Dennis Twombly: Welcome, everybody. It's nice for you to join our career development award present. I'm going to start off with a broad overview of the career development programs for those of you who aren't really as familiar with them, and after I do my part, I will turn it over to Ryan, who will talk about the post-award issues that they encounter over in the grants management branch. All right. So what are career development awards? These are awards to individuals who are generally at the senior postdoctoral level through early faculty level, and what they do is provide protected time and salary support to conduct research and career development activities leading to independence in any of the disciplines that NIH supports, medical, behavior or clinical sciences. As you'll see during my part of the presentation, there are multiple types of K awards, and I'm sure many of you are confused as to which ones are used for what, and hopefully I will be able to clear that up to some degree as we go along. The first major category that we support at all of the NIH institutes pretty much are the mentored career development awards, and those are for early-stage investigators who need additional mentored research training. Some of those individuals have had research experience before. Some of them have very little research experience, and so these awards allow them to work with a mentor and gain the experience and track record they need to hopefully move towards independence. There are some non-mentored awards for already independent investigators so they can either acquire new research skills or to support their mentoring activity. I won't spend much time talking about those, but just to know that those are available. I included them with the slide presentation. And then finally, we have what we're calling the institutional career development award. They are K12 programs, K02 programs. There are different types of them. These are awards to the institutions, and the funds that we provide support multiple slots for scholars on those awards, so if you're familiar with K32 programs, these institutional K programs work in a similar way. NIH has a number of training awards for individuals who have different types of backgrounds, such as PhDs or MDs, and the programs are tailored towards specific sections of the training pipeline. Sorry, I don't have a pointer that works very well here for you, but in the middle panel here, you see at the top graduate students and medical students, and they have fellowships and training grants to support them, and then postdoctoral fellows, who start bringing in different types of awards, and for senior postdocs and early faculty, you see this list of yellow highlighted K awards, and those are the ones that I'm going to be focusing on today. The independent ones are down here at the bottom, but by definition most of these require investigators to already have research funding, but for everybody else, we provide these mechanisms to hopefully bring them to the point where they can apply for research grants as principal investigators, where those grants might be R03 small grants, R21 exploratory-developmental grant or the gold standard R01 research project grant. So here is a short list of not all of the K awards but a few of them just to point out which ones are the most common. The K01 is used by many of the institutes of NIH, mostly for PhDs but MDs are also eligible. Anyone with a doctoral degree is eligible, but then these other ones I wanted to show you just to point out the K08, which is a mentored clinical science development award for basic science. The eligible individuals include MDs, MD PhDs and PhDs in clinical disciplines, so people who have clinical degrees as opposed to a research degree such as PhD. The other similar award is the K23. Again, these are for individuals with clinical degrees, and this is the mentored patient-oriented research development award, and this is for patient-oriented as opposed to more clinical science, basic sciences up here with K08. And at the bottom, you see the K99/R00. That's a type of award that was started up in 2007 and has become very, very popular. Most of the applicants are PhDs, but it is open to anyone with a doctoral degree. I will show you some of the eligibility criteria later, but this is one that we receive probably most of our questions are on as [Indistinct] understand. So first off, you need to be sure that the type of application you submit is responsive to the mission of the supporting NIH institute. I've highlighted NICHD and NIMH here. We have our own areas of focus, but we also have overlapping areas of focus, and it's important for applicants [Indistinct] awards as well as research project grants to know which institute might be supporting their research because if it's outside of our mission at NICHD, we will not provide funding for it, so you need to figure that out up-front. How do you do that? There are funding opportunity announcements. That's the broad term including PAs and PARs and RFAs, and there are published documents. The funding opportunities for every one of these programs is published so that it's available for you to look at. The example here is for the Parent K99/R00, and basically this document shows you which institutes at NIH support the program. NICHD is one of the ones listed here. There are actually 18 other ones on the list, and so this allows you to see whether NICHD participates at all. If you don't see our institute listed there, we won't provide funding through that program, so that's the first thing you need to figure out. Down here at the bottom, this paragraph says "special note." I'm simply going to read that to you because it's so important. It says, "Not all NIH institutes and centers participate in parent announcement. