Intellectual Property Understanding Requirements, Rights & Recipient Responsibilities

>> Joel Snyderman: Hello, welcome to "Intellectual Property, Understanding Requirements, Rights and Recipient Responsibilities." My name is Joel Snyderman, I'm the Acting Director of the Division of External Inventions and Technology resources here at the National Institutes of Health. I'll be joined by my colleague, Scott Cooper. We'll be going over a high level overview of invention reporting requirements, and then Scott will be talking to you all about Bayh-Dole Act and your responsibilities as a recipient of NIH grants. Specifically, we're going to cover where to get information to appropriately manage data, inventions, publication, and other resources developed with NIH funds, learn why and how to safeguard intellectual property, understand your rights as a recipient, learn when and how to report inventions to NIH and learn the new invention compliance requirements. I'd like to point out the reason that new invention is bolded and in red is because that doesn't mean just new compliance requirements for inventions, as the requirements and regulations were updated in 2018, but also the requirements for new inventions because all of those new requirements from 2018 are for new inventions going forward. Also going to learn how to share NIH funded data and other research resources to advance research for the benefit of the public and public health, understand the balance between protecting inventions and data sharing, and then we'll have an opportunity for questions and examples. Broad overview, in addition to this presentation, I have a lot of resources here where you can find out more information about managing data inventions and publications for NIH grants. Specifically, of course, the NIH Grants Policy Statement which is a term and condition of every NIH award, your notice of award, which may have additional specific terms and conditions. For newer information on grants policies, you can check the NIH grants information links. We also have specific resources for data sharing and iEdison, which is our main hub for reporting, has its own frequently asked questions and resources sections. All these are fantastic resources for you, so please check them out. Overall, I want to touch on technology transfer goals. As you know with NIH grants, one of the big things we have is outcomes, not just publications, not just advancing scientific knowledge specific to intellectual property, turning that intellectual property into technology, commercializing development and technology, attracting new research and development resources, obtaining a return on the public investment, of course stimulating economic development, benefiting the public health for organizations to be financial returns to owners and investors. For your academics, there could be rewards, promotions, tenure. All of these things link together for the overall technology transfer goals. So what is intellectual property? This could be creations of the mind. Specific to intellectual property laws, they are protected. There's patents, trademarks, copyrights, intellectual property systems. These sorts do aim to foster an environment in which your creativity and innovation is created, supported, developed and, of course, protected, all while providing benefits to the public. This enables you as a creator to earn recognition and financial benefits from what you invent or create. So what do patent rights protect? Patents protect inventions, which is a discovery or a finding. An invention must be novel, useful, and non-obvious, and there are various types of patent applications including provisional, non-provisional, utility, which we'll cover a little more in a few slides, designs and plants. And for more information on this, please see the U.S. Patent and Trademark Office website. So what is patentable? This really can be anything new and useful. It can be processes, machines, manufactured articles, compositions of matter or really any new and useful improvement of the above. So what are your rights and terms under patents? This can include the patent protection rights, the rights to exclude others from making, using, offering for sale or selling your invention throughout the United States or importing your invention in the United States and its territories and possessions. Patents have about a 20-year life cycle from the earliest priority filing claimed. They may also be extended for certain pharmaceuticals and other certain circumstances as prescribed by law, and any delays from the patent and trademark office issuance of a patent. And mentioned utility applications are non-provisional patents for the utilization of your intellectual property. So not just an idea or suggestion. In these cases, extensive data is not required but good to have. And patent specifications with claims describing the metes and bounds of the invention to be protected, usually diagrams and additional supporting documentation, although that additional supporting documentation can be submitted later during the patent prosecution, the length of which usually runs about three years and can cost you between $40,000 to $60,000 in costs and attorney