

Extramural Invention Reporting Compliance Responsibilities Electronic (iEdison) and Paper Mechanisms

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. iEDISON
<p>Employee Agreement to Disclose All Inventions: The agreement to be obtained by the grantee/contractor organization is that the employee will abide by the terms of the patent rights clause.</p>	<p>At time of employment —term of employment.</p>	<p>Grantee/contractor organizations must have policies in place regarding ownership of intellectual property, including conflict of interest issues.</p>	<p>401.14(f)(2)</p>	
<p>Invention Report: The grantee/contractor must submit a report of any “subject” invention. The report must identify inventor(s), federal agency(ies) grant or contract number(s), and date of any public disclosure. Date of submission establishes time frames for all future actions. Must be complete in technical detail. The report should be directed to the lead agency. The term “subject invention” means any invention of a grantee or contractor organization conceived or first actually reduced to practice in the performance of work under a federal funding agreement (grant, cooperative agreement, contract).</p>	<p>Within 2 months of inventor’s initial report to the grantee/contractor organization.</p>	<p>There is no single format for disclosing the invention to the government. The communication should include: the title of the invention, date of any public disclosure, names of all inventors, source(s) of federal funding (i.e. grant or contract number), a written description of the invention in technical detail. The invention disclosure should ideally be signed by the inventor(s): at the very least signed by a grantee/contractor institutional official.</p>	<p>401.14(a)(2) 401.14(c)(1)</p>	<p>Submission of the invention report may be done electronically by uploading either a PDF, TIFF, or text file through iEdison. Alternatively the document can be faxed to the lead agency, or submitted through U.S. mail.</p>
<p>Rights to Inventions on Subcontracts: Subcontractors retain rights to their subject inventions.</p>	<p>Same reporting responsibilities, obligations and time frames as prime grantee/contractor organization.</p>	<p>Prime grantee/contractor organization cannot require ownership of subcontractor’s subject invention(s).</p>	<p>401.14(g)(1) 401.14(g)(2)</p>	<p>Invention disclosure, confirmatory license, and proof of government support clause may be submitted electronically through iEdison.</p>

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Election of Title to Invention: Grantee/contractor organization must notify the federal agency sponsor that it will retain ownership of invention and take steps to commercialize the invention.	Within 2 years of reporting the invention to the lead federal agency sponsor. (If disclosed publicly, this period is decreased.)		401.14(b) 401.14(c)(2) 401.14(f)(1)	Election of title handled electronically using iEdison, otherwise a signed paper document is required.
Confirmatory license: The grantee/contractor organization must provide a nonexclusive, nontransferable, irrevocable, paid-up license for the government to practice or have the invention practiced on its behalf throughout the world.	Commensurate with report of any initial patent filing, unless the invention is being licensed as an unpatented biological material or research tool.		401.14(f)(1)	Submission of the confirmatory license may be done electronically by uploading either a PDF or TIFF file through iEdison. Alternatively the signed document can be faxed to the lead agency, or submitted through U.S. mail. See http://iedison.gov/iEdison/license.jsp
Nonelection of Title to Invention: Grantee/contractor organization must notify the federal sponsor that it will not retain ownership of an invention.	Within 2 years of reporting to federal agency sponsor. (If disclosed publicly, this period is decreased.)	Effectively a waiver to the government. After further review the federal agency sponsor may elect title on behalf of the government. Title does not actually vest with the government until government elects to retain title.	401.14(c)(2) 401.14(d)	Handled electronically through iEdison, otherwise a signed hard-copy request is required.
Assignment of Invention Rights to the Inventor: The inventor may request assignment of invention rights. Agencies support requests of this type to variously. In all cases, documentation is required when a grantee/contractor organization waives rights to the invention and the inventor(s) wishes to retain the invention rights.	At the time the grantee/contractor organization elects not to pursue title and the inventor requests rights in the invention.	First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must request the assignment of rights, agree to all terms associated with invention reporting as detailed in 37 CFR 401, and must pursue commercialization of the invention through patent filing or licensing as a research tool. Specific procedures for any agency should be determined prior to initiating the request. For NIH, see inventor certification .	401.14(k)(1) non-profits	This status can be indicated using iEdison; all other issues (such as outstanding required documents) should be resolved prior to proceeding further. Paper receipt (via fax) of inventor certification signed by each inventor and organizational official.

