

Extramural Invention Reporting Compliance Responsibilities

**Extramural Invention Reporting Compliance Responsibilities
Electronic (Edison) and Paper Mechanisms**

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
<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>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Invention Report: A report of an invention that identifies inventor(s), federal agency grant or contract number, and date of any public disclosure. Date of submission establishes time frames for all future actions. Must be complete in technical detail.</p> <p>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 (NIH) funding agreement.</p>	<p>Within <u>2 months</u> of inventor's initial report to the grantee/contractor organization.</p>	<p>There is no single format for disclosure, acceptable in any form. Cover letter stating existence of invention, and written technical detail, signed by the inventor. Must be in writing, fax copy acceptable.</p>	<p>401.14(a)(2) 401.14(c)(1)</p>	<p>Notification of existence of invention done electronically, invention disclosure document (signed by inventor) accepted via fax.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</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>May submit as a paper document, or electronically if an Edison account has been established.</p>	<p>Grants or Contracts Management Office</p>
<p>Election of Title to Invention: Grantee/contractor organization notifies NIH that it will retain ownership of invention and take steps to commercialize the invention.</p>	<p>Within <u>2 years</u> of reporting to NIH.</p> <p><i>If disclosed publicly, this period is decreased.</i></p>		<p>401.14(b) 401.14(c)(2) 401.14(f)(1)</p>	<p>Election of title handled electronically using Edison, otherwise a signed paper document is</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>

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				required.	OPERA
<p>Confirmatory license: The grantee/contractor organization must provide a nonexclusive, nontransferable, irrevocable, paid-up license to practice throughout the world.</p>	<p>Commensurate with report of any initial patent filing, unless the invention is being licensed as an unpatented biological material or research tool. At this time, NIH must be the primary agency for the particular invention in order to exercise this licensing option. In this situation, as there will be no initial patent filing, the confirmatory license is due to NIH at the time the licensed but not patented status is elected in Edison.</p>	<p>See http://edison.gov/Edison/license.html</p>	<p>401.14(f)(1)</p>	<p>Paper form generated electronically and faxed, or via paper documentation.</p>	<p>Extramural Inventions and Technology Resources Branch, OPERA</p>
<p>Nonelection of Title to Invention: Grantee/contractor organization notifies NIH that it will not retain ownership of an invention, or grantee/contractor does not elect to retain title within 2 years from date invention is reported. Title then vests with the government.</p>	<p>Within <u>2 years</u> of reporting to NIH. <i>If disclosed publicly, this period</i></p>	<p>Effectively a waiver to the government. Cognizant NIH ICD Technology Development Coordinator may elect title on behalf of the government.</p>	<p>401.14(c)(2) 401.14(d)</p>	<p>Handled electronically through Edison, otherwise a signed hard-copy request is required</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>

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	<i>is decreased.</i>			is required.	OPERA
<p>Inventor Certification: Documentation needed when a grantee/contractor organization waives rights to the invention and the inventor is interested in pursuing the invention. The government must waive its rights before any other party can elect title. The inventor or third party has the same responsibilities as the grantee/contractor organization.</p> <p>Grantee/contractor organization can waive rights to the inventor with permission of NIH. The inventor must actively pursue development (i.e., patent rights and commercialization) of the invention.</p>	At the time the grantee/contractor organization elects not to pursue title and the inventor requests rights in the invention.	<p>First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must agree to all terms associated with invention reporting as detailed in 37 CFR 401 and must pursue patent prosecution and commercialization. Must be in writing, fax copy acceptable.</p> <p>See inventor certification.</p>	401.14(k)(1) non-profits	Status indicated using Edison; all other issues (such as outstanding required documents) should be resolved prior to proceeding further. Paper receipt (via fax) of inventor certification.	<p>NIH/OER/OPE RA (Extramural Research Administration) assisted by:</p> <p>NIH/OIR/OTT (NIH Technology Transfer) for licensing potential</p> <p>NIH Institute TDC (Technology Development Coordinator) for scientific review.</p>
<p>Initial Patent Application: Inform the government of the initial patent application. Provide application number and filing date assigned by the USPTO. A copy of the full application is not required.</p>	Within <u>1 year</u> after election of title, unless there is an extension.	<p>Time frame may vary if invention becomes public.</p> <p>The term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3).</p>	401.14(c)(3) 401.2(n)	Most data submitted via edison, with 2 pages via fax. Paper reporting requires full patent application copy via U.S. mail.	Extramural Inventions and Technology Resources Branch, OPERA.