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interests and requirements at," and here is a link, the table of IC-specific information requirements and staff contacts website. So this type of link on the K99 as well as all of the other parent K's you will see right after all of the institutes that are listed here in the participating organizations. You need to go to that to find out, what are the specific areas of science at NICHD or other institutes support? Here is the K99 entry for NICHD. If you scroll up or down, you will see NIDCD down below us and NIMCI is up higher, but in the middle box, you see a description of the types of research NICHD supports. Over here on the left side, you see a scientific program contact. My name is listed here. It could be a training officer. It could be program staff member, and you will see a different individual for each institute. There are usually also grants management contacts, and Ryan is listed here for [Indistinct] institute, but if you go to the table, you will find out not just what NICHD supports and who to contact, but at the bottom of the entry here, you see salary support, and for our institute, it says, "For the K99 phase of the award, NICHD provides salary of up to 75,000 plus fringe benefits per year, and for research support, up to $25,000 per year." So that's important because that's information you need to put into the application, and the numbers are similar for some other institutes, and they're different for others, and you won't know that without going to this so-called IC table. All right. Let me drill down a little bit on what these mentored career awards are used for. It's to develop new research skills and provide release time, as I said before. Eligibility for most of them is any kind of a doctoral agree, except as I mentioned before, the K08, K23, it requires a clinical degree. All of the K awards except for K99 require US citizenship or permanent residence. That's important to know, though we have a lot of foreign applicants for ... or actually foreign scientists working here in the country who are applying for the K99. By definition, the K99 applicant has to be a postdoctoral fellow. The rest of them are for generally early faculty. These are providing 3 to 5 years of support and require 75 percent effort on a full-time commitment, and as I said, the salary ranges from 75,000 to 100,000 and even higher for some of these. The Pathway to Independence award, the K99/R00 is a two-phase award to help new researchers secure a tenure-track position, first off, and then in the second phase, launch their independent research career. The first phase, phase one, the K99 phase acts much like other K awards, except it's shorter in duration. It only lasts 1 to 2 years. All of the institutes require at least one minimum on the mentored phase but a maximum of 2 years, so that's the amount of funding we will provide for the K99 part of this, and after the postdoctoral fellow completes their postdoctoral work, they're ready to move on from their mentor's laboratory, they hopefully are searching nationwide for positions, and once they do secure an independent position, we will activate the R00 independent phase. That's a 3-year phase. Here in the bullet, you see that it requires tenure track or equivalent faculty position. We have lots of questions about what "equivalent" means. If it's clearly tenure track, then there's not a problem, but there are soft money positions and other position titles where it's not so clear if it's a tenure-track equivalent or not. Best thing to do in that case is to contact the program officer or training officer and ask. This phase provides $249,000 in total costs. That's not current costs. That's total costs per year for those 3 years. K99 eligibility, I want to point out a couple of things that are really important for the K99. First off, it can be used for intramural scholars to help them finish up their work in the intramural program and then move to an extramural institution. This is the only K that provides support for non-citizens. And here is probably the most important one in terms of the questions we get: Applicants can have no more than 4 years of postdoctoral experience when they apply for either the initial application or a resubmission. Plenty of people wait too long and they send us messages asking if they can get exceptions and extensions. We generally do not do that except for certain things. We do it for childbirth. We'll do it for family medical leave emergencies, and more recently we had some exceptions for COVID impacts, so that's the 4-year rule. It's very important. Some of these other ones down below here show types of awards that a K99 applicant cannot have received in order to remain eligible, so I'll just let you read those real quickly. So importantly, these are for postdoctoral positions or postdoctoral equivalent positions. Anyone who's already had a faculty level position is no longer eligible. We have a few non-mentored K awards. These are for faculty who are already independent, and I think most institutes require active funding either in general or active funding through that sponsoring institute in order to be eligible. Some of the ones you may have heard about, there's the K02. The K24 is more for patient-oriented research and mentoring. Mentoring is a big aspect of the K24, and then there are others as well that I won't go into. The effort requirements can be anywhere from 25 percent to 50 percent, so what you need to do is get a funding opportunity announcement and look that up. As I said before, the funding opportunity announcement explains everything you need to know about the program, what we're looking for, who's eligible, how to apply, what the review criteria are and so forth. Some of the NIH institutes sponsor institutional career development programs. K12 and K02 are the most common, and as I explained before, these are awards that provide support for multiple scholars at the same institution. There are a couple different models. Some are given to an institution such as UCLA where they have three or four slots for scholars. Other are nationwide programs where one institution will be in a hub, so to speak, and they will screen applications and place scholars at institutions around the country, so those are the so-called nationwide programs. Eligibility for scholars is much like other K's. They have similar effort requirements, and most of them request 75 percent and then also reserve 25 percent for other duties such as clinical activity or administrative [Indistinct]. Duration of these institutional slots can go from 2 to 5 years, and some of the institutes have a composite requirement of no more than 6 to 8 years of cumulative support on institutional and individual awards, so