fees. Issuance of a patent, of course, talks about the U.S. Patent and Trademark Office. It can take them about 2 to 3 years to process one of those utility patent applications, although some can be issued the same year they're filed. There's additional rules for international patent applications that may take 6 to 8 years, and the priority date will still be the date that the first application is filed. So what information do you need to include in an issued patent? Need all this, including the owner of the patent, the date that application was filed, if the PCT application is filed, invention, title, abstract, filing background and related patents, diagrams. We mentioned already a description of the invention, and, of course, we're talking about NIH grants, of course, so the statement of government rights. So what does this mean for NIH funding in general? Well, in the average year, there were about 2,500 new U.S. patents issued to NIH contractors citing NIH funding. That translates to about 10 new patents every business day directly related to NIH funds. And you'll note here that I said, and this slide says, NIH contractors, and that's because, well, most of what we're talking about in this presentation is specific to NIH grants. The rights associated with invention reporting, the regulations, the federal act behind them, all apply both to NIH grants and NIH contracts. So this is really comprehensive to both. You're learning here both about NIH grants invention reporting and also NIH contracts. Now that we've talked about how to obtain a patent, let's talk about the different ways under patent law that you can lose your rights through public disclosure. So most international rights can be lost by making an enabling public disclosure before filing a patent application, and there are some limited exceptions here where the time for where that would be would be between 1 year to half a year depending on the country. Specifically for United States rights, they can be lost by making what we call that enabling public disclosure more than one year before filing a patent application. Your requirement is to, of course, as an NIH recipient, protect the government rights and all inventions and patents. So prompt reporting of the date of an invention's first public disclosure within iEdison is important. And you do risk losing all rights by failing that timely disclosure to the government, and I will cover that more when we talk about the Bayh-Dole Act in a few slides. So what does that mean to protect rights through public disclosure? This means filing that enabled patent application prior to disclosure to the public, such as even disclosing through posters, presentations, publications, which here can be ... That doesn't necessarily mean peer-reviewed scientific publications. It can be really any kind of publication or presentation, any talks you do, et cetera. Those really can be that disclosure to the public, so please be mindful of that. And do not have substantive discussions or exchanges with a third-party unless you have them under a confidentiality agreement. So please use those confidential disclosure agreements whenever possible to protect your rights. In addition, to protect your rights through public disclosure, please be mindful of the abstract or summary that you include with your grant application because that is the one part of the application that, upon funding the award, will be made publicly available. So if you look at the NIH general application guide instructions, we specifically remind you to not include any proprietary confidential information or trade secrets in that summary or abstract because if the application is funded, that project summary will be entered into an NIH database, specifically the NIH research portfolio online reporting tool or reporter, and become public information. As for the rest of the application, although that is confidential, please be mindful that, and this is tying back to the NIH grant's policy statement, application and applicants are discouraged from submitting information that would be considered proprietary. And if you're going to do it, any pages on which you're going to include any kind of commercial, trade secrets, financial information, other privileged information, please specify those pages as confidential. And look at the NIH application instructions for more details on how you can do that to protect your public disclosure rights. Finally, the Freedom Of Information Act, just be mindful that in addition to everything we've already talked about about safeguarding grant applications, a lot of these requirements for trade secrets are already protected information, so the Freedom Of Information Act, please, like I said, make sure in those applications you're marking information specifically as trade secrets or commercial or financial information. And that's pretty much your background on patents, patent rights, and ways you can lose them. Please don't do the latter of those. And now I'm going to turn it over to my colleague, Scott Cooper, who is going to be talking to you specifically about the Bayh-Dole Act and the regulations supporting invention reporting, patents and patent disclosure. Scott?

