Inventions, Bayh-Dole, and Reporting Requirements

>> Scott Cooper: Hello, everybody. My name is Scott Cooper. I am an analyst with the Division of Extramural Inventions and Technology Resources, and today we're going to be talking about invention reporting under Bayh-Dole. Some of our objectives today, we're going to learn how to disclose new inventions to the NIH, learn how, when and where inventions are reported to NIH in iEdison in the RPPR and in the Final Invention Statement. We're also going to learn how to request extensions of time to fulfill specific reporting requirements, learn how to protect the government's interest in NIH-funded inventions and learn new invention compliance requirements, and at the end of our presentation, we will discuss your questions and examples. So let's get started with invention reporting under Bayh-Dole, so what is the Bayh-Dole Act? Well, the Bayh-Dole Act is United States legislation that deals with inventions that arise from federally funded research. The 2018 Bayh-Dole regulations were revised, and these changes were implemented by the NIH October 1st, 2018. Now let's go into some selected definitions of the Bayh-Dole Act, so let's begin at the beginning with an invention. The Bayh-Dole Act says that an invention is a discovery which is or may be patentable or otherwise " because if you have an invention, even if that invention ... Even if you never intend to move forward with patentability or commercialization of the invention, that invention if it is a subject invention, which we'll talk about, still must be reported to the federal government. So let's look at what a subject invention is. A subject invention is any invention as defined above of the contractor that is either conceived or first actually reduced to practice in the performance of work under a funding agreement, so if you have an invention and that invention is federally funded, you now have a subject invention that is reportable under the Bayh-Dole Act. So why is it important to report your subject inventions to us? Well, the subject inventions are conceived or first actually reduced to practice in the performance of the NIH-funded work, so these invention reports identify those subject inventions to the NIH, and inventions are one of the results of NIH-funded research that informs the public through annual and final reports and the United States Patent and Trademark Office, so when you have the subject invention and you report to us, you are reporting to us the results of the taxpayer-funded research that you have performed under your grants. The invention reports also provide to us a technical description and information about your subject inventions. They also provide information regarding any kind of research publications that cited NIH funding. Now invention reports are specifically required by the Bayh-Dole Act and the terms and conditions of the NIH's awards, so that information regarding reporting requirements can be found in the Grants Policy Statement in chapter 8 and also the Bayh-Dole Act itself and its regulations. In the past, if there is a failure to comply or a lack of compliance, the NIH has contacted grantees and worked with grantees to assist them in becoming compliant with the Bayh-Dole Act. On occasion, a third party will contact the NIH concerning the lack of compliance from an NIH grantee, and in those cases, the NIH will contact either the president of the university or the CEO of the small business and discuss noncompliance issues with you. So what happens if you don't report your inventions and patents to the NIH as required by the Bayh-Dole Act? Well, the NIH can take enforcement actions in order to ensure that reporting is done timely and properly. We can withhold further awards to either the investigator or the funding recipient. We can suspend or terminate an award or any future awards to the institution, and we can require the transfer of ownership of the invention and patents to the NIH. Let's talk about the Invention Disclosure document. So this Invention Disclosure document will be submitted to the NIH via the iEdison system. It must be ... And this is important. It's very specific in the Bayh-Dole Act. It must be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, so you must give to us as much information as you have letting us know what this invention is because the government has certain rights in this invention, and we need to know in what do we have those rights. What is it that you have created and invented and are putting forth to the NIH as your discovery? So if the invention report that's created in iEdison doesn't meet that sufficient detail requirement, we will reject your disclosure and require additional information. Now we talked about subject inventions and that they must be reported to the NIH using the iEdison system, and that must be done within 60 days of the inventor disclosing that invention to the technology transfer office or to the sponsored program office of your institution. So what do we disclose? Again, any invention either conceived or first actually reduced to practice in the performance of the NIH-funded research. If you conceive of the invention before receiving federal dollars and you later reduce that invention to practice using federal dollars, then Bayh-Dole attaches, and you must report that to iEdison. Similarly, if you use the federal dollars to conceive your invention, then Bayh-Dole attaches, and you must report it to us. There are a couple of exceptions in which funded research does not have to be reported to the NIH, and those are when you receive federal funding that are primarily for educational purposes. So our fellowship awards, some construction awards, training grants, those