

~~Bayh-Dole Reporting:~~ How-To for Compliance Managers

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The following presentation reflects the personal views and thoughts of Michele O'Shea and Gina Smutz, and is not to be construed as representing in any way the corporate views or advice of Borman and Company or Washington University in St. Louis and their Affiliates, Subsidiaries or Divisions, nor the views or advice of the Association of University Technology Managers (AUTM). The content is solely for purposes of discussion and illustration, and is not to be considered legal advice.



Is a Vibrant Compliance Program Possible?



YES!



WHAT WE NEED...



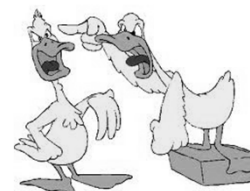
- ✓ Acknowledgement by management of need (and support for) staffing of personnel for compliance reporting.
- ✓ Resources- Personnel requirements based on number of inventions/patents and status of reporting - is there a significant backlog?
- ✓ Half-time or full-time position? Will this person also be managing other responsibilities?
- ✓ Development of SOPs/templates for compliance reporting; department acceptance and cooperation with responding to deadlines; compliance docketing reminder system.
- ✓ Training: data management, patent prosecution, iEdison training.
- ✓ Other resources: Patent Search Sites (USPTO PAIR, Google Patents), AUTM online webinars and conferences (Tools & Compliance courses); NIH online webinars and conferences.



WHAT WE NEED...

COMMUNICATION

- ✓ Licensing Managers, Agreements/Finance Depts.
- ✓ Inventors/PI's
- ✓ Sponsored Programs Office
- ✓ iEdison Help Desk
- ✓ Federal Agencies
- ✓ Law Firms: Requesting amendments to GSC
- ✓ Other Technology License Office Compliance Personnel: Obtain reporting information for jointly owned inventions; develop network of compliance professionals



WHAT WE NEED...

PATENT MANAGEMENT DATABASE

- ✓ Track inventions/patents/compliance/agreements/finance/contacts.
- ✓ Track and report compliance requirements.
- ✓ Ability to create reminders and track missing data.
- ✓ Track and create custom compliance reports.
- ✓ Finance Reports pertaining to federally funded licensed inventions for utilization reporting.



BAYH-DOLE FOR EVERYONE



Bayh-Dole applies equally to any grantee regardless of status/size.

37 CFR 401.1(2)(b) This part implements 35 U.S.C. 202 through 204 and is applicable to all Federal agencies. It applies to all funding agreements with business firms regardless of size (consistent with section 1, paragraph (b)(4) of Executive Order 12591, as amended by Executive Order 12618) and to nonprofit organizations, except for a funding agreement made primarily for educational purposes. Certain sections also provide guidance for the administration of funding agreements which predate the effective date of this part. In accordance with 35 U.S.C. 212, no scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.



Employee - Patent Agreements



A contractor now must agree to require, by written agreement, its employees to assign to the contractor their entire rights to each invention made with federal funding;

“37 C.F.R. § 401.14(f)(2) 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 in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government’s rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c)(1), above. **The contractor shall instruct such employees through employ agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.**”



DATA COLLECTION - INVENTORS

- ✓ Status at the time of invention (institution, student, department, visitor)
Communicate with joint institutions/companies regarding funding and compliance.
- ✓ Current Status (e.g., Employee of Institution or Company)
May list a new employer or institution but invented somewhere else.
- ✓ Principal Investigator
Funding confirmation, who’s lab and locating Grant Managers.
- ✓ Inventor Contact Information
Add a link to your website and a request to your disclosure instructions to notify TTO of changes.
Make notes in inventor contact records of dates of change.



DATA COLLECTION - PUBLICATION

- ✓ Publishing Entity
- ✓ Dates of Publication
 - If you are not converting or filing the invention/patent must be waived **60** days prior to the publication bar.
- ✓ Dates of Submission
 - If it has been submitted for publication, when and to which publisher. If it has been accepted, when?
 - Notify the government if there is a post disclosure publication.