that's something you need to check on the IC table. How do you apply? You go to the landing page for the SF424 application guide, and for individual K awards, you click on the K block here and go through the PDF. For institutional K awards, oddly enough, you follow the T instructions for institutional training. That's something a lot of people don't really understand, and you just follow the instruction on the 424 guide and compare those instructions to the funding opportunity announcement. The 424 instructions are the default. If there are instructions in the funding opportunity that are different, you need to follow the funding opportunity instead. One set of new policies that was rolled out a few years back are the clinical trials requirements, so it's really important to determine whether your work is going to be a clinical trial or not, as defined by NIH. This will determine which funding opportunity you apply to, so there are multiple funding opportunity announcements, depending upon, is it a clinical trial? Is it not a clinical trial? Some of these are clinical trial optional, so there are three funding opportunities for each K mechanism in this, so you need to pay attention to that. This is important because there are certain sections in the application you have to fill out, the human subjects clinical trial form for example, and then there are specific review criteria that apply to clinical trials but do not apply to other types of application. Down here at the bottom is where you can go to find more information. I just wanted to quickly alert you that you need to determine ... If you have human subjects at all, you need to determine if it's considered a clinical trial before you start working on the application. This is just some of the questions that you need to ask yourself. I'll leave it in the slide set, but that really does it. That's all on the website here listed at the top. K application content, I won't go into this either. You can look at it at your leisure in the slide set that you have. There was previously a talk on how to write a K application by Kay Lund, and the decision this year was to not have that presentation, but I think it is archived and available to you if you want to look it up, but basically there's different sections of the application to pay attention to. One question we often get is, for the plans and statement of mentor and co-mentors, is the six pages, the six-page limit, does that apply to all mentors and co-mentors? And yes, it does, and there is a separate section called letters of support from collaborators, contributors and consultants, which is another six pages. The review criteria for these are all listed in the funding opportunity announcement, and as you can see on these bullets here, those review criteria parallel the different sections of the application, so anybody who's wanting to put in a K application should go to the funding opportunity, read through the review questions so that they know how that application is going to be reviewed by reviewers. Finally, this is a graphic that I like to include because NICHD covers child development and pregnancy and K02, so this is a mnemonic device to help you get a feel for how long it takes for an application to percolate in the review system, so the receipt dates for K awards are February, June and October 12th for new applications, and it's 1 month later, so March, July and November 12th for resubmission, so for new applications, if you put it one one of these new dates, it will be reviewed 4 to 6 months later. It will go to council for second level review about 4 months after that, and then if you're successful, you get a great score, it will take another 1 to 2 months for the grants management branch to do pre-award check-ups and correspond with you and get extra information and then we'll award the award. So the total time overall is something on the order of 9 to 10 months. That's for a single initial submission. If the application does not meet the pay line and has to come back in, you revise it, resubmit it. It will take another two cycles probably, so the total time for a new plus resubmission will be closer to 12 to 18 months, so people don't really appreciate how long this all takes, so what applicants need to do, whether they're individual scholars or [Indistinct], talk to your department chair. Talk to your sponsor program's office and figure what the timeline is going to look like. The last thing I want to point out is the so-called ESI program, the Early Stage Investigator program. This started out as a program for new investigators as defined here. These are applicants who have not previously competed successfully as principal investigator for a significant NIH independent research award such as R01 grant. This only applies to the R01 program, but I'm pointing it out because at some point, we hope that K recipients will be thinking about when to apply for their own independent support by either an R01 or some other type of [Indistinct]. After this was launched originally, we came up with a more restrictive definition of early stage investigator, same kind of thing. You cannot have previously completed successfully as PI for an independent grant, but also an early stage investigator has to be within 10 years of the terminal doctoral degree or the end of formal clinical training. This is absolutely important to know because the NIH, all the NIH institutes fund ESIs at more favorable pay lines, and it's really a substantial difference in some cases, so some institutes have a 3 percent to 10 percent better or more generous pay line. So if it's a senior applicant, somebody who's been an assistant professor for a couple years, and they're trying to figure, "Should I apply for a K23 or should I apply for an R01 as an ESI?" You need to work with program staff to try to figure out, "Well, do you have enough publications? Do you have enough of a track record to make an ESI application fly?" At that point, let me just move over now to Ryan. He's going to talk about what happens after somebody's successful and an award is made. He'll actually talk about what they look for at the Grants Management Branch in terms of launching one of these awards, so, Ryan, go ahead and take it over. I will advance the slides for you.

