

# *How to Prepare for the New*

# BAYH-DOLE REPORTING REQUIREMENTS



As of May 14th changes to the compliance requirements of the Bayh-Dole Act are in effect. For Tech Transfer Offices, it is critical to stay informed, not only of the new reporting requirements as they are documented, but also ongoing interpretation of these changes as they impact tech transfer operations.

Earlier this month I attended the NIH seminar in Washington D.C. that highlighted the Bayh-Dole regulatory changes and also sat in on the recent AUTM Webinar. My understanding is that NIH and other agencies are in a transition period; they are currently working to provide grantees ongoing information about how they can best comply with the new requirements, via iEdison and other reporting systems.

That said, what are the important steps for your Tech Transfer Office to consider right now?

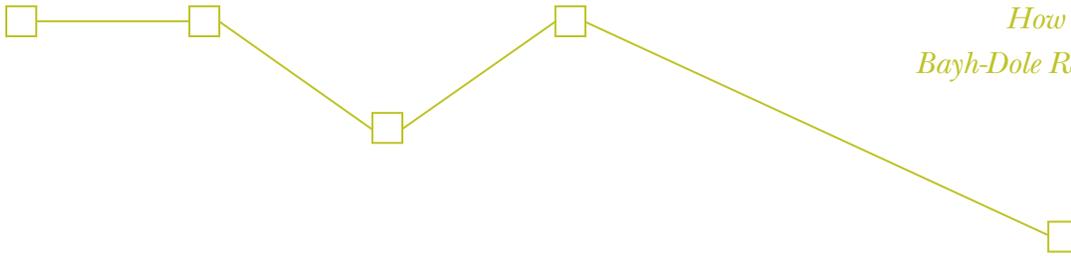
**1) Review the new reporting requirements** that can be found here: <https://federalregister.gov/d/2018-07532>

**2) Communicate with your patent counsel about the new reporting requirements**

**3) Focus on these key reporting changes:**

- a) The new regulations apply to inventions under grants developed or amended after May 14, 2018. You may start to get inventions that were developed under these awards in the near future. The best way to prepare is to work with your Sponsored Programs office to determine how your office will track new awards and review older awards that are subsequently amended to see if the new Bayh-Dole requirements apply. **Consider adding a field in your database and/or your disclosure form for the award date of each federal grant. You will now have to track inventions that fall under the old or the new Bayh-Dole requirements.**
- b) Going forward, Contractors are required to have written agreements in place that require all employees to (hereby) assign the entire right, title, and interest in each subject invention. This can be done via the employment agreement, the invention disclosure form, etc. **This is a good time to make sure that your employment and disclosure forms and other documents are up to date in this regard.**





- c) Provisional applications are now considered to be the first filing, and need to be reported to federal sponsor(s). Title needs to be elected in Edison prior to filing and reporting a provisional filing or any other first filing. A confirmatory license is required for provisional patent filings. Contractors must file a non-provisional patent application within 10 months of the provisional filing date. A one-year extension will be automatically granted, but you will need to request it. NIH requires that the request for the automatic extension be via email for each provisional filing for which you need to request the extension. Under the old Bayh-Dole requirements, it was not required to report the provisional filing. If you send a request for an extension for provisional filed under the previous requirements, it may not be granted. **Contractors should begin to plan now for how to determine which provisional filings will require the automatic extension. Under the new requirements, there is no penalty for requesting automatic extensions across the board for provisionals that fall under the new Bayh-Dole reporting requirements.**
  - d) The time period to notify the Government of your decision not to file a patent application on an invention on which there is a publication has changed from 30 days to 60 days prior to any statutory bar date. **Contractors should have a system in place for tracking publications and the due dates for notifying federal sponsors of any decision not to file.**
  - e) The time period for notifying the Government of the decision to discontinue prosecution, not pay a maintenance fee, or of any statutory bar has increased from 30 days to 60 days. **Contractors should monitor these due dates in order to report these decisions on a timely basis.**
  - f) Under the new regulations, it is required that the Government support clause contain the exact wording that is in the regulations. NIH requires that its grants reference “National Institutes of Health” as the sponsor, and not the name of the Institute that awarded the grant.
- 4) Mark your calendar for the AUTM Compliance Seminar in Bethesda, MD on November 5-7, 2018.** NIH expects to have additional information regarding how grantees can comply with the new requirements using iEdison. Representatives from NSF, DOE, NASA, and some DOD agencies will provide guidance on the new reporting requirements and their requirements for compliance reporting going forward.

NIH and AUTM (with presenters from NIST and COGR) have provided guidance on how institutions need to comply under the new Bayh-Dole regulations. NSF just published its updated reporting requirements.

Check back at Tech Transfer Compliance Central for updates in the coming months.

