Understanding NIH Career Development K Awards

>> Dennis Twombly: Good afternoon, everybody. This is Dennis Twombly from NICHD. Welcome to the NIH Virtual Fair. This is the presentation "Understanding NIH Career Development" or "K Awards." I'm the training officer for NICHD and the Deputy Director of Extramural Policy, and I'm joined by Ryan Talesnik, who will introduce himself now.

>> Dennis Twombly: Hi, it's Ryan Talesnik, Senior Grants Management Specialist, also at Eunice Kennedy Shriver National Institute of Child Health and Human Development. Good afternoon.

>> Dennis Twombly: Okay, let's go ahead and get started. The basic purpose of career development awards is to provide scholars with protected time to conduct research and career development activities leading to independence in any of the areas that NIH supports. There are multiple types of K awards, and it can be baffling to many individuals, but they are designed for specific educational or scientific backgrounds and career stages, and I will be going through those as this presentation moves along, and hopefully by the end, if you're a grants administrator or you're a potential applicant, you will have a good feel for what K awards are appropriate for you. They can be broken down into three main categories. They're the mentored awards for early stage investigators who need mentored research training. There are the non-mentored awards for those investigators who are already independent, and there are institutional awards that are supporting multiple K-level scholars, so those institutional awards, the K12 and KL2, function a lot like T32 programs, for those of you who administered those. Just as a reminder: This should be obvious to everybody, but any application for a K award, as well as any research project grant application, must fit the mission of the institute that you're applying to. So there are 27 institutes. We all have different missions. We all have different eligibility standards. We have different budgetary requirements, and you need to figure all of that out before you submit the application. This schematic shows where career development awards fit in the general progression of training, so NIH has a variety of fellowships and K awards for specific stages, starting from graduate/medical student stage, where we use fellowships and T32 programs to provide support for graduate work or, in the case of MD-PhD programs, the research part of those dual-degree programs. We have F32 and T32 awards for postdoctoral fellows, and then we started the transition stage, as people move from postdoctoral training to faculty, and we have a number of K awards to facilitate that transition. One is the K22, which is the career transition award. It's mostly used for intramural programs now, but NCI and other institutes use it still, too. The K99-R00 Pathway to Independence award is very popular nowadays. Started in 2007, and this is a two-phase award that helps people transition from postdoctoral training to faculty. The other K awards that I have listed here, the K12, the K01, the K08 and K23, are really for early faculty, all those people who are technically eligible to apply while they're still senior postdoctoral fellows. Some institutions do not allow their postdocs to apply for these K awards. Some do. So this is what I'm going to be talking about mostly are these mentored career development awards, and the goal is to bring people to the point where they can apply independently for research project grants, so the R03, R21, R01. Having gone through the training pipeline, then they are ready to launch their independent scientific career and begin applying for support, independently from mentors or other faculty. Finally, we do have a couple of the non-mentored awards, the K02 and K24. These are for people who already have independent funding, so I will go into more detail on each one of these things in the next few slides. These are the mentored K award programs. There are quite a few of them. There's something like 15 different K awards overall. These are the most commonly used mentored awards. The K01 is used by many institutes, but often it's tailored to specific individuals. Some are tailored to promoting diversity. In our case at NICHD, we use them for only three very narrow scientific areas. The K99 at the bottom is open to clinicians, as well as basic scientists, and I'll have a lot to say about that in a few minutes, but the two that are highlighted here in brown, the K08 and K23, are specifically for individuals who are clinically trained, so think MDs or MD-PhDs, but also other clinically trained individuals. The eligibility list includes DDS, PharmDs, some different types of rehabilitation degrees and so forth. PhDs are usually not eligible unless they have a PhD in a clinical discipline, such as clinical psychology. The one thing I wanted to point out here is that some individual might be eligible for not just one of these, but they could be eligible for two or three different K awards, and to save you the time of waiting through all the program announcement, I think the easiest thing to do is just contact program staff or the training officer at the institute you think would host your application, and just ask them whether you would be eligible for those, or which ones would be most appropriate. Now, this is the program announcement for the K99/R00 award. We often call these FOAs, Funding Opportunity Announcements. These are the documents that lay out all of the purposes, the eligibility factors, review criteria, budgetary limits and so forth for virtually every single program that NIH sponsors. In this case, it's for the K99. As you see in the middle here, it lists which institutes participate in this program, and not all institutes participate in every single one, so you need to check to make sure. Down at the bottom of this first section, you'll see this special note, and in the middle of that