Notice of Award Arrives….Now What

>> Bryan Clark: Good afternoon, and thanks for tuning in to our session "Notice of Award Arrives ... Now What?" I'm Bryan Clark, along with Roger Sorensen, who will be presenting a number of post-award topics today from both the Grants Management perspective and Program perspective. I am in Grants Management and will be the counterpart to the Research Administrators, while Roger is counterpart to PIs. So what do we have on the agenda? Roger?

>> Roger Sorensen: Thanks, Bryan, and welcome, everybody, to our session. So I am Roger Sorensen. I am a Program Official, but I'm also Chief of the Integrated Neuroscience branch at the National Institute on Drug Abuse, and today, Bryan and I are going to present on the topic of the Notice of Award. So you have received that wonderful news, that Notice of Award. You have a funded grant, congratulations. Now Bryan and I are going to discuss some of the administrative requirements associated with receiving the Notice of Award. Our topics today are going to include the Notice of Award document itself, some issues concerning prior approval of any changes you want to make towards the grant award. We're going to talk about reporting requirements during the active grant award, and when all things, good things, come to an end, we're going to talk about close-out of the award. Okay? So, Bryan, take it over.

>> Bryan Clark: Thanks, Roger, and actually in the introduction, I didn't mention that I'm with NICHD in Grants Management as the Chief Grants Management Officer. So with the Notice of Grant Award, as we call the NoA ... We really like our acronyms. We have a lot of them. So with the NoA, I'll go over the different sections. So what is Notice of Award Letter? It is a legally binding document. It identifies the grantee and PI, establishes a funding level and a support period. A support period is between 1 and 5 years for the project period. It sets forth the terms and conditions, both the standard terms and specific terms and conditions, which we'll talk about later, and includes the contact information for the assigned Program Director and Grants Management Specialist. This is important because any questions you will want to direct to these contacts on a Notice of Award, and it's at the end of the Notice of Grant Award Letter, and it's sent to the business official. It's e-mailed. Just want to make note here that any NIH award is made to the recipient institution and not directly to the PI, and so they make the decisions about ... help make decisions on changes to the Notice of Award, and that's through the AOR of the institution, through the sponsored programs office, and it also shows it's available in the Commons Status. So what's new is the face page, the new page one, and this is across all agencies that issue Notice of Awards, and this will be effective October 1. You can see this notice. I have the link here, along with viewing the Notice of Award webpage. So this will ... It'll essentially give more information on page one than it has in the past. So going through the sections, the components of the Notice of Award, Section I gives the award data and fiscal information, summary of the totals of the current and future years or the future year commitments, as they're called, and it also identifies the fiscal year of the award, and our fiscal year goes through September 30th. October 1 through September 30th is the fiscal year. The Section II provides the grant payment information and the OIG Hotline information. So for payment of the award, which you're most interested, I know, you'll want to look at the information to find out, that's on the notice in Section II, which provides the Payment Management System information for downloading forms and inquiries, and you'll be working with the Payment Management System to draw down funds. So I've included the link here, which should give you all the information about working with PMS to draw down funds. There's also hotline information for if, unfortunately, there's any fraud, waste or abuse that needs to be reported, such as a whistleblower situation, that this is included. This is also available to the public, which can be used to report any fraud, waste or abuse. The reports are confidential. You can either call, or you can go online, submit an online report. Section III are the standard terms and conditions. I won't go through each of these, but as standard, they're on every Notice of Award. Next, there are specific terms and conditions. This is something, I want to emphasize, is very important to review because if your Notice of Award is revised, these terms will state what the revision is. For example, if you've asked for a change in organization, it will identify that that's what the revision is for or change of PI, any other such revision. If it's a cooperative agreement, there will be specific terms for that. Restrictive terms, if, for instance, your IRB is due, and we need to restrict the funds for human subjects until that IRB has been viewed, also then it has the staff contact information, which I mentioned, and a spreadsheet summary. So the grantee acceptance, when does that actually happen? That happens when you draw down the funds from the Payment Management System. So you're agreeing to the terms and conditions, you and the ... if you're the PI or the institution drawing down the funds is agreeing to the terms and conditions, which includes the amount of the award. You're acknowledging the fact that that amount is sufficient and appropriate for getting the project completed. You can request supplements. We'll talk about that later, but this is also included in the acceptance of the award, and that's in the first paragraph of the award letter. So prior approvals, prior approvals are certain award actions that require approval ahead of time and of the Grants Management Officer. This link will give you on this next slide all of the prior approval requirements, everything that needs prior approval. There are some authorities that you have that you do not need prior approval. One example is the first no-cost extension. You can go in the comments and provide that to yourself. All of these require prior approval. We're not going to cover all of them. There's 17 total. We're going to go over those that are in bold and in red. So in requesting the prior approval, you can go online to request a number of these. They're not all on the eRA Commons. There's a user guide. You can get that if you would like to see if the prior approval, your approval you're requesting can be done online. Otherwise, most are still being done in writing, and this gives the requirements. Essentially, it needs to be countersigned by the AOR and signed by the PI and submitting the request, and it must be sent to the IC's Grants Management Specialist no later than 30 days before the proposed change.