Ryan Talesnik: Okay, great. Thanks, Dennis. So as Dennis mentioned in the information at the beginning, I'm Senior Grants Management Specialist with Child Health, and so I'll be talking briefly. I know we're kind of almost out of time for the presentation portion of this, but I'll try to go through this relatively quickly, but with trying to highlight what we need to, so the question you see in the slide says, "You have a fundable score, so now what?" So we'll find out we do with that. So, Dennis, if you could next slide. So in the pre-award review portion of what we do is, as with other NIH grants, there's going to be a request for what we call Just-in-Time, and these are materials that are required pretty much right before an award would be made, and the type of things that you would see for a K award would be other support for the principal investigator. It's not required for mentors because they aren't committing a measurable effort. IRB and IACUC approvals, if there's human subjects or animal subjects involved, and if there's human subjects, also the Human Subjects Protection Education information, and then we often will ask for updated PI salary information if it's below the caps that are mentioned in the FOA. We also will look and confirm that the institutional commitment letter is included and ensure that it's noting that there's protected time for the PI to complete their career development plans. Also with their clinical trials, as Dennis mentioned, there are some additional requirements such as milestones between the PI and the program officer and possibly some internal risk assessment that's done. I know we do that at NICHD and some other ICs as well. Next slide. So each year, again as with other NIH grants, there is requirement to submit what we call the Research Performance Progress Report, the RPPR. This is due, for most K awards is due 45 days prior to the next start date. It's 60 days for institutional awards, and except for institutional K's, they are under the SNAP, the Streamlined Non-Competing Award Process. Some of the components that are included in that RPPR that are of special interest is the publication listing that must be in compliance with the public access policy, informational responsible conduct of research, a mentor's report for the progress completed during that year, any changes to the key personnel, basically any effort changes for the PI, any changes in the mentor, other support changes and any large unobligated balances, usually defined as 25 percent or more of the previous year's award. Next slide. There are some post-award actions that due not require NIH prior approval. The biggest one which is, again, for most awards is that first no-cost extension of up to 12 months. This is provided for all NIH career awards except for the K99. That does require prior approval. Rebudgeting that's within scope, any equipment purchases again within scope, carryover from one K award budget period into the next, again except for institutional K awards, temporary off-site training experiences of less than 3 months and then any leave of absences less than 3 months. Next slide. Again, then there are some post-award actions that do require prior approval, so again, prior approval meaning that they have to be done prior to the change being made, so again, some of the things, some of the larger ones, change in institution, and we most ... or I wouldn't say most, but you will want to check to see that the institution that you're with or the ... sorry, the NIH IC, I should say, will allow a transfer. NICHD does but not always does, and there are additional requirements such as ensuring you maintain the effort, mentor information, maybe an updated or new institutional commitment because you're moving and other support, so there aren't additional information that's required to move a K as opposed to a research project again. Any changes in mentor is a prior approval as well as unpaid leave for up to 12 months is allowed but is a prior approval. Any leave at all greater than 3 months, any temporary off-site training experiences greater than 3 months, any requests for temporary effort reductions, also any additional no-cost extensions for most K's, so beyond that 12-month period, or it's also required for all K99 awards. There's no automatic ... sorry, automatic no-cost extension allowance for K99s because there's the idea that we want to see where you are in your career path to getting towards that independent phase, so that's why there's no cost extension allowed directly through the ERI comments, and any time that there's early scholar termination or institutional K award, that's also a prior approval. Next slide. So just go through this really quickly, we do allow a temporary reduction in efforts down to 50 percent on K awards that have 75 or 100 percent effort requirement. That could go down to as little as 50 percent for up to 12 months, and this is for such things as personal or family situations as parental leave, childcare, a medical issue or disability. It's not allowed to accommodate job opportunities, clinical practices or other type of activities that are job-related and referenced there in those guide notices. Next slide. So this is always a big question that we receive, and this is always just a very basic but very important slide to keep in mind