note, you see you need to consult the table of IC-specific information requirements and staff contacts to go hand in hand with what you find in the rest of the funding opportunity, so this so-called IC table contains all sorts of information you need to know about how that particular institute participates in the parent announcement. Here you see the entries for NICHD for the K99. On the left, you see contact people. I'm listed as the program contact. Ryan Talesnik is listed as the branch management contact, and then in the middle is NICHD-specific information, so we describe what our mission is very quickly there. You can find more information on our website, but this gives the general sketch of what we support and the types of career development awards we support, and it also lays out some of the budgetary considerations for, in this case, the K99, but the same would be true for any of the other Ks, so each K would have its own IC table. And as you see here, for the K99 phase, we will contribute up to $75,000 per year, plus finished benefits and research support up to $25,000 per year. So those numbers will differ for different institutes, and if you scroll up and scroll down on this website, you'll see those limits for each of the other institutes that participate. The purpose of the mentored awards is for the candidate to develop new research skills, provides research time, generally 75 percent research time for those individuals to research training with the help of the mentor, and there are also career development activities that they need to pursue during that time frame, and they propose all that in the application. Eligibility: These are typically junior faculty-level applicants. Importantly, most of the Ks require the applicant to be a US citizen or permanent resident. The only exception is the K99, which allows pretty much anybody to apply, but there are important other eligibility factors that I'll talk about in a minute. For most mentored K awards, the applicant cannot have been on a prior K award, and they cannot have been PI on on a sizable research project grant or be the component project lead on a program project or large center. Okay, so these are really for people who have yet to become independent. Duration is 3 to 5 years. It's not renewable, and it requires a full-time 75 percent effort commitment. Salary levels and research support levels you'll find on the IC tables. The K99/R00 was started in 2007. It's a very interesting program. It's a two-phase award that helps people finish up their postdoctoral training, and provides support for that, and it also supports the first 3 years of their independent research as a faculty member, so here is how the two phases work. The first phase, the K99 phase, is mentored, so basically these people are staying with their postdoctoral mentor, and they're finishing up their research projects, their training and get publications out, and what they do during that time frame is start shopping themselves around for faculty positions. We encourage people to look nationwide, if they can, because those who get these awards are very, very attractive faculty candidates, and that's partly why we have this award. So at some point, they will get an offer for a faculty position, and then they will apply for the R00 independent phase. It lasts 3 years. It requires a tenure track or equivalent faculty position. Again, it's 3 years, so that they can launch their own program independently, and it provides $249,000 per year in total costs, so that's direct costs and indirect costs, so the direct cost, depending upon the institutional rate, is going to be $160,000 to $180,000. Eligibility is very important to pay attention to for the K99 because it's pretty tightly limited in some cases. People who have basic degrees and PhDs are eligible. People who have clinical degrees are eligible. They simply have to be a postdoctoral fellow or equivalent. All right. So any kind of a fellow, clinical fellow, it could be. These can be submitted by extramural institutions or the intramural program at NIH, so this is something intramural, one of the few things, the only thing, actually, that intramural fellows can apply for. As I mentioned before, this is the only K program that allows non-citizens to apply, and we have a lot of foreign scientists who come train in the United States. They intend to stay here, and they will apply for the K99 as a way of finishing up their postdoctoral work and starting a faculty position here in the states. Now this next bullet, the fourth bullet, is really a key consideration. We have a lot of questions about this. The requirement is that the applicant can have no more than 4 years of postdoctoral research experience at the time of any K99 application, so that includes the first application or a resubmission. Okay. There are exceptions that we can make for childbirth, adoption, family care, for critical health issues, medical leave, or if somebody is doing purely clinical work and no research, we can extend that time limit for those people. Importantly, the applicant cannot have had an independent faculty position previously, and they cannot have been PI on pretty much any kind of NIH research project grant or large-scale private foundation grants. The three main non-mentored awards are the K02, the K05 and the K24. I'm not going to go into detail on that. You can simply look at the funding opportunity, but these are individuals who are already independent, and they are trying to get release time to launch new research directions for, in the case of the K24, to pursue mentoring activities. The institutional K programs, again, these are awards to an institution to support multiple scholars. The requirements for the scholars themselves are pretty standard for K, so a 75-percent time commitment. The duration can be anywhere from 2 to 5 years, and one thing I have to point out is that some institutes, including ours, apply