DATA COLLECTION - FUNDING

Federal Grants	Foundations
Federal/State Contracts	Material Transfer Agreements (MTAs)
Subcontracts	Computational Agreements
Cooperative Agreements/Grants/Contracts	Facility Agreements
Corporate Sponsored Research	Equipment/Instrument Agreements
Gifts	



DATA COLLECTION - FUNDING

- ✓ Know your grant – confirm prime of the grant/contract via funding agency websites (NIH Reporter and NSF Award Search) and/or your institute’s internal accounting system or research office.
- ✓ Review grant/contract/agreement IP provisions to understand your requirements and notify (do not include the disclosure) the prime contractor of your institution’s invention (contract close out).
- ✓ Work with PIs, inventors, grant managers, sponsored research, foundation relations and your contracts departments to ensure you have correct information.
- ✓ Develop a system to follow disclosures with incomplete/missing funding information.



DATA COLLECTION - FUNDING

Bayh-Dole 2 - NIH

NIH Notice No. NOT-OD-18-233

“applies to all new and continuation awards dated on or after October 1, 2018”

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-233.html>

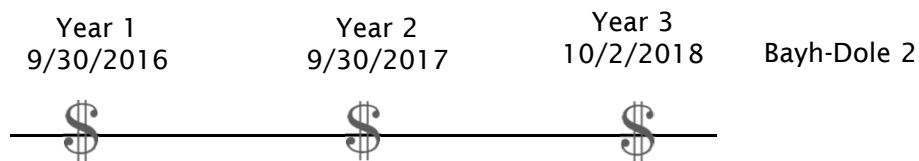
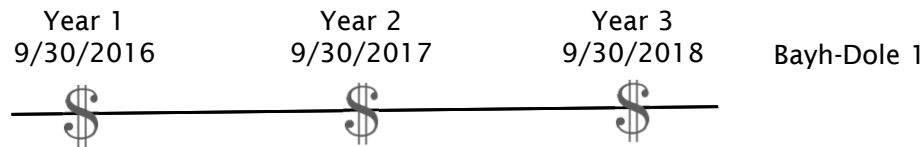
Enter the Federal Award Date in the iEdison Invention Explanatory Notes if an award date is after October 1, 2018 AND the date of the disclosure is AFTER October 1, 2018.



FOLLOW THE MONEY



DATA COLLECTION - FUNDING



DATA COLLECTION - FUNDING

Bayh-Dole 1

The effective date of the revised rule is May 14, 2018. The revised rule does not apply to a funding agreement (contract, grant or cooperative agreement) in effect on or before May 14, 2018, and a provisional application that was pending on May 14, 2018 would not fall under the revised rule.

Bayh-Dole 2

If a funding agreement in existence on or before May 14, 2018 is thereafter amended, the funding agency may, but is not required to, recite in the amended funding agreement that it will be subject to the new rule.

An amendment for this purpose is any formal communication from a funding agency informing the contractor that the revised rule will apply. A funding agency is not limited to any particular form or type of funding agreement amendment, and may amend a pre-existing funding agreement solely for the purpose of requiring compliance with the revised rule.

<https://www.nist.gov/tpo/bayh-dole-regulations-faqs>



DATA COLLECTION - DOCUMENTS

- ✓ Confirm that the invention information is complete and is not missing referenced attachments, supplemental data or figures.
- ✓ Before disclosing an invention to the Government make sure it complies with 37 CFR 401.14 (c) (1)...
Subject Invention: Any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement, etc.
- ✓ Gather data quickly. Check disclosures as soon as they are received. It is easier to get data upfront. On federal grants and contracts we only have 60 days to disclose the invention.
Use the data tools you have available, run reports for all new disclosures each month.



