses and/or options are or were active?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to run reports on how many federally funded inventions are non-exclusively licensed. - Used by agencies to calculate the number of federally funded inventions that are non-exclusively licensed. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
8	Utilization Report	Name of each non-exclusive licensee	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to identify number and names of companies or individuals that that are licensing inventions resulting from federal research dollars.
9	Utilization Report	In the designated reporting period, how many licenses and/or options of any type to small businesses (as defined by relevant SBA regulations) are or were active?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to aid in calculation of ROI (including impact) from federal research dollars. - Used by agencies to track fulfillment of legislative objective to benefit small businesses.
10	Utilization Report	In the designated reporting period, what was the total gross income received as a result of license or option agreements?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to run reports on how much revenue resulted from the licensing of federally funded inventions. - Used by agencies to aid in calculation of ROI from federal research dollars.
11	Utilization Report	Other than U.S. Preference (35 U.S.C. 204), is the invention subject to any U.S. manufacturing requirements (e.g. U.S. Competitiveness provision, a U.S. Manufacturing DEC, etc.)?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies as a mechanism to determine which set of domestic manufacturing requirements are imposed on the Contractor and subject inventions by the funding agreement.
12	Utilization Report	In the designated reporting period do all grants to any person of the exclusive right to use or sell the subject invention in the United States require that any products embodying the subject invention or produced through the use of the subject invention will be manufactured	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to confirm if Contractors are including domestic manufacturing requirements in their license agreements as required by 35 U.S.C. 204.

		substantially in the United States as required by 35 U.S.C. 204?			
13	Utilization Report	In the designated reporting period are all products embodying the subject invention or produced through the use of the subject invention manufactured substantially in the United States for all grants to any person of the exclusive right to use or sell the subject invention in the United States as required by 35 U.S.C. 204?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to confirm if licensees are compliant with domestic manufacturing required by 35 U.S.C. 204.
14	Utilization Report	In the designated reporting period, do all licenses include a requirement that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States (including manufacturing requirements other than 35 U.S.C. 204)?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to confirm if Contractors are including domestic manufacturing requirements in their license agreements as required by the other domestic manufacturing requirements listed in their funding agreement.
15	Utilization Report	In the designated reporting period, are all products embodying the subject invention or produced through the use of the subject invention manufactured substantially in the United States(including manufacturing requirements other than 35 U.S.C. 204)?	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to confirm if licensees are compliant with domestic manufacturing required in the Contractor's funding agreement.
16	Utilization Report	What was the calendar year of the first commercial sale? (YYYY)	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to run reports on which of their federally funded inventions have resulted in a sale. - Used by agencies to identify how many federally funded inventions have made it into the marketplace. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
17	Utilization Report	Product Name (for products made through the use of or embodying the subject invention)	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to link federal funding to products and to identify number of and names of products. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
18	Utilization Report	Name of manufacture(s)	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to identify number and names of manufacturers that are making products resulting from federal research dollars.
19	Utilization Report	Manufacturing Country	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to determine what products are being manufactured in the United States versus in other countries. - Used by agencies to determine if

					Contractors are enforcing requirement that exclusive licensees are manufacturing products substantially within the United States (or obtaining a waiver for this requirement) - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
20	Utilization Report	Manufacturing State (if Manufacturing Country is the United States)	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to determine where in the United States products are being manufactured. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
21	Utilization Report	Notes			- Used by Contractors to provide any additional information they feel might be necessary to establish compliance or explain special situations to agencies. - Used by agencies to help determine compliance.
22	Utilization Report	Commercial Product Name of Any FDA-Approved Product Utilizing Invention*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to link federal funding to FDA approved products. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
23	Utilization Report	FDA Approval Number*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to link federal funding to FDA approved products.
24	Utilization Report	FDA Approval Type*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to link federal funding to FDA approved products.
25	Utilization Report	Selection to Make FDA Product Information Public*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by Contractors to indicate that they want FDA information to not be published by agencies. - Used by agencies to filter out certain products so that the remainder can be posted publicly.
26	Utilization Report	Approx. Number of US-based Jobs Created Because of Commercialization Efforts During Reporting Period*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
27	Utilization Report	Number of new US-based Companies Created from Commercialization Efforts During Reporting Period*	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
28	Utilization Report	Unique Commercial Products made (with NAICS code if applicable) †	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to link federal funding to products in the marketplace. - Used by agencies to aid in calculation of ROI (including impact) from federal research dollars.
29	Utilization Report	Number of Each Commercial Product Made at Each	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to determine if Contractors are enforcing

		Location [†]			requirement that exclusive licensees are manufacturing products substantially within the United States (or obtaining a waiver for this requirement)
30	Utilization Report	How Development Complies with US Manufacturing Requirement [†]	35 USC 202(c)(5)	37 CFR 401.14(h)	- Used by agencies to determine if Contractors are enforcing requirement that exclusive licensees are manufacturing products substantially within the United States (or obtaining a waiver for this requirement)

[‡] This is not a required field for participants

* Information only required for NIH funded technologies

[†] Information only required for DOE funded technologies

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.

There are no in-depth statistical analyses being conducted at this time and no plans for publication of in-depth statistical data.

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.

The expiration date will be clearly displayed with the OMB Control Number.

18. Explain each exception to the topics of the certification statement identified in “Certification or Paperwork Reduction Act Submissions.”

There will be no exceptions to the certification statement and NIST certifies compliance with 5 CFR 1320.9 and the related provisions of 5 CFR 1320.8(b)(3).