an overall limit on individual K and mentored ... I'm sorry, institutional K and mentored Ks of up to 6 years, but no more than 6 years, so if somebody's been on a K12 for 3 years, they're only eligible for 3 more years on a K23, for example. So this is, again, something you'll see in the Funding Opportunity notes on the IC table. All right. How to apply? Simply go to the SF424 instructions for the K series that you see here highlighted in green and follow the instructions. The default is to follow the instructions in the 424 guide. If there are specific instructions in the Funding Opportunity that replace or supersede some of the standard instructions, you should follow the Funding Opportunity. Application content, you'll see that in the FOA, but there's a candidate section. There's a research plan section, where you describe the research project for, in the case of the K99, both phases, not just the R00 phase, so the K99 phase would be finishing up the postdoc and any remaining career development activities needed to be pursued then, and then when the transition is made to the R00, that's an independent research phase that usually does not require or include career development activities, but it can. These are other things that go in the application: plans and statements of the mentors, co-mentors, letters of support, environmental commitment, RCR training. These are all things that are required, and they're all reviewed. They're all very important, so don't skip any of them or omit some at the expense of others. So finally, mentor ... Sorry, reference letters for mentored Ks are separate from the application, so these are letters that are written by other individuals, maybe collaborators, but they are separate from the mentor and co-mentor statement. Okay. K award budget, I don't need to say anything more about that. I think I've covered that, but this is a section of the K application that you need to fill out and follow all the 424 instructions for this. Clinical trials requirements, so a couple of years ago, NIH started a whole new paradigm for handling clinical trials research. They define clinical trials in a very specific way, so anybody doing human subjects research needs to figure out whether their project is considered a clinical trial. This dictates which funding opportunity you would apply to, and it details which review criteria are involved in the scoring, and also the PI would eventually have to report the clinical trial in clinicaltrials.gov. The website at the bottom, that gives you all the details you need, and includes case studies, so that you can figure out, is your research really considered a clinical trial by NIH? The main part of the determination is to first answer these four questions of, does it involve human subjects? Does it prospectively assign human subjects to interventions? Does it evaluate the effect of the interventions? Does it have a health-related biomedical or behavioral outcome? If the answer is yes to all those, then NIH would probably consider it a clinical trial, and in that case, you need to apply to a Funding Opportunity that allows clinical trials. If you apply to the wrong one, your application will be withdrawn by the Center for Scientific Review. Okay, these are some of the review criteria. Some of the review takes place at CSR. Much of the review for Ks occurs at the institute review branches. That's how we do it for NICHD. The main scored review criteria are listed here. The overall impact score is not a numerical average of those, so sometimes people say, "Well, I got ones and twos for all these other things, but the overall score wasn't really that good, so what happened?" So it's not a numerical average. These are just split up to help you figure out where the strengths and weaknesses were for your application. There are additional review criteria that do enter into the score, and there are additional review considerations that do not enter into the score. Timeline for applying: We have three receipt dates per year for K awards: February, June and October for new applications; March, July and November for resubmissions. For those cycles, the review takes place 4 to 6 months later. Council is 3 to 4 months after that. The award takes about 2 months to write up. Advanced management, and so the total time, if you add it all up, is 9 to 10 months, so just to help you remember, NICHD is an institute that funds research on pregnancy and perinatology, so this will be a mnemonic device to use, so think 10 months from the due date, 9 to 10 months from the due date, but that also assumes that you've spent a couple of months before that planning your application and writing your application. If the score was not fundable and you need to resubmit, the total time can be closer to 12 to 18 months. Last slide, I just wanted to point out for people who have received Ks, or even those who are not applying for Ks, that we have a very specific program for new investigators and early stage investigators that gives them advantages in applying for R01 grants, so a new investigator is somebody who has not previously competed for an R01-level grant. An early stage investigator is a new investigator who is within 10 years of the PhD or the end of clinical training, so why am I telling you this? NIH funds early stage investigators at much more favorable pay lines, so if you are eligible for that, you should be thinking about when to apply for an R01 as an early stage investigator. A K is not really going to get your program launched very well. An R01 is really going to be the full-size grant that gets you on your feet independently. The differences in pay lines can be 3 to 10 percent, depending upon the institute, and so think about applying, if you have the preliminary data to apply. At this point, I will turn it over to Ryan, who is going to talk about the award management after you receive a fundable score, so thank you very much.