DATA COLLECTION – CO-INVENTORS

- ✓ Send a copy of the disclosure to the co-inventor's employer/institute's Technology Transfer Office.
- ✓ Inquire if any federal funds support the contributions of the co-inventor. If both institutions are funded, communicate as to which one will do compliance and give "view rights" to the other. Multiple institutes can enter disclosures but there can only be one patent record.
- ✓ Inquire regarding any publications or pending manuscript submissions.



REPORTING INVENTIONS

Description can consist of one or more of the following:

- ✓ A summary provided in the disclosure form.
- ✓ Additional information such as an abstract, presentation, etc.
- ✓ If you have filed a patent application, you can submit the disclosure with a copy of the provisional or U.S. non-provisional application if it has been entered in iEdison and if the GSC is correct. In order to do this, you need to elect title prior to submitting the filing with the disclosure. If any of these steps are missing, the disclosure will be rejected.



REPORTING INVENTIONS

PUBLICATIONS

- ✓ The first publication date needs to be entered in iEdison.
- ✓ If an application is not filed and reported within one year of that date, iEdison will change the status to "BARRED"
- ✓ If you have in fact filed, you can enter a patent filing and then change the status to "elect title"
- ✓ If you haven't filed, the status will remain as "BARRED".



REPORTING INVENTIONS

NEW

Election of Title

- ✓ **Must elect title prior to or on initial patent application filing date.**
- ✓ The time to elect title is two (2) years from disclosure date or 60 days prior to a publication:
 - ✓ NIH will consider extension for election of title, if requested.
 - ✓ Upon the execution of a license agreement (licensed as a patented biological material or research tool).



REPORTING PATENTS - Provisionals

PROVISIONALS ARE NOW INITIAL PATENT APPLICATIONS...



REPORTING PATENTS

GOVERNMENT SUPPORT CLAUSE (GSC)

Statement as defined at (37 CFR 401.14 f (4)):

“This invention was made with government support under (contract/grant) awarded by (Federal Agency). The government has certain rights in the invention.”

It is now a federal requirement that the wording of the GSC be exactly as it is worded in the CFR.



REPORTING PATENTS

PATENTS

Government Support Clause and Confirmatory License Reporting Tips:

- ✓ Prior to submission of documents, confirm that the grant information is consistent in your database, iEdison, and the patent application. If it is not, you will receive a rejection.
- ✓ If funding is identified in the GSC that you were not aware of, the reporting will need be corrected from the beginning as needed (disclosure, election of title, license, GSC).



REPORTING PATENTS

PATENTS – ELECTRONIC PATENT ASSIGNMENT SYSTEM (EPAS)

- ✓ EPAS is used to amend/add the Government Support Clause in abandoned, waived and/or expired patents (except provisional applications).
- ✓ EPAS can be used to upload all Confirmatory Licenses.

Upon request, NIH will provide a copy of the EPAS instructions:
Website: <https://epas.uspto.gov>.



REPORTING UTILIZATION

IEDISON UTILIZATION REPORTS

- ✓ Utilization reports begin upon election of title.
- ✓ Utilization reports must be submitted to Federal Agency annually and must include negative reports.
- ✓ NIH and DOE require utilization reports; if you have questions about other agencies, reach out to them to review specific requirements.
- ✓ Utilization reports are due according to awardee-defined 12 month reporting cycle in iEdison. This defined period can match your fiscal year calendar.



REPORTING UTILIZATION

IEDISON UTILIZATION REPORTS



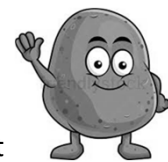
- ✓ Coordinate with Finance Group
 - ✓ Agreement data needs to be up to date and accurate;
- ✓ Track entity status of licensees;
- ✓ Identify any products and their FDA Nos.;
- ✓ Confirm formula for reporting income: i.e., how to calculate income if there are several cases under a single license;
- ✓ Save utilization data for batch upload to iEdison
 - ✓ iEdison batch uploads can be awkward, and instructions are on the website https://era.nih.gov/iedison/bulk_upload_S2S.htm.