are either primarily for educational purposes or not primarily for research purposes as are the construction grants, so if that is the only federal funding that you receive, then you need not report that to us per the Bayh-Dole Act. So here is a good little tool that we don't require, but it's very helpful to us, and it's very helpful to you because it will assist in not having your invention disclosure rejected by the NIH. We recommend that you use a cover sheet with these data points. You put on the date that you're reporting to us. You put your institute's docket number, which is a number that you create in order to identify your invention and link it to the invention report number that the iEdison system creates and assigns to your invention. The EIR number, your Extramural Invention Report number, that is the number that the system creates. The date the invention is reported to your institution, and in iEdison, that is the Invention Report Date, not the date that you report to us but the date that the inventor reported the invention to the institution. We want to see your invention title. We want to see a list of all of the federal grants that were used in the creation of your invention. We also want to see the award dates, and the award dates are crucial because that will determine whether the old Bayh-Dole regulations apply pre-2018 or the new Bayh-Dole regulations apply after October 2018. We also want to see a list of all of the inventors that created the invention, and these are not only the inventors that may be at your institution but the inventors that may also be at other institutions with whom you collaborated and got together with and created this invention, and finally the date and location of any first publications that are enabling, in other words, that they provide sufficient detail that would allow someone of sufficient knowledge in the field to recreate your invention. Okay, so how do we report a subject invention in iEdison? Well, after creating your iEdison account and logging into the iEdison system, you would select the link to Create Invention Report. After creating the Invention Report, select Submit. That will create the report, and then you would click on Submit on the Create New Invention Report confirmation screen, and a permanent Invention Report number is assigned. You may then upload your disclosure document along with the optional cover sheet as part of that Create New Invention Report process. Just make sure that you have either the Invention Report number or the invention docket number on either your invention disclosure document or that cover sheet. Okay? After creating the new Invention Report, just note for your records the new EIR and invention docket numbers from the confirmation screen. So let's talk about some common reasons why the NIH would reject your Invention Report. Many times, we will have inventors or institutions upload an invention disclosure that is almost a duplicate of the grant application, and in that case, what you're doing is you're describing something that you hope to invent after you receive the funding, and what we want is something that you created after you receive the funding, not before, so make sure that you describe what the invention is and not what the invention would be if funded. Another common reason is that all of the awards that you typed into the iEdison system are not included on your Invention Report document and vice versa, and also, please ensure that all of the awards that created your ... that were involved in the creation of your invention are included in that disclosure. Some other common reasons. The award numbers are incorrect. The NIH award number begins with a two-letter institute code followed by six numbers. If you don't include that institute code or if you only include five numbers or if numbers are transposed, this is a check that we have on the system, and we want to make sure that the grant numbers ... that they match. Similarly with the title in the Invention Report should match the title in your document. Also, ensure that all inventors are included in the document, the same inventors that you include in your Invention Report screen, and if your inventor names do not match, then we will reject your Invention Disclosure. This is an important point, the Date of First Publication, Sale or Public Use field. If you indicate in your Invention Disclosure that you have a publication which need not be a written publication, and in this sense, publication means a disclosure to a third party. It could be oral. It could be a talk that you gave at a conference. If that discussion was enabling, then that is a first publication, and you must include that date of first publication in the iEdison system. So if your disclosure includes a publication and you don't populate that field, then we will reject your disclosure. Similarly if you include a manuscript with no publication date, if it hasn't been published, please indicate not published on the cover page with a manuscript. If the publication includes authors who are not inventors but they appear to be inventors on the publication, please ensure that you specify which authors are inventors and that those inventors are included in your iEdison submission. These are some noncompliance notification messages along with ways to resolve these notification messages. I won't go through them all. I'll leave them here for your reference, but these are very helpful. The iEdison system will send you notifications if there are concerns or actions to be taken on your part, and on this chart are ways to resolve those notification messages. So thank you very much, and now I will hand off some additional discussion to my colleague, Carolyn.