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<p>Initial Patent Application: The grantee/contractor must inform the government of the initial patent application that related to any subject invention. The patent application must include a government support clause.</p>	<p>Within 1 year after election of title, unless there is an extension.</p>	<p>Time frame may vary if invention becomes public. The term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3). The notification must include the patent application number and filing date assigned by the USPTO. A copy of the full application is not required.</p>	<p>401.14(c)(3) 401.2(n)</p>	<p>All filing data can be submitted via iEdison. Evidence of inclusion of government support clause may be submitted electronically as either a PDF or TIFF file through iEdison. Alternatively, a hard copy may be submitted via fax or U.S. mail.</p>
<p>Assignment to Third Party: Documentation necessary when a grantee/contractor wishes to assign invention rights to third party. If the grantee/contractor is a non-profit, the government must approve the assignment. For profit or small business grantee/contractors do not need to seek approval. If the rights are assigned, new rights holder assumes the same reporting responsibilities as the grantee/contractor organization.</p>		<p>If assignment approved, third party must pursue commercialization of the invention through patent filing or (for NIH) licensing of the invention as a research tool. Specific procedures to request third party assignment may vary between agencies. Consult lead agency prior to initiating request.</p>	<p>401.14(k) for non-profits. Note the distinction between small businesses and non-profit organizations.</p>	<p>Extent of information available about this process varies according to agency. Consult agency links on the iEdison Home Page.</p>
<p>Issued Patent: Grantee/contractor must provide federal agency sponsor with patent issue date, number, title of patent, and evidence of government support clause.</p>	<p>At the time of issue.</p>	<p>Patent must include government support clause.</p>	<p>401.5(f)(2) 401.14(f)(4)</p>	<p>All issued patent information can be received using iEdison. Evidence of inclusion of government support clause may be provided electronically as a PDF or TIFF file through iEdison. Alternatively, a hard copy may be submitted via fax or U.S. mail.</p>
<p>Request for Extension of Time: An extension of up to two years may be requested for election of title, or one year for filing a patent application.</p>	<p>Prior to any statutory bar.</p>	<p>Extension of 2 years for title election and one year for patent application are preapproved for funded inventions. Additional extensions need written approval from the federal agency sponsor.</p>	<p>401.14(c)(4)</p>	<p>Can be requested electronically if using iEdison; otherwise request must be in writing.</p>

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Discontinuance of Patent Application, Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Grantee/contractor must notify federal agency sponsor of changes in patent status.	At anytime in the process, but prior to established deadlines.	Relevant information and documents (e.g., patent application or patent) must be provided such that a determination to protect government interests can be made. The federal agency sponsor has the option to pursue the patent application or the patent if not being properly pursued or maintained. Any change in status must be reported at least 30 days prior to pending PTO office actions.	401.14(f)(3) 401.6	Indication may be made via iEdison or through written correspondence.
Annual Utilization Report: For agencies that require utilization reporting the report is for all subject inventions that have had title elected or are licensed without a patent. Report includes stage of development, date of first commercial sale or use, number and type of licenses, gross income, licensing to small business, status of U.S. manufacturing and identification of any FDA-approved product names.	Annually for agencies that require utilization reports.	Not all agencies require invention utilization reports. When in doubt, organization should consult the lead agency on the invention in question. For NIH grantee/contractor establishes a 12 month reporting cycle beginning in the month of their choosing. Information requirements defined in iEdison.	401.14(h)	Can be submitted electronically using iEdison, otherwise submission of the same data may be made in writing.
Final Invention Statement and Certification: Report all subject inventions derived or reduced to practice during the performance of the grant or contract.	Due within 90 days after the project ends.	If no inventions occurred during the award period, a negative report must be submitted. The report is to be submitted to the awarding unit grants or contracts management office.	401.5(f)(1)	The completed form must be submitted in hard copy. No electronic submission is yet possible.
For general information contact: Division of Extramural Inventions & Technology Resources National Institutes of Health (NIH) 6705 Rockledge Drive, Suite 310, MSC 7980 Bethesda, MD 20892-7980 (301) 435-1986 FAX (301) 80-0272			Interagency-Edison Home Page: http://www.iedison.gov E-mail: Edison@nih.gov	