WAIVING INVENTIONS AND PATENTS

Waiving of Inventions

- ✓ Must elect/waive within 2 years or within 10 months of first patent application;
- ✓ If there is no election of title and there are no filings in iEdison, invention will be “Barred” if there has been a publication more than one year ago;
- ✓ If inventor(s) would like to request return of rights, need to consider upcoming publication dates and take into consideration the new deadline requirements.



WAIVING INVENTIONS AND PATENTS

Waiving Patents

- ✓ Patents/patent applications must be waived at least 60 days prior to the discontinuation of patent prosecution or decision not to pay a maintenance fee.
 - ✓ Track these dates through docketing or reminders in database.
- ✓ If inventor(s) would like to request return of rights, need to consider upcoming due dates to make sure the Inventor(s) have time to take over the patent prosecution/maintenance fees prior to the deadline.
 - ✓ Inventor(s) need the Federal Agency approval to return of rights, which usually takes longer than 30 days.
 - ✓ Once inventor owns the patents, compliance is transferred to a new iEdison account, which will be managed by the inventor(s).



WAIVING INVENTIONS AND PATENTS

PRACTICAL TIPS FOR TRACKING DATES

- ✓ Set up reminders for your Licensing Managers, Inventors, Licensees, etc.:
 - ✓ 90 days prior to publication bar;
 - ✓ 9 months after the filing of a provisional patent application to convert or request extension. Note: Decision to waive must be made and provisional must be waived iEdison within 10 months of filing;
 - ✓ 90 days prior to discontinuation of prosecution;
 - ✓ 90 days prior to non-payment of maintenance fee;

These reminders give decision makers one month to decide prior to government reporting deadlines for compliance manager.



MANAGING NOTIFICATION MESSAGES

GOOD NEWS



- ✓ Notification messages are manageable.
- ✓ Notification messages are designed to help compliance manager remain in compliance.
- ✓ Notifications can be filtered by category (inventions, patents, utilization) and by agency.

Note: the recommendations for management of notifications apply primarily to NIH funded inventions; other agencies may review inventions differently, and inventions and documents may be rejected for different reasons.



MANAGING NOTIFICATION MESSAGES

How to Export Notification Messages:

1. View notification messages from the landing page
2. Select all in your search results

Notification Messages Search Results					
Notification Message records found, displaying 1 to 20.					
<input checked="" type="checkbox"/>	No.	Posting Date	Message	Due Date	Invention Report Number
			The Invention Disclosure		

3. Export messages at the bottom of the page
4. Show download in folder
5. **Rename file to .xls**

4679701_2018-10-31.xls

iEdison Reports Administration

- [Search/Modify Existing Invention Reports](#)
- [Search/Modify Existing Patent Reports](#)
- [Search/Modify Existing Utilization Reports](#)
- [View Notification Messages](#)
- [View Submitted Documents](#)
- [View or Download Reports on iEdison Records](#)

Suppress Message Export Message

4679701_2018-10-31
<https://public.era.nih.gov/iEdison/notificationMessages.do>

Show in folder



MANAGING NOTIFICATION MESSAGES

Disclosure Rejected Due to Insufficient Description

If after internal review your institution feels that the description is adequate you can ask NIH to review it and reconsider it for acceptance; you can also re-upload it with additional documents (publication, patent application, etc.) Going forward, review all disclosures prior to submission to iEdison and ask inventor(s) or Licensing Manager to provide additional information up front to decrease these notifications.



MANAGING NOTIFICATION MESSAGES

Disclosure Rejected Due to Insufficient Description-Concept? Is Disclosure premature and thus not reportable?

If the disclosure (and accompanying materials) do not meet reporting requirements, it may be considered a premature disclosure (Concept), in which case it is not reportable under Bayh Dole until/unless it meets the description requirements . If a premature disclosure has already been reported to iEdison:

- ✓ Need to write to NIH to have the disclosure voided (provide reason);
- ✓ With void request need to submit NIH final invention statement that does not list the invention in question – FIS may need to be amended;
- ✓ Need to set up review procedures for incoming disclosures, so as not to report them if they are premature.