that all K awards have a minimum effort requirement for most awards, for I'm thinking most of the mentored awards, which NICHD is the majority of what we work with. There is a 75 percent effort requirement. The remaining 25 percent can be devoted to other activities, and within that, we do allow salary supplementation on the 75 percent effort. It can be supplemented, but it has to come from non-federal sources and cannot basically interfere with the K award. For the other 25 percent, that salary can come from what we call instead of supplementation but compensation, so that could be salary from either institutional or federal or non-federal activities. Next slide. What we also allow is what we call concurrent support on a mentored K, and that is for a K award, a mentored K award that's 3 to 5 years in duration, we do allow the PI to reduce their effort from 75 percent down to 50 percent if they have successfully competed as a PI on a federal research grant or other grants being supported by non-federal sources if it's for $100,000 direct cost or more, so again, that's only in the final 2 years of the award on a 3 to 5 year mentored K. We do allow that reduction. Next slide. So again, as Dennis mentioned, one of the ... probably the biggest program that we get questions about and one that's one of the most popular ones is the K99 to R00 project, and again, we do get a lot of questions about how to transition to the R00 phase. All this information is included in the K99-R00 program announcement, but this just gives you some basic information. We do require prior to transition that the PI have at least 1 year in the K99 phase but no more than 2. You are required to request a transition at least 2 months prior to the start of that R00-eligible position. That gives us enough time to receive the application, review it and make sure there's no issues so it's issued at the time that the R00 position starts. It's conducted as an administrative review, so NICHD has an NICHD transition committee that basically looks at what is indicated there, types of faculty position, the academic environment as well as the start-up package and other information. During R00 phase, which sometimes trips people up, there is a 75 percent effort requirement, or sorry, research effort requirement I should say, but it doesn't have to come specifically from the R00 only. The PI may get, say, 25 percent from the R00, and then the remaining 50 percent from other research program grants that they are involved with. As Dennis mentioned, there is a $249,000 total cost per year budget allowance, and this is again indicated in the notice of award, or sorry, in the program announcement, but you are recommended and strongly encouraged to contact your program officer 6 months prior to the transition to get the ball rolling on getting the transition. Next slide. And then this just very quickly about the close-out of the award, that there is a requirement for a final research progress report. This is required for all K's except for K22s and K99s, assuming that the PI transitions to the R00. They would need to provide a final RPPR if there is no transition. There is also the requirement to submit a FFR, federal financial report. This is typically done at the end of the budget ... sorry, project [Indistinct], except for on institutional K's, which have to submit it every year, and also the final amended statement is required, except for on institutional K's. Next slide. So just to finish out, these are some resources that you can go back to. It was the question, you will be receiving the slides for all presentations including this one will be made available, and at the end ... I'm not sure if they're available now or if they might be available at the end of the seminar, I guess after Thursday, so these are always available to you. Next slide. Again, some more resources. Next slide: And this is just some information about where to look for guidance, looking at the program announcement, the RFAs will provide information about eligibility, allowable costs, the table of IC-specific information that Dennis mentioned. Those are referenced in all the different K award mechanism funding opportunity announcements, and that again will provide all that information. You can go to the NIH Office of Extramural Research page also as well as the Center for Scientific Review if you have questions about the review process or to the website for the different institutions if you want to see the program areas. Any PI should work with their mentors to help develop an application, their department chairs, administrators as well as their sponsor proctors offices ... excuse me, and other colleagues and faculty, and of course we always make ourselves available for any questions you may have. Next slide. So this is it. This is our last slide, so basically as you see, this just provides the contact information for Dennis and myself. Always, if you have any grants management questions, you can always feel free to send me an e-mail. I know sometimes it can be a tricky, tricky road to navigate sometimes, so please feel free to e-mail us with any questions, and then during the course of the remainder of the research seminar, please visit us at the NIH booth or the Ask a Training Officer booth to provide more information, so thank you. That's all for me.

