

Notice Regarding 2018 Bayh-Dole Act Final Rule - Rights to Federally Funded Inventions and Licensing of Government Owned Inventions

Notice Number: NOT-OD-18-233

Key Dates

Release Date: September 24, 2018

Effective Date: October 1, 2018

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

This Guide Notice summarizes the new 2018 policy requirements and the amendments to the regulations that implement the Bayh-Dole Act.

BACKGROUND

Recipients of NIH funded research awards are required to report all inventions that result from NIH funded projects. See the Bayh-Dole Act at 35 U.S.C. § 200-212 (<https://www.gpo.gov/fdsys/granule/USCODE-2011-title35/USCODE-2011-title35-partII-chap18-sec200/content-detail.html>) and the implementing regulations at 37 C.F.R. 401: <https://www.federalregister.gov/documents/2018/04/13/2018-07532/rights-to-federally-funded-inventions-and-licensing-of-government-owned-inventions>

The Bayh-Dole Act permits all funding recipients i.e., universities, nonprofit research institutions, and large and small businesses to retain ownership of the inventions made under federally funded research grants or contract programs, while also giving the government a license to practice the Subject Invention. In return for retaining ownership, funding recipients are required to pursue the invention to practical application, such as by licensing the invention under reasonable terms for the benefit of public health whether the invention is patented or treated as an unpatented biological material or research tool.

IMPLEMENTATION REQUIREMENTS

Effective October 1, 2018, NIH will implement the new final regulations of the Bayh-Dole Act. The new regulations will apply to all NIH new (including renewals) and continuation awards beginning on or after October 1, 2018.

NEW POLICY REQUIREMENTS

The following is a summary of the new policy requirements of 2018 Bayh-Dole. For more detailed information please refer to NIH's Grants Policy Statement for 2018 at <https://grants.nih.gov/policy/nihgps/index.htm> and the Bayh-Dole Act (See the links provided above).

- **Applies to all new and continuation awards dated on or after October 1, 2018.**
- **Redefined** Initial Patent Application as “the first **provisional or non-provisional** U.S. national application for

patent . . . **the first international application filed under the Patent Cooperation Treaty . . . which designates the United States, or the first application for a Plant Variety Protection certificate.**" 37 C.F.R. 401.2(n)

- **Government assignment to funding recipient of rights in invention of government employee - Federal agency** employing such co-inventor, in consultation with the recipient, **may submit an initial patent application**, provided that the recipient retains the right to elect to retain title. 37 C.F.R. 401.10(a)(2)
- If the funding recipient files a provisional application as its initial patent application, it **shall file a non-provisional application within 10 months of the filing of the provisional application.** 37 C.F.R. 401.14(c)(3)
- **Requests for extensions of the time for disclosure, election, and filing** under paragraphs (1), (2), and (3) of this clause may, at the discretion of the Federal agency, be granted. When a funding recipient has requested an **extension for filing a non-provisional application after filing a provisional application, a one-year extension will be granted without the need to provide additional information unless the Federal agency notifies the recipient within 60 days of receiving the request.** 37 C.F.R. 401.14(c)(4)
- **60-day window for Federal agency to request title after it learns of the failure of the recipient to disclose or elect within the specified times has been eliminated.** 37 C.F.R. 401.14(d)(1)
- Recipient now has **60 days (previously 30 days)** to notify the Federal agency of any decisions not to continue to prosecute a non-provisional patent application. 37 C.F.R. 401.14(f)(3)
- **Disclosures, election of title, close-out reports, and all compliance documents now "must" be electronically filed in iEdison.** 37 C.F.R. 401.16(a), (b), & (c)
- Requires the funding recipient **by written agreement** to obtain an assignment from its **researchers of the entire right, title and interest in and to each subject invention made under a funding award** and to execute all papers necessary to file patent applications and establish the government's rights in an invention. 37 C.F.R.401.14(f)(2)

Inquiries

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