Carolyn MosbyHi. I'm Carolyn Mosby. We'll start with a discussion of the Research Performance Progress Report and the HHS 568 Final Invention Statement and Certification. The Research Performance Progress Report inventions are listed in Section C, Products, of the annual RPPR. All inventions are reported in iEdison, and below are the specific due dates. The Streamlined Noncompeting Award Process awards are due 45 days before the start of the next budget period. Non-SNAP Awards are due 60 days before the start of the next budget period. Multiyear are due on or before the anniversary date. The HHS 568 Final Invention Statement and Certification is for grants or awards. They are reported by the grant at the time of grant closeout and due 120 days following the end of the project period. This slide is a screenshot of the 568 with details on completing the form. Please note this is for invention reporting, not patents. The entire grant or award number must appear in the designated box on the form, the original effective date of support through the date of completion or termination of the award. The date reported to DHHS should reflect the date the invention was reported in iEdison. If no inventions were inserted ... If no inventions were involved, insert the word None in the first block under the item Title of Invention. Each statement requires the signature of an institutional official authorized to sign on behalf of the institution. NIH verification. NIH searches iEdison for disclosed inventions using the grant award number. Please ensure the grant number is complete and accurate. For inventions that are generated as a result of the award search, NIH determines if the title, grant number and investigators listed on the 568 match what has been reported in iEdison, and this form can be accepted. For inventions that are not shown on either the 568 or in iEdison, NIH communicates the findings to the institution's invention reporting office with a 30-day reminder. Failure to report inventions may result in risk of losing title to the invention or other actions. We're going to move forward with discussing extension request. There are three types of extension requests: to file an Invention Disclosure, to elect title to a subject invention and to file an initial patent application. 2018 Bayh-Dole requirements will be discussed in detail later. Request for an extension of time to file an Invention Disclosure. Specify the request in a e-mail to edison@nih.gov in advance of the 60-day reporting deadline. Include in the request an explanation of the reasons why an extension is needed and include in the request the name of the organization requesting the extension and indicate in the subject line Invention Disclosure Extension Request. The NIH will review the request and reply by e-mail to the requester. This request is rarely made. Generally if a technology is not a subject invention, it shouldn't be reported until it meets the Bayh-Dole definition. However, if you have already created a record and have not submitted the disclosure, you will want to make a request. Request for an extension of time to elect title to a subject invention. Election of title must be made before reporting a filed patent application. Choose from the drop-down box in the Request Title Extension Years field, either 1 or 2 additional years. Attach your request for an extension to the iEdison invention record in the Other Document section. Provide details as to why an extension is needed and identify the document being uploaded as an Extension of Time to Elect Title. Only this document title can be used for submission. Then click Submit at the bottom of the invention page. If the title of the document submitted is Extension of Time to Elect Title Request, a submission will trigger a notice to NIH, and the request will be reviewed. If the title of the document submitted is not Extension of Time to Elect Title Request, submission will not trigger NIH, and the request will not be reviewed. Following NIH's review, the invention record will reflect whether the request was approved and/or provide an explanation if the request was not approved. Request for an extension of time to file an initial patent application. Choose Yes in the Request One Year Extension to File Initial Patent Application. Attach your request for an extension to the iEdison invention record in the Other Document section. Provide details as to why an extension is needed. Identify the document being uploaded as Extension of Time to File an Initial Patent Application. Only this document title can be used for submission. Click Submit at the bottom of the invention page. If the title of the document that is submitted is Extension of Time to File an Initial Patent Application, submission will trigger a notice to NIH, and the request will be reviewed. If the title of the document submitted is not Extension of Time to File an Initial Patent Application, submission will not trigger NIH, and the request will not be reviewed. Following NIH's review, the invention record will reflect whether the request was approved and/or provide an explanation if the request was not approved. Changes in Bayh-Dole to request extensions of time. NIH implemented this October 1st, 2018. The contractor must submit an e-mail to edison@nih.gov to request an extension for filing a nonprovisional patent application after filing a provisional application. A 1-year extension will automatically be granted unless federal agency notifies the contractor within 60 days of receiving the request. Remember to elect title when filing an initial patent application in order to receive the extension. Although the extension is automatic, please send an e-mail via edison@nih.gov with the following statement. Provisional patent application is reported in iEdison - Request one-year extension. NIH will respond, "2018 Bayh-Dole Extension Granted." 