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<p>Licensing of a Research Tool. As an alternative to patent application filing, the grantee/contractor organization may elect to license an unpatented biological research resource: research tool.</p>	<p>At any point from initial reporting through the deadline for patent application filing (total of 3 years without time extensions)</p>	<p>The government confirmatory license must be executed and submitted to the NIH as part of each licensed research tool in order to protect the government's rights in the invention.</p>	<p>NIH Policy adopted: NIH GUIDE, Volume 25, Number 16, May 17, 1996</p>	<p>Handled electronically through Edison, otherwise a signed document is required.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Assignment to Third Party: Grantee/contractor organization must first waive rights to the invention. NIH Office of Technology Transfer must decide whether to take title on behalf of the government, allow a third party to obtain rights, or move the invention into the public domain. Decision must be coordinated through cognizant NIH Technology Development Coordinator and OPERA.</p> <p>Note: Non-profits cannot assign rights without the government's permission.</p>	<p>Action must be taken during the <u>2 year</u> disclosure period, plus any extensions in time.</p>	<p>If waiver approved, third party has 1 year to file patent and is bound by same conditions imposed on grantee/contractor organization. If not filed, government takes title. Third party responsible for keeping government informed.</p>	<p>401.14(k) for non-profits. Note the distinction between small businesses and non-profit organizations .</p>	<p>Information available on Edison Home Page. Require signatures of grantee/contractor organization and third party. At present, this cannot be done entirely electronically.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Issued Patent: Provide NIH with patent filing date, number, title of patent, issue date and 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 data received electronically if using Edison, otherwise information required in writing.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Request for Extension of Time: For election of title, or filing a patent application.</p>	<p>Prior to any statutory bar.</p>	<p>The first extension is preapproved. Additional extensions need written approval from OPERA, with good cause shown in writing.</p>	<p>401.14(c)(4)</p>	<p>Can be requested electronically if using Edison; otherwise request must be in writing.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>

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<p>Discontinuance of Patent Application, Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Must notify NIH and provide relevant information and documents (e.g., patent application or patent) such that a determination to protect government interests can be made.</p>	<p>At anytime in the process, but prior to established deadlines.</p>	<p>NIH has the option to pursue the patent application or the patent if not being properly pursued or maintained.</p>	<p>401.14(f)(3) 401.6</p>	<p>Indication may be made via Edison or through written correspondence.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Annual Utilization Report: Required for all inventions that have had title elected or are licensed without a patent. Report includes latest stage of development, date of first commercial sale or use, number of licenses, and gross royalties and sales.</p>	<p>Annually.</p>	<p>Due September 30. Format as defined on Edison.</p>	<p>401.14(h)</p>	<p>Can be submitted electronically using Edison, otherwise submission may be made of the same data in writing.</p>	<p>Extramural Inventions & Technology Resources Branch, OPERA</p>
<p>Annual Invention Statement (on continuation grant application) (specific to grants only). Grantee organizations must certify whether a subject invention was made or reduced to practice during the previous budget period. This includes non-competing continuation (PHS 2590) and competing continuation (PHS 398) applications.</p>	<p>Part of the preaward application submission and review process.</p>	<p>For grants, response to question on the face page of the PHS 2590 grant application or as a check list item on the PHS 398 grant application. Additional details may be included in the body of the application.</p>	<p>401.5(f)(3)</p>	<p>An invention reported on a continuation application must ultimately be established in the Edison system. Use either hardcopy of electronic entry.</p>	<p>Grants Management Office of Awarding NIH Institute or Center</p>

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<p>Final Invention Statement and Certification (Form HHS 568): For grants and contracts, report all subject inventions derived or reduced to practice during the performance of the grant or contract. If none, submit a negative report. Submit all reports to the awarding unit grants or contracts management office.</p>	Due 90 days after the project ends.	<p>Must be reconciled by grants/contracts management and OPERA with previously submitted information.</p> <p>Information available on Edison web site regarding HHS 568 submission.</p>	401.5(f)(1)	At present, this final closeout form is paper-based .	Grants Management Office of Awarding NIH Institute or Center

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