MANAGING NOTIFICATION MESSAGES

Disclosure Rejected Because Inventors/Grant Numbers/Title Do Not Match What is in the EIR (iEdison Invention Report)

The disclosure is only accurate as of the moment it is submitted. We often receive additional inventors, grants, and title changes after the fact. If the invention disclosure has not yet been accepted, it needs to be re-submitted with the additional information. Once the disclosure is accepted by the system, it doesn't ask for an additional disclosure or amendment of disclosure data.



MANAGING NOTIFICATION MESSAGES

A Confirmatory License is Due

Check the patent records first, as license may in fact not be due. It is possible that the filings are not linked. A license is not due for each application. If the filings are not linked, iEdison is programmed to ask for a license for each filing. You won't accurately be able to determine how many licenses are in fact due until the filings are linked in the system.

A License is due for the first U.S. provisional application (or U.S non-provisional filing if no provisional) and for CIP applications.



MANAGING NOTIFICATION MESSAGES

Government Support Clause (GSC) Does Not Have Correct Language or Funding Data

“This invention was made with government support under (grant/contract#) awarded by (agency). The government has certain rights in the invention.”

Correction is made by uploading an Amendment to an application or Certification of Correction to an issued patent (need to upload proof of filing, with Amendment such as OFR).

Notify counsel of funding and the correct statement when patent(s) is filed. Include this statement in your general procedures to outside counsel.

If abandoned, waived and/or expired use EPAS.



MANAGING NOTIFICATION MESSAGES

Remember... “THE BEST DEFENSE IS A GOOD OFFENSE”

BE SURE:

- ✓ The disclosure is complete.
- ✓ Patent Counsel includes an accurate GSC in compliance with Bayh Dole in ALL applications.
- ✓ Confirmatory Licenses are uploaded for each patent family (first provisional or non-provisional and any CIP applications).
- ✓ Develop a system of for monitoring and addressing notification messages.



