

A Must-do List for BAYH-DOLE COMPLIANCE

As tech transfer offices await instructions from the various federal agencies about the timing and implementation of the amended Bayh-Dole reporting requirements, there is much that institutions can do now in order to have their compliance procedures operating smoothly in the new world order.

To recap, NIH has posted directives on Edison; all institutions are to begin complying under the new regulations as of 5/14/18 with NIH using 10/1/18 as the start date. What is less clear is *how* Edison will accommodate the new reporting requirements. For the time being institutions need to include additional reporting information in the explanatory notes of iEdison. That said, institutions face the challenge of how to report disclosures that are likely to start coming in under grants awarded after 5/14/18.

By being proactive, the benefits of competent compliance will be assurance of clean title to your institution's inventions and more accurate compliance reporting data. In order to properly comply, it is important to ensure that there is adequate bandwidth, training and expertise across functions, both internally and with collaborators outside the university.

With that goal in mind, here is a short list of actions we recommend you take now to assure that your institution remains compliant under the new Bayh-Dole reporting requirements:

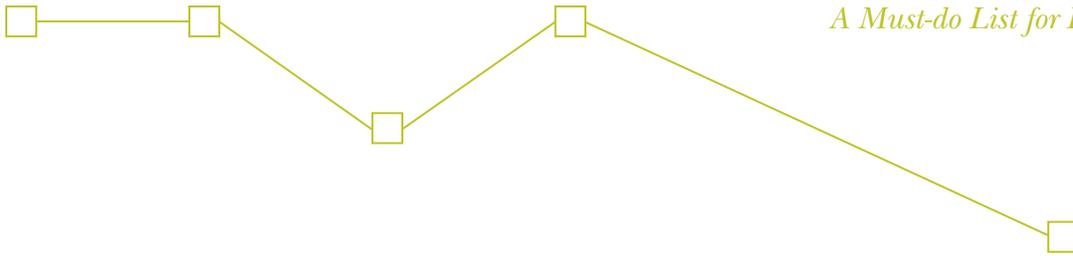
- **Clean up invention, patent, financial, and Edison data:** We are now in a compliance world bifurcated by May 14, 2018. Invention disclosures, both before and after the date of the updated regulations, are under increased scrutiny. If your related data is not accurate and complete, now is the time to address the problem. And it's not a trivial challenge!
- **Collaborate with Sponsored Programs:** TTO's need to track incoming inventions based on the award dates of the grants that funded them to determine whether to report using the old or new reporting requirements.



MICHELE O'SHEA

As a leading expert in government compliance and invention reporting, Michele O'Shea has advised many of the leading universities and medical institutions on how to run an effective program for Bayh-Dole compliance. She is a frequent speaker on compliance matters at AUTM and has been active in providing input to the developers of Bayh-Dole Edison reporting requirements. To discuss your compliance program with Michele, send her an email at moshea@bormanandco.com.





- **Educate TTO staff:** Include Management, Licensing Officers, and IP/Finance staff in training about the new reporting requirements in order to comply with the new shortened reporting deadlines.
- **Educate your PI's:** Hidden in the pages of the new regulations is the mandate that institutions train their inventors in their obligations for disclosure in a timely manner prior to the information becoming public. Institutions need time to file for patent protection and to notify federal sponsors of any decision not to file a patent application 60 days prior to a publication bar.
- **Instruct your legal team:** If attorneys are involved they need to file Government Support Clauses using the language in the regulations – that is a requirement. Failure to use the exact wording will lead to rejection notices from the funding agencies.
- **Rethink roles and responsibilities:** For many institutions compliance operates as a siloed function. In the new compliance landscape TTO's are well served to move toward a collaborative approach that spans departments and includes licensing officers, PI's, faculty inventors, sponsored research, and law firms.
- **Provide feedback to federal agencies:** Now is the time to ask questions and provide feedback to the various agencies, among them NIH, NIST, NSF, DOE, the Army, USDA, and NASA. A specific opportunity to comment is offered in the draft paper [Unleashing American Innovation](#) recently issued by NIST that seeks to improve the ROI spent by the federal government on R&D.

In an atmosphere of greater scrutiny, both by the government agencies and public watchdog groups, the best practice in all events is to take a proactive position on all compliance matters; educate your staff, clean up your data, network with peer tech transfer professionals and above all—maintain a sense of humor!

To keep up to date with the ongoing implementation challenges of the new Bayh-Dole requirements, check back here at [Tech Transfer Compliance Central](#) in the coming months.

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