>> Scott Cooper: Hi, so, we're going to talk about the Bayh-Dole Act and the Bayh-Dole regulations. The Bayh-Dole Act was enacted in 1980. It was intended to encourage grantees and potential grantees to seek out NIH grants and federal funding in general so that they could create inventions, file patents, stimulate the economy and, at least in NIH's world, to improve the public health. So the Bayh-Dole Act is codified at 35 U.S.C. 200 and it's implemented in our regulations at 37 C.F.R. 401. The Bayh-Dole Act was changed for the first time in 2018. There were various edits to it. It applies to most federal funding agreements. The Bayh-Dole Act does not apply to training awards or to fellowships. It applies to grantor contracts that are intended for research purposes and not primarily for educational purposes. So what the Bayh-Dole Act does is, it sets forth your rights and responsibilities, and the government's rights and responsibilities for inventions and discoveries that are made with federal funding, whether in whole or in part. If there is a single dollar of federal funding that went into your invention, then the Bayh-Dole Act is initiated and there are the rights and responsibilities that follow. So let's move onto the policies and objectives of the Bayh-Dole Act. I mentioned that the Bayh-Dole Act was intended to promote the utilizations of inventions that arose from federally funded research to encourage small businesses to seek out federal funding. In fact, it requires preference in licensing by nonprofit organizations. It was also intended to promote collaboration among commercial concerns and nonprofit organizations. It ensures that inventions are used in a way to promote free competition and enterprise without hindering or encumbering future research. It was also intended to promote commercialization and public availability of inventions that were made with public support, and we will talk a bit about the importance of that commercialization and the ability of these inventions to be made publicly available. And finally, it's important to note that the Bayh-Dole Act ensures that the government obtains sufficient rights and federally supported inventions and that is done through a government support clause in patent applications and issued patents. And also through a confirmatory license that provides the government with a license to use the invention without having to pay royalties to the grant recipient or the inventor. So let's move onto a couple of definitions. The Bayh-Dole Act states that an invention is a discovery that is or may be patentable or otherwise protectable. So whether you ever intend to file for patent protection or not, if it may be patentable, you must report it to the government. Mostly with NIH, we're not talking about plants. We're talking about other types of inventions. Joel mentioned utilization applications or utility applications, provisional patent applications and PCT applications. The subject invention, when we hear that term, what we're talking about is an invention that was either conceived or first actually reduced to practice in the performance of work under a funding agreement. So once you have that federal funding involved with your invention, it is now a subject invention, and Bayh-Dole attaches to it. Let's talk a bit about reporting requirements. This slide has a few bullets on the steps that are involved and some deadlines and dates. You have to implement an employee agreement which generally says that the inventor is required to report to the grantee when there is an invention that was created with federal funds. You have to then disclose each invention to the government within 60 days. And then you have to elect title or waive title to the government within 2 years. Basically that tells us that you're going to continue with commercializing your invention or, if you're not, you waive it to the government and then the government will then own the rights and the invention. You must file for patent protection within a year of title election. And we mentioned the importance of commercialization, receiving federal dollars and moving forward with those dollars to ensure that your invention, that your creation, benefits the public and improves public health. You must provide that confirmatory license to the government when you elect title. You must indicate government support in your patent and patent application. That's the government support clause. And it is required that if you substantially manufacture your invention, it must be done in the United States and not abroad. There are some exceptions to that which will be discussed in another presentation. The NIH requires and Bayh-Dole Act allows us to require that you report on the utilization of your invention. In other words, every year, you tell us what has been done with your invention so we are aware of the progress that's being made with your invention, and its movement toward commercialization. And finally, a final invention report which you file at the closeout of your award. So next, we'll talk about compliance requirements under Bayh-Dole. We talked a bit about your invention disclosure. Your invention disclosure is submitted to the NIH through the iEdison system, and we'll talk a bit about what that system is, but it is a system that is used by 25 plus federal agencies that allows you, the grantee, to report inventions to us. So aside from the final invention statement that you would submit on the grant side, on the invention side, you submit the invention disclosure, which has to be very complete in technical detail, including inventor names, the dates of disclosures, grant numbers, et cetera. If there is not enough detail in there to tell the NIH what your invention is, then we will likely reject your invention disclosure for being too vague and not having enough detail. The government support clause is very specific, and it's outlined in the Bayh-Dole Act in quotation marks, and that has to be included in your patent applications including a provisional patent application and included in your issued patent. If it's not, then that would have to be corrected, and that can cost you folks some money. The confirmatory license is the license that