PATENT CERTIFICATION

CONTRACT/PROJECT
(\$) REPORTING

NIH Commons
NSF Fast Track
PAMS
EPIC
NTTS
FedConnect

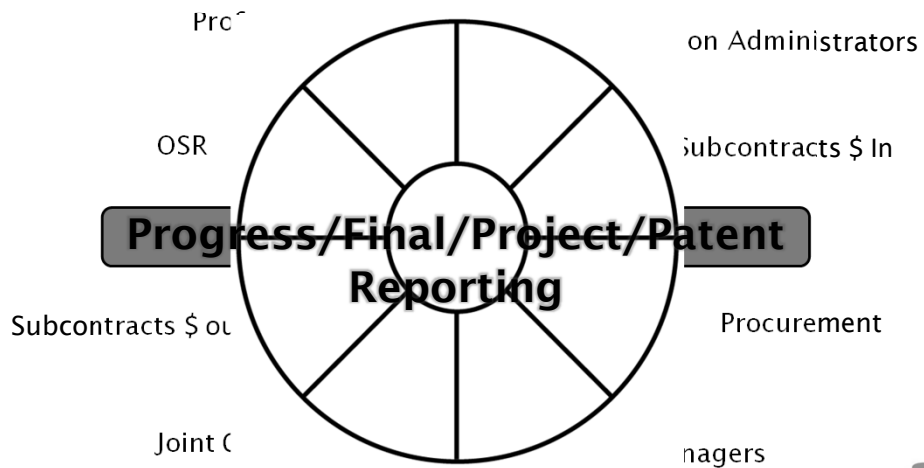


BAYH-DOLE (IP)
REPORTING

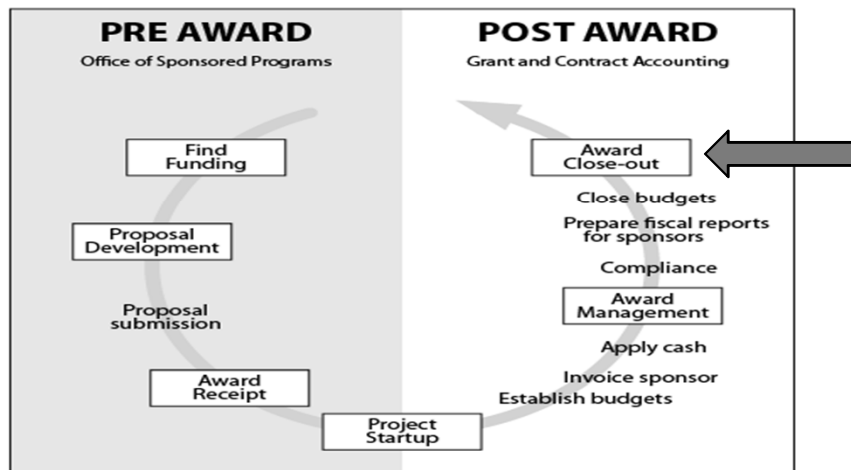
iEdison
eNTR
Email
Snail Mail



Patent Certification



Patent Certification



Patent Certification

REPORT TYPES

- ✓ **Progress Reports**
 - ✓ Progress reports are required at least annually to document recipient accomplishments and compliance with terms of award. Describe scientific progress, identify significant changes, report on personnel, and detail plans for the subsequent budget period or year.
- ✓ **Final Invention Reports**
 - ✓ Awardees of research grants must submit a Final Invention Statement and Certification within 90 days of the termination of award.



Patent Certification

WHY?

- ✓ Sponsor must confirm that the grantee has met its IP requirements under the grant before proceeding with “final payment” and closing their files
- ✓ The report is a “Safety Net” to make sure disclosures and information reported by the PI in grants system have also been disclosed and reported in iEdison.
- ✓ Provide invention data to the funding agency program offices.



Patent Certification

A computer monitor icon with the text 'iEdison' on the screen.

iEdison

A computer monitor icon with the text 'Commons' on the screen.

Commons

- ✓ Reports require the signature of an institutional official authorized to sign on behalf of the institution.
- ✓ Invention/Patent Certification needs to be approved by the Principal Investigator (PI).
- ✓ Regardless of who is completing and/or signing a Report an Invention/Patent Certification is needed from the Tech Transfer Office (TTO).
- ✓ Discrepancies need to be reconciled by TTO and approved by the PI.
- ✓ Must include subcontract final reports.



Patent Certification

“Public reporting burden for this collection of information is estimated to vary from 5 to 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.”

NIH - HHS 568



Patent Certification

DOE Interim/Final Patent Certification

DOE CONTRACT AND PROJECT NUMBER		DATE REPORTED	
PATENT CERTIFICATION			
Contractor _____		<input type="checkbox"/> Interim Certification <input type="checkbox"/> Final Certification	
DOE Prime and/or Subcontract No. _____			
Contractor hereby certifies that:			
1. All procedures for identifying and disclosing subject inventions as required by the patent clause of the contract have been followed throughout the reporting period.			
2. There were no subcontracts or purchase orders involving research, development, and demonstration except as follows. [State none when applicable.]			
3. No inventions or discoveries were made or conceived in the course of or under this contract other than the following. [Certification includes (C), does not include (N) an subcontractor]. [State none when applicable.]			
TITLE	INVENTOR	DATE REPORTED	DOE-“S” NO.*
4. The completion date of the contract is as follows:			
5. The following period is covered by the certification:			
Month	Day	Year	to Month Day Year
Contractor _____		Signature _____	
Address _____		Date of Certification _____	
* Also include Subcontract No. if available.			