1-year extension is from the date the provisional expires. It can be requested at any time before 10 months of filing the provisional. Moving on to resolving the statutory bar, the Date of First Publication, on Sale, or Public Use of the Invention must be filled in when any of the following occur. The subject invention or any enabling portion thereof is published, or the subject invention is placed on sale, offered for sale, or the subject invention is used publicly, no nondisclosure agreement in place that is signed by all who have access. The status of the invention will change to barred 1 year from the publication, on sale or public-use date if there is no patent application reported for the EIR within 1 year of the publication, used publicly or the on-sale date. The associated patent application filing date must be within a year of the publication, used publicly or the on-sale date. To clear this status, a patent record filed prior to the statutory bar date would need to be created. The patent record can be created with the invention status as barred. Once created, the invention status will automatically update. The patent application may be of any type: provisional, nonprovisional, PCT or issued. Let's discuss the government support clause. What is a government support clause, GSC? A government support clause is a statement acknowledging federal support of a subject invention that must be included in the specification of a US patent application or a US-issued patent. The government support clause reads as follows, "This invention was made with government support under, identify the contract or the grant, awarded by the National Institutes of Health. The government has certain rights in the invention." The following are reasons as to why the GSC may not be accepted and does not meet the requirements of the Bayh-Dole Act: conditional language, missing the leading zero or another number, listing the institute of NIH like NCI rather than the awarding agency, which is NIH. Note that the two letters of the award identify the institute, so make sure that you acknowledge NIH rather than NCI or any other institute. The NIH process for accepting a GSC. To satisfy the government support clause requirements, the government support clause must be uploaded within the full patent application along with the USPTO Filing receipt. For provisional and PCT patent applications, a USPTO cover sheet that references the provisional or PCT application number will be acceptable. EPAS requirements. Grantees must upload the notice of recordation received from the USPTO for filing in EPAS, the GSC fillable form that was provided by the agency and a notice of abandonment for which the application abandoned. A screenshot showing the application abandoned or issued patent expired from the USPTO or Google Patents will also suffice. I'll explain EPAS in the next slide. Utilizing EPAS for GSCs. What is EPAS? Electronic Patent Assignment System allows grantees to correct a government support clause statement free of charge to their organization or institution. When can EPAS be used? EPAS can be used for previously waived records, abandoned nonprovisional patent applications and expired issued patents. EPAS does not apply to provisional and PCT patent applications. Who can use EPAS, and where can I get all the documents necessary to file in EPAS? Currently, EPAS can be applied to records where NIH is the primary awarding agency. Changes in Bayh-Dole for reporting government support clauses, again, NIH implemented this October 1, 2018. So how does this affect the reporting process for a government support clause? A government support clause will be required for provisional patent applications. What happens if the government support clause is missing or incorrect in the provisional patent application? Provisional patent applications cannot be amended. Therefore, if patent prosecution will continue, the GSC will need to be corrected in the next patent application, either the nonprovisional or PCT. If patent prosecution will not be further pursued due to abandonment or a waiver, you will need to submit a request to nih@od.nih.gov for additional assistance. And this slide just indicates how to resolve GSC noncompliant messages. Moving on to confirmatory licenses. What is a confirmatory license? The CL is used to notify the public of granting to the government nonexclusive, nontransferable, irrevocable paid-up licenses for the US government to practice or have the invention practice on its behalf throughout the world. The Executive Order 9424 CL language must be standard license language, and the document must be signed and dated by the institutional business officer, someone who has signature authority on behalf of the institution or organization. Excuse me. Digital signatures authenticated by a signature authority with a certificate are okay. Please do not simply type an individual's name in lieu of a signature. The document must be signed and dated by the institutional business officer, someone who has signature authority on behalf of the institution or organization. Again, the digital signatures authenticated by a signature authority with a certificate are okay. The confirmatory license requirements. Please note if you have an accepted CL on the earliest patent filing, this will cover all child filings that are listed within the same record. If a child filing are listed in other patent records, this is okay only if a parent/child linkage has been established between the patent records to reflect the relationship. You can locate the confirmatory license requirements on the iEdison FAQ page. Please note that currently a notification will not trigger in iEdison requests in a CL to be created or submitted on a provisional ... Excuse me. When a provision is reported in the patent record, you will need to submit a request to edison@nih.gov for additional assistance. Resolving iEdison CL noncompliant messages. This slide shows the acceptable digital signature authenticated by a signature authority with a certificate. Changes in Bayh-Dole for reporting confirmatory licenses, NIH grants implemented October 1, 2018. How does this affect the reporting process for a confirmatory license? A confirmatory license is required for all patent applications, provisionals, PCTs, nonprovisionals, continuations, divisionals and issued patents. Again, I just want to bring to your attention that a notification will not trigger in iEdison requesting a CL to be created or submitted when a provisional is reported. You're still responsible for creating and submitting a confirmatory license in iEdison. Confirmatory license, common errors. Title does not match the invention record or the patent record. Inventors listed on the CL do not match the inventors listed in the patent record. The grantee provides filing or issue dates for a different patent application, or the grantee lists multiple patent applications and issued patents on one CL. Grantee lists a PCT patent application number in the foreign applications filed/intended in countries field instead of the names of the countries. The grantee does not include the leading zero if applicable in a grant number, and a grantee will change the Executive Order 9424 standard language. The execution date is not legible. Institutional Business Officer is missing. Title of Institutional Business Officer is missing, and/or the business address is missing. The grantee may provide department name/research foundation instead of grantee/contractor organization name. NIH prefers the CL be prepopulated directly from the patent record to avoid these common errors. This concludes my session. Thank you and have a good day.