Shoshana Kahana: Thanks, Dennis and Ryan. First of all, just want to quickly let you know that we have many questions but also lots of compliments for the terrific graphics on the slides, so thank you. Thank you so much. Now, again, I am confessing that I may or may not have pushed these questions up to you correctly. Are you seeing any questions in the dismissed function?

Ryan Talesnik: No, I don't see any in there. I see ones in the "open" and ones in the "answered."

[ Chatter ]

Dennis Twombly: The Q and A section or ...

Shoshana Kahana: Yes, in the Q and A section.

Ryan Talesnik: Yeah. Now, I know we're pretty much out of time or close to it. I think we could possibly look through these. We have access to the questions, and I know Dennis has to go relatively soon because he's going to be doing his next session on NRSA awards, on F and T awards soon, but what I would say is just in general, if you have a question that didn't get answered, and again, if it's grants management related, feel free to contact myself. Send me an e-mail, and if it's program related or eligibility related, a lot of times I know Dennis is the expert on that or he can direct you where to go, and so again, I apologize. Unfortunately we didn't have as much time as we usually do for these sessions, so we did kind of run out of time for the Q and A position.

Shoshana Kahana: Yeah.

Dennis Twombly: Yeah, I'm not seeing anything under "dismissed," Shoshana, but yeah, so from my perspective, we can usually talk you through and answer in a situation much quicker than your hunting around through multiple program announcements and so on, so we definitely encourage applicants, mentors ... Actually, if you're a mentor of a student or a mentor of a K, prospective K recipient, have those people contact me because as a mentor, you should be familiar with all of this, and part of the process of teaching these people the system is to have the trainees and new investigators get in touch with us and develop a relationship with the program staff and grants management staff, so definitely take advantage of that. Some program officers are a little bit slow. We have tons and tons of e-mails coming in all the time. Just be patient. Keep asking us. Be a pest. Say, "Have you had a chance to think about the question I sent earlier?" Most of what we get is along the lines of, "Dear Dr. Twombly, I do research on autism and mechanisms underlying it. Attached is a specific aims document or a project description. Is this project in line with the mission of NICHD, and can you set up a program officer for me to talk to about additional guidance?" And so what I do as a referral officer, and I'm the lead contact for NICHD, is I will look at it and I'll say, "Okay, this belongs in our Child Development and Behavior branch." I will forward it to them, and they will assign a project officer who can then get in touch with whoever asked the question and do some one-on-one counsel, so that's kind of the best way to go about it. So like I say, some program officers are so busy. They're traveling. They're doing other things. They're arranging meetings and workshops, so you just have to keep at it, and we aren't offended if you keep asking the same question over and over again, but just keep working with us until you get an answer. If you don't hear from the program officer, you're welcome to contact me. I had the same problem. I have too many e-mails too, but we'll all work as a team to try and get your questions answered. Like I say, for individual counseling during the meeting, go to the booth or e-mail me. I am happy to do a Zoom chat with you or do some one-on-one chats if it's a personal or confidential type of situation.

Shoshana Kahana: That would be great, yeah. Again, I can just tell from the comments here that people definitely have a lot more questions to ask, so go to the NICHD booth, the general training booth. There are a lot of folks that are taking part in this meeting that I know would be eager to share their time and thoughts. So with that, I have 2:45 on my phone. I think that is the time that we need to wrap this up, and so again, for any questions that were not answered, please, please, please come and find us, and we will do that. We will answer them ...

Ryan Talesnik: Yes, and I just want to give a sort of a quick thanks to Mary and Hazel in NICHD Grants Management branch as well who were helping to answer some of those behind-the-scenes questions as we were doing the presentation, so thank you guys so much.