>> Bryan Clark: So now, I'll turn it over to Roger to talk about one of the prior approvals, and that is status of PI. Take it away, Roger.

>> Roger Sorensen: So Bryan and I thought we would highlight some of the common prior approval issues that we typically deal with, and the first one, as Bryan said, is a change in the status of the PI. So if you must notify us if there is a change of 25 percent or greater change in effort of the PI or other key personnel on the project. You should notify us if the PI will be absent for longer than 90 days or more. If the PI withdraws from the project, please let us know for any reason, and then you notify us if you have requests to change from a multi-PI to a single PI model or, conversely, from a single PI to a multi-PI, or if there's a change in the makeup of the PIs or multi PIs on the award. The issue with this is that we want to ensure that we maintain the leadership and the expertise on the project to keep it going during the active status of the award. Another typical request that we receive is a request to change the recipient organization. As Bryan mentioned at the beginning, the award is made to the institution by and far for the majority of grant awards and not to the PI. So with a change of recipient organization, and the PI wants to transfer the grant to a different institution, the current institution must relinquish the grant. They must provide a Relinquishing Statement as well as Final Invention and Federal Financial Report, essentially closing out the grant from the institution, and the new institution will submit a transfer application for review. We will review the application. We will look for the progress to date on the project and what's going to be pursued during the remaining term of the grant. We're going to look for adequacy of new resources and the environment and availability of the expertise to ensure that the project can continue, and any other potential problems in equipment or whatever that may be a kind of a barrier towards progress. We want to ensure that the project can continue at the new institution. A third issue is perhaps a request in the change of the scientific scope. What does that mean? By definition, we're saying change in scientific scope is a significant change in the specific aims or goals, the methodology, the approach or other aspects of the project objectives as reviewed and approved by study section peer review and by program staff. So by and large, all applications should remain within scientific scope for the duration of the project. Some examples of potential changes would be changes of specific aims, the use of animals or animal models or human subjects, the research emphasis or goals, wanting to include new technology and a change in key personnel and expertise, and again, we're looking at this to ensure that the project can be pursued and continue moving forward, but, as well, we can't just haphazardly approve of any type of change. We really want to keep applications within the scientific scope as much as possible. A lot of times, we want you to spend all the funds that are available for the project, but things occur, we understand, and you might not have spent all the funds, and so you want to request a carryover of the unobligated balance. So you will submit this for prior approval, and what we're looking is a justification for the rationale on why the funds were not spent during the year and how they would be used in the following year, and again, we want the justification to be tied to the scientific aims and the goals of the research project. You submit it to justify the financial need for maintaining and continued use of these unspent funds, and we are expecting that the carryover funds be spent in the following year, if at all possible. As the example says, if we allow carryover of $250,000 in Year 10, we expect that money, plus the award for Year 11, both amounts to be spent as much as possible during the next year. Bryan mentioned that no-cost extensions. The first no-cost extension may be approved without prior approval for up to 12 months. You submit this electronically through the eRA Commons account, and you will make sure that all certificates and assurances are updated, as it would be with the active status of the grant. For a second or additional no-cost extensions, this requires prior approval. In that request, we're going to ask if there's any funds remaining that are available to continue the project. We're going to ask for that progress report. We're going to ask you for an explanation of why you couldn't finish and the rationale for continuing, and this is approval from both Program and Grants Management. Lastly, I'll talk about adding additional funds after you receive your Notice of Award. One way you can do this is through submitting a competing revision. This used to be called competitive supplements. So this is a application that is peer-reviewed in the same study section as the parent grant was reviewed. Competing revisions will expand the scientific scope. So here's the issue is that now, we are having this peer review, so we can change the scientific scope through an awarding of a competing revision to the parent grant, and again, it follows that you're expanding the scientific scope and goals of the parent grant as we talked about what scientific scope means, and you submit the application electronically, and we also have administrative supplements. Now these are reviewed by program staff and not by study section, and it's a request for additional funds that would enhance the scientific scope or value of the parent grant. With the administrative supplement, we're staying within scientific scope, but we're enhancing the value, or we are providing funds to cover unanticipated expenses, such as catastrophes or natural disasters which have hindered progress of research, salary increases, the phaseout of a grant and as you will. So administrative supplements should be maintaining the scientific scope and can provide additional funds. These are not well-funded. They really have to enhance the value in some way or another, and with that, I'll turn it back to Bryan to talk about reporting requirements.