- ✓ Submitted in FedConnect
- ✓ Name of Inventor(s)
- ✓ Title of Invention
- ✓ Date Invention Reported (iEdison)
- ✓ DOE File Number



Patent Certification

DEPARTMENT OF DEFENSE Interim/Final Invention Report

REPORT OF INVENTIONS AND SUBCONTRACTS (Pursuant to "Patent Rights" Contract Clause Flow Implementation on DOD)				Form Approved OMB No. 0704-0188 Expires Jan. 01, 2009	
<p>The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, reviewing and collecting the data, and reviewing and approving the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Paperwork Reduction Project (0704-0188), Washington, DC 20301. Respondents should be aware that notwithstanding any other provision of law, no person shall be penalized for failing to comply with a collection of information if it does not display a currently valid OMB control number.</p> <p>PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO THE CONTRACTING OFFICER.</p>					
1. NAME OF CONTRACTOR/SUBCONTRACTOR		2. NAME OF GOVERNMENT PRIME CONTRACTOR		3. TYPE OF REPORT (a, only)	
a. ADDRESS (Include ZIP Code)	b. ABBREVIATED CITY	a. ADDRESS (Include ZIP Code)	b. ABBREVIATED CITY	a. INTERIM	b. FINAL
SECTION I - SUBJECT INVENTIONS					
5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR (If "None," so state)		ELECTION TO FILE PATENT APPLICATION (If "None," so state)		CONFIRMATORY PATENT OR AGREEMENT FORWARDED TO GOVERNMENT OFFICE OF DEFENSE	
a. NUMBER OF INVENTIONS (Each Item, include serial)	b. TITLE OF INVENTION	a. YES	b. NO	a. YES	b. NO
6. EMPLOYER OR INVENTOR(S) NOT EMPLOYED BY CONTRACTOR/SUBCONTRACTOR		8. SELECTED FOREIGN COUNTRIES IN WHICH A PATENT APPLICATION WILL BE FILED			
a. NAME OF INVENTOR (Last, First, Middle Initial)		b. TITLE OF INVENTION			
c. ADDRESS OF EMPLOYER (Include ZIP Code)		d. FOREIGN COUNTRIES OF INVENTION APPLICATION			
SECTION II - SUBCONTRACTS (Continuation of "Patent Rights" clause)					
4. SUBCONTRACTS AWARDED BY CONTRACTOR/SUBCONTRACTOR (If "None," so state)					
a. NAME OF SUBCONTRACTOR	b. ADDRESS (Include ZIP Code)	c. SUBCONTRACT NUMBER	d. DATE WHEN REPORT IS DUE	e. DESCRIPTION OF WORK TO BE PERFORMED UNDER SUBCONTRACT	f. DISCLOSURE OF INVENTIONS TO GOVERNMENT OFFICE OF DEFENSE
SECTION III - CERTIFICATION					
7. CERTIFICATION OF REPORT BY CONTRACTOR/SUBCONTRACTOR (See comment 7. at end of instructions) (Print name and address of reporting organization)					
I certify that the reporting party has procedures for prompt identification and timely disclosure of "Subject Inventions," that such procedures have been followed and that all "Subject Inventions" have been reported.					
8. NAME OF AUTHORIZED CONTRACTOR/SUBCONTRACTOR		9. TITLE		10. SIGNATURE	
a. ADDRESS (Include ZIP Code)		b. TITLE		c. DATE SIGNED	

- ✓ Grant Directed
- ✓ Name of Inventor(s)
- ✓ Title of Invention
- ✓ Disclosure/Application/Patent Number
- ✓ Election/Confirmatory License
- ✓ Subcontracts



Patent Certification

PROCESS EXAMPLE

1. OSR (Office of Sponsored Research) requests list of inventions funded by a specific grant for which they are doing an interim or final report from the TTO.
2. TTO responds with a positive reply, listing all of the inventions that were funded by that grant to date, or a negative reply, indicating that no inventions were funded by that grant to date.
3. OSR requests that the PI indicate their agreement with the response from TTO.
4. The PI (Principal Investigator) provides their agreement, or disagreement with the response from TTO. The TTO works with the PI to ensure that the correct invention information is included on the final invention statement.
5. OSR then provides the sponsor with the list of inventions that were funded by that grant.



Q & A



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