>> Ryan Talesnik: All right. Thanks, Dennis. Something that was covered, in his kind of the higher view of his, was determining which K awards to apply for, how to apply, and then the review process and scores. So the question is, an application gets a fundable score, so now what? So there's a pre-award review that occurs. The majority of that is within the just-in-time, or JIT, request and submission. Now, we get a lot of questions on, "JIT or just-in-time request, does that mean I'm going to get funded?," or "Does that mean an application is going to get funded?" And the answer we always gives is no. That just means that if we ... We need this additional information to allow us to complete that pre-award review in the event that we're able to actually fund that application. Some of the components of the just-in-time is similar to other awards, such as other support, IRB and IACUC approvals for human and/or animal subjects and human subjects protection education information. Something that's specific to Ks, especially mentored Ks, that occurs is we do ... Typically, most ICs will request the current salary and fringe levels, if the application was submitted below whatever the cap for that K mechanism is. We'll also often look at the institutional commitment letter, to ensure that projected time is well spelled out, and then if there are critical trials involved, as Dennis mentioned, there's a clinical trial involved in an application, there are additional steps, such as establishing milestones between the principal investigator and the program officer, and then also some ICs, such as NICHD, do conduct an internal risk assessment to help us determine the risk level for that clinical trial, and that may require some additional reporting typically, depending on the risk level, and that would be all spelled out in the Notice of Award. So once the award goes out, typically, we ... the progress is mostly reported in the annual Research Performance Progress Report, which is or the RPPR. For most mechanisms, that's due 45 days prior to the next budget period, though it's 60 days for the institutional K awards, K12s and K32s. I'm sorry, KL2s. And most are under the SNAP provisions, which streamlines the process for what information is needed for the RPPR. Some of the highlights of what's needed in the RPPR is the publication listing for the last budget period for the PI, information or any updated information on responsible conduct of research, mentor reports on the progress that's been achieved during the last budget period. Also any changes that may have occurred, such as effort changes, mentor changes or other support changes for PI, and also if there's a large unobligated balance, typically considered 25 percent of the award, just information on how the balance exists and how that's going to be brought down in the next budget period. Now, during the project period and for some points immediately afterwards, there are, obviously, some post-award actions that may occur. Some require NIH prior approval and some do not. The list of actions that do not require prior approval, the biggest one is probably the first no-cost extension of up to 12 months, which is allowed in all K mechanisms, except for the K99, and going to that in a minute. Also rebudgeting and equipment purchases, if those are within scope. Most K awards, except for the institutional Ks, also have automatic carryover from one budget period into another. That doesn't require prior approval. Also, temporary off-site training experiences and leave of absence requests of 3 months or less do not require prior approval. Obviously, there are actions that may occur that are large enough or significant enough that they do require prior approval, and this is typically done in a written letter to your grants management specialist and program officer, the PIs, PO and GMS, and this includes such actions as: change of institution, if the PI is moving from institution to another during the K award; changes of mentors, especially the primary mentor; any requests for unpaid leave of up to 12 months; any leave or temporary off-site training experiences which are greater than 3 months; requests to temporarily reduce effort for the PI, and I'll get into that in a moment; and also additional no-cost extensions beyond that original 12-months period and all K99 extension requests, and we often do get questions. "Why is the K99 really the only one that does have that automatically?" And as Dennis has kind of discussed a little bit, the idea is that there's ... These awards, the K99 is meant to facilitate the PI's transition to a faculty position, and if there are delays or issues with that transition, then we want to know about it, want to know about the status of career, of the, I'm sorry, the faculty job search and how that's going, so that's why we require that on K99s, and also any early scholar terminations on institutional K awards also require prior approval. Now, as I mentioned, we do allow some temporary effort adjustments. PIs may temporarily reduce their effort down to 50 percent for up to 12 continuous months during the project period. Now, this provision is only allowed on K awards that have a 75 percent effort requirement or higher. Some, not very many, but some, have a 3-to-6-month requirement, and in those, the temporary adjustment would not be allowed. It's only for the 75 percent and higher. And the effort adjustments would be for usually personal or family situations, such as parental leave, childcare, eldercare, medical conditions or disability. It would not be allowed to accommodate such, say there's job opportunities, clinical practice, clinical training, instances where the PI is still involved in the career development or the research. If that's the case, then such a temporary effort adjustment would not be allowed, and as you can see, there's an NIH guide notice and NIH Grants Policy Statement