>> Bryan Clark: Okay, thank you, Roger. So with the reporting requirements, on this first slide, you'll see that there are annual reporting requirements, and there are also closeout reporting requirements. We have a separate section for closeout that I'll discuss after the annual reporting requirements. The first five I'll go through but not in a great amount of detail, and we'll spend a little bit more time on the RPPR. So inventions reporting, inventions and patents: You need to report to NIH any patentable discoveries and as soon as possible, and then if there is going to be an invention, then that invention needs to be reported using iEdison. That's iedison.gov, which is at the bottom of this slide. Essentially, it follows the Bayh-Dole Act which allows the recipient to retain the patent as long as they are compliant with the Bayh-Dole Act, and there's a number of implementing regulations that are included in the policy that you can look into further, which we have the link here to be able to do that. Now the next report is the FFR, the Federal Financial Report. It's due 90 days after the end of each budget period. If you happen to have a multi-funded award, multiyear-funded award which are a bit rare, those, the FFR is due at the end of the project period. If it's 3 years, it's at the end of that time period. If it's 4, at the end of that time period. This reflects the funds that were expended in a budget period. So it also shows what's unobligated on the FFR, and that balance can be used with a carryover request, as Roger reviewed previously, and it must be submitted before the carryover requests are considered. So the FFR must be in and submitted prior to any carryover request. It also needs to be submitted prior to a non-competing grant being awarded. So the grant will not be processed if the FSR is not submitted and accepted in the system through OFM, Office of Financial Management. So next is another report, the FCTR, the Federal Cash Transaction Report. This is done through the Payment Management System, and it's a quarterly report, while the FFR is annual. Here is a table of the quarters for which it's due. There is good news that the department is working on discontinuing this report, and there would just be the FFR, but that remains to be seen. For now, both are due. It's very important that they're both submitted and accurate because they need to align with one another, or else you could actually put the organization into Federal debt. So you need to be very certain that these are accurate and submitted on time. The Financial Conflict of Interest, FCOI, this is for the PI and other investigators on the award. If there is a conflict of interest that's identified, it must be managed by the institution, and it must be reported. There is a signature on this submission that certifies a number of items that are on the slide that you can take a look at, but this is very important to be submitted and that each institution must have a process to identify FCOI, the conflict of interest, and to be able to manage them. Audit reporting: There's both state and local government and nonprofit organizations. For-profit is a little bit different for each, but audits are required for any awards that are 750,000 or more, and there's more information on that, for those who have awards at that level. So now turning our attention to the RPPR, the Research Performance Project Report. The RPPR in the eRA Commons, there are very helpful information about the due dates of your awards, and there's access to prepopulated face pages on the eRA Commons as well, and I've identified the link here. So what is the Research Performance Project Report? There are three different types. Again, the one that's bold and in red, we'll take more time with, but there is the Final RPPR that's due at closeout, and the Interim Progress RPPR is used if there's a Type 2, a competing renewal application, is not funded, the Interim RPPR will serve as the final RPPR for the project, and we'll close out. If the Type 2 is funded, the interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. So that's how those work, the three: the Annual, Final and Interim RPPR. And so with the next slide, the Progress Report, there's a streamline noncompeting award process, which we call SNAP. In general, these are the K awards and R awards, and the RPPR is due approximately 45 days before the next budget period start date, and there is automatic carryover with SNAP. With non-SNAP, this is Ts, Us, Ps, non-Fast Track Phase I SBIRs and STTRs and clinical trials and R35s. The RPPR is due 60 days before the next budget period, and this does require a detailed budget request and annual FFR, and carryover requires prior approval with non-SNAP. So Roger will take over here with the SNAP administrative and fiscal requirements.