grants to the government the use of the subject invention and resulting patents. This is a license that can be created within the iEdison system, and we file it with the United States Patent and Trademark Office, and finally that utilization report that is filed annually. So let's move onto government rights. We talked about the government use license. Joel talked about when the government may obtain title. There are also march-in rights. There are certain conditions under which the government can march in and take the rights in the invention. There have been, in the past, some cases where march-in was requested. But to date, the NIH has never marched in on an invention and taken rights from the inventor or the grantee. It doesn't mean we won't do it or can't do it. There just hasn't been a case yet in which we have done it. And finally, subawardees also retain Bayh-Dole rights in their inventions. Okay, the government use license. "For any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world." These terms here are very important, nonexclusive. Once the government retains its license, you can license to others and profit from those licenses. So it is a nonexclusive license. The last part of that piece, on behalf of the United States any subject invention throughout the world. So it's not only rights within the United States but all over. So we'll get into a little bit more detail on conditions when the government may obtain title to an invention. "The contractor conveys to the Federal agency," in our case NIH, "upon written request titled to any subject invention," if you fail to disclose or elect title to this subject invention within the time frames, in those countries in which you fail to file patent applications within the time specified and in any country in which you decide not to continue the prosecution of any patent application. So if you have filed a patent application and you determine not to continue with that prosecution, you must let us know so that then we can take that invention and make it available to the public to improve public health if we deem necessary. So the subawardee, if you receive the grant and then you subaward a portion of that grant to another entity, then that subcontractor retains all of the rights provided to the contractor and also has the responsibilities to report back to us through iEdison. So we mentioned iEdison quite a bit, so what is it? iEdison is an electronic database. It's used by not only the NIH but more than 25 federal agencies, and it's a reporting system. The information submitted to iEdison is confidential under statute. So when you submit to us that invention disclosure that contains all of the information that would enable someone else to create your invention, that invention disclosure document is never revealed to anyone, and it is protected under the Freedom Of Information Act. So unless it is otherwise made public, for example by the grantee, NIH will not make that invention disclosure public, which is important because it means that that is not a publication that would impact your rights in your invention. Information provided by you, the grantees, the technical information on the inventions which is submitted through the invention disclosure. It identifies legal protection and is timely and properly obtained, provides notice of the required regulatory compliance. There are reminder messages that are sent out in iEdison to let you know when things are coming due, and again, the annual utilization reports regarding commercialization status that are due to us. So here's a little chart that shows the iEdison in the award process. So it's post-award, meaning it begins after you receive your award and once you create the invention. Again, even if you never have any intention to patent it, it's that invention that is reportable to us. So there's post-award. You perform your work. You make discoveries. You close out your grant, and you must report that invention to us using iEdison. The recipient process is this, the NIH awards to the grantee the grant. The grantee then receives the funds and creates the invention, discovers the science that backs the invention, and then the disclosure is submitted by the inventor to the grant recipient, usually through the office of technology licensing, and that's when you make your initial report to the NIH. We're going to quickly talk about four types of waivers: Inventor waivers, where the grantee waives the rights in the invention to the inventor; U.S. manufacturing waivers, when you cannot manufacture your invention, your patentable invention in the United States; third-party waivers, if you waive your rights to another entity; and general waivers or waivers to the federal government. All transfers of ownership of a subject invention that are made by a nonprofit to an inventor, those are the inventor waivers, or a third-party, require NIH's prior approval. Simply choosing in the drop-down box on iEdison waive to inventor does not effectuate that inventor waiver. It has to be reported to us first, and then we must either approve or not approve that inventor waiver, and all requests for manufacturing waivers, the substantial manufacturing of any product outside the U.S. also must receive prior approval from the NIH. We're going to talk a bit about data issues. I'm going to go quickly here in the interest of time. You, the grantees, own the data that you develop with federal funds. That's referenced in the NIH NIH Grants Policy Statement in chapter eight. We have a public access policy that's also outlined in the NIH Grants Policy Statement, and you could view final peer reviewed manuscripts and they must be published at pubmedcentral.nih.gov. We also have a data sharing policy, and you can reference that, again, in chapter eight of the NIH Grants Policy Statement. Okay, there will be another session that we will discuss in more detail when, where and how inventions are reported to the NIH and iEdison, how to request extensions of time to fulfill specific reporting requirements, how to protect the government's interest in NIH funded inventions, and some more detail about what the new invention compliance requirements are. And we will take your questions. Thank you.