sections that refer to those allowances. Now, we do get a lot of questions about how salary is determined or, I should say, supplementation for salary for K awards, and there are some provisions. I think this pie chart gets a pretty basic understanding of how that works. Most K awards have a 75 percent minimum K effort requirement, and for that effort, salary supplementation is allowed, but can only come from non-federal sources. For that additional effort not committed to the K, which is typically 25 percent or less, salary compensation may come from federal or non-federal sources, but it has to be different than the aims of the K award, and again, there's a Guide notice and Grant Policy Statement section on that. For mentored K awards, in their last final 2 years for a 3-to-5-year individual mentored K award, we do allow the PI to reduce their effort to down to 50 percent, a minimum of 50 percent, if they successfully compete as a PI or PD on a federal research award or grant of $100,000 or more of direct costs from non-federal sources, such as a foundation, and the idea is that that reduced effort would be taken up by that research award. It would get effort as well as salary from that research award, and the requirements, though, with that reduction, is that the effort, minimum effort, between the K award and that research award has to remain at 75 percent or higher, even with that reduction. Now, as Dennis mentioned, we do get a lot of questions about the K99/R00, and especially the ... obviously, at the end of the K99, near the end of the K99 phase, about transitions to R00, and so there's basic information, as mentioned. As well, most ICs do require 1 year in the K99 phase, but no awards left more 2 years. Though, we do allow some no-cost extensions, especially considering with the COVID-19 disruptions. The application is typically required to be submitted, that R00 application is required to be submitted 2 months prior to the start of that faculty position, and the reason being is that we need enough time to be able to review the application, which is done internally by ... It's not done through CSR, like a regular application is done ... internally by an IC. To make sure, if we have any questions or any concerns, that we can resolve those and be able to get the application out, or, sorry, the R00 award out as close to the start of the faculty position as possible. This is just some information about some of the things that are considered in a R00 application. The review committee or transition committee will look at: the type of faculty appointment; academic environment, including the faculty resources and reputation of that new institution; the progress that was conducted on the K99 related to the research and career development objectives; the start-up package, and we also want to ensure that there is a ... that the PI will be able to commit 75 percent effort to research, and the question we always get is, "Do the ... Is all the effort of that 75 percent have to come from the R00?" And the answer is no. That's the ... R00 award usually makes up a portion of that. Another large question we get is, "What happens to the remainder of the K99 budget, if there's a balance?" And each IC deals with this differently. Some do allow the PI to utilize those funds. I could tell you, at NICHD, we do not. That will ... What occurs is that those funds are actually offset on a later year of the R00, and that's all spelled out in the Notice of Award, both in the K99 award and the R00, so nobody is kind of blindsided by that condition. As Dennis mentioned, the R00 does have a $249,000 total cost per year cap, so you need to keep in mind that, if based on the F and A rate for that institution, and we, though it sounds really far ahead, but we do recommend that the PI consult with the program staff 6 months prior to the transition to make sure everything is going well and that there are no hiccups along the way moving to the next phase. So at the end of the K award, there are, as with other awards, close-out requirements and final reporting. All K awards are required to submit a final RPPR. The exception are the K99 and K22 transition K awards because those transition applications, such as the R00 application, would include progress on the K99 phase. They're also required to submit a federal financial report at the end of the project period. Though, for institutional Ks, that's actually done on annual basis. And in fact, a final mentor statement is required, except for institutional Ks. So this is just a list. The next, I think, two slides are just lists of resources that are available to you about the different types of K awards, how to apply, sections on the NIH Grants Policy Statement relating to the K awards. Also FAQs that have been put out by NIH OER for how to apply, what to do, if you have questions, and then there's also, just wanting to provide some sources of guidance to any applicant, and this is just a wide overview of where you can go if you have questions. Obviously, on the program announcement, or if there's an RFA, provides information on the purpose, eligibility, allowable costs, review criteria for an application. You can go, if you want to know the mission of NIH or specific ICs, you can go to the NIH website, or that IC-specific website. You can, obviously ... A PI should talk to their mentors, or either current mentors or proposed mentors, as well as department chair administrators, and to hopefully the sponsor projects programs office, projects office, should have information. And then, obviously, always ... You should always feel free to contact your NIH program officer before applying and during and after review to see how the progress is going. So that's it for us. Here is the information, if you need to contact Dennis or myself, as well as our website for information on NICHD, and we thank you for attending our session today. Have a good day.