>> Roger Sorensen: Thanks, Bryan. So under SNAP authority, we're trying to make is a bit more easier, a bit more simpler in submitting your RPPR report, annual progress report. So as you can see, detailed budgets are not required for the RPPR. The Federal Financial Reports are due at the end of the competitive segment, and there is automatic carryover of funds. However, it is very important that you address three specific questions. The first one is: please list any change in other support of the PI or key personnel. Alright? We want to know about new grant awards. We want to know about grant awards that have ended. We don't need to know about pending awards. We are using this information to further check for scientific overlap in funded awards and whether the overlap would affect the conduct of the research grant itself, research project. Number two, we want to know, as I said previously, about the change in the level of effort of the PI and key personnel. Do we have new personnel added? Have we lost personnel? Have they been replaced? Do we still have the same expertise to be able to conduct the project as proposed? And briefly describe the reason for change, and then here you can list if there's any anticipated unobligated balance greater than 25 percent of the previous budget period. Again, this is essentially requesting the carryover of these funds. Here, you will provide a brief description of the future use of these funds towards the project itself, and if you're replacing personnel, and thus you haven't spent funds that were intended to support personnel salaries. So if you replace them, provide the duties and expertise of the new personnel. I also wanted to strongly highlight the Public Access Policy. So the NIH Public Access Policy says that you must submit or have submitted to PubMed Central an electronic version of manuscripts for publication. We want to know that these manuscripts have been entered into the PubMed Central system, and so if you've submitted, we are going to check. If you cite applications, please ensure that it says that the applications are responsive to Public Access Policy or in process. This is one thing that holds up issuing the award for the next budget period, so don't wait until the progress report is due, and I'll turn it back over to Bryan to talk about non-SNAP RPPRs.

>> Bryan Clark: Thank you, Roger. So with non-SNAP, this requires a categorical budget, a detailed budget and justification, unlike SNAP. It also requires an updated IRB and IACUC, if that's appropriate, and you do still need to address any unobligated balance greater than 25 percent, and this is the total costs are as the commitment base, whatever was committed for this year, the particular year, and also the annual FFR is also due. So what not to submit with the RPPR, so sometimes we will get requests in the RPPR that require prior approvals, like carryover or requests for supplements or additional time. Sometimes recipients will add that to the RPPR. Well, that's not allowable. We need these administrative actions to be addressed separately, as we reviewed previously for prior approvals and how that is done, and so to not submit it in any RPPR, SNAP or non-SNAP. Now we'll talk about closeout, this final part of the grant cycle, and there are a number of, or three things that are required, reporting that is required for closeout, and these must be submitted within 120 days of the project period end date, and that is the final Federal FFR, Federal Financial Report, the final Invention Statement and Certification and the final RPPR is also due, and if after 180 days, if they're not submitted, the award enters what we call a unilateral closeout. This means that NIH can then close the award without these reports. So you really don't want to get into that situation because, for instance, with the Federal Financial Report, we used the last drawdown of the award as the balance of the award, and so that may not be accurate, if you haven't submitted the final Federal Financial Report. So it's very important to do this within the time frame. It's actually late after 120 days, and then it's very late after 180 days, and it enters unilateral closeout. So the final Federal Financial Report, this explains it in more detail. I won't go into this. You can review this, but it is the last Federal Financial Report for the award for closeout, and the final Invention Certification, I talked earlier about what the invention reporting is. If there are any inventions, they must be submitted as the final Invention Statement and Certification. Even if there is no invention, it still is required to be submitted, and simply state that there are no inventions. So that's very important to note, and here are a few differences between the annual RPPR and the final RPPR. One, for the final RPPR, of note is the project outcomes. That's somewhat new as compared to what was under the annual RPPR, and so, Roger, if you want to ...

>> Roger Sorensen: And just to follow up, the most important thing about the final progress report is reporting the project outcomes. What was determined through the research that was supported? What were the final conclusions or what has been obtained? This is going to be publicly available information, which is analogous to the abstract of the application itself. So this is a summary of the outcomes. You have a limit on what you can do, but this is, what we want you to do is to write this in plain language for the general public so they can see exactly what you were able to accomplish through the support of your research project. Bryan and I have included ... And we are ending our presentation. Bryan and I have included a couple of resource links towards grants and the Grants Policy Statement, as you will, for further information. Bryan and I hope you've enjoyed our presentation. We tried to highlight a lot of the administrative issues that we see once you've obtained that Notice of Award Letter, and Bryan and I thank you, and we'll entertain questions.