Writing an Effective K Application

>> Kay Lund: Okay, this is Kay Lund from the Division of Biomedical Research Workforce at NIH, and I'm going to talk about writing an effective K Application.

So NIH includes 27 institutes and centers, each of which has a different area of focus. So it's important to really know if you're going to put in a K Award, which institute should be the place to apply to. And I'll give you some direction as to how you might be able to do that.

NIH has a pretty large budget, and this shows their breakdown of the budget. Only 2 percent of the entire NIH budget, which is $36 billion -- that was in 2018 -- goes to the career development, or K Awards. But the good news about that is the success rates of the individuals who are applying is actually pretty good.

So what I'm going to focus on today are the K01, the K08, the K23, the K99 and the R00. The K25 is currently to support career development to the investigators with quantitative engineering backgrounds, but to go on and try and do something in biomedical research. There's a new K25 that is under development, so I'm not going to go into a lot of detail about that, because there aren't a lot of individuals who have a K25. It is important though for anyone who may be listening to this to know about the loan repayment programs, because if someone receives a K Award, they are eligible to apply for a loan repayment program. And also, the diversity supplements -- take a look at that. This may be something that if you're not yet ready to apply for a K Award but you wanted to apply for a diversity supplement first to get some experience, some data, that way those diversity supplements do help.

So the other important thing, and I'll talk of them in a little more detail later, is definitely take a look at the NIH Research Training Website. This was launched in 2015. But one of the most important parts of this is that it has up to date information on all the active -- currently active -- K Award FOAs, so people at that early research career development kiosk is the place to go.

So this gives you a little more detail. The K01 is a Mentored Research Scientist Career Development Award, which is supportive postdocs and early career scientists. You have PhDs, typically. The K08 is a Mentored Clinical Scientist Research Career Development Award, which is for those with a clinical degree; M.D., M.D. PhD., can be DVM as well, although a lot of the [INAUDIBLE] medicine scientists will apply for K01s. And then the K23 is a Mentored Patient-Oriented Research Career Development Award, so it's to provide support for clinically trained professionals who have made a commitment to patient-oriented research. And then the K99, R00 is a Pathway to Independence Award. This is one that supports the initial mentored research experience through the K99, followed by independent research. Basically what happens is that individuals submit a K99, and then the R00 is decided upon by each individual NIH Institute or Center. So definitely go to the website and click on the K Award type to view active FOAs, and I'll give more detail right now about what are active.

So the K99/R00 has goal to facilitate transition from a mentored postdoctoral research position to an independent research position with independent NIH research support. And this is to try and do this at an earlier stage than the current norm. The K99 has a phase of one to two years, typical two years. It's a mentored phase, then the individual who applies for this must be affiliated with an institution, typically within four years of attaining their PhD or completing clinical training. Although due to the COVID, as listed down here, there's been a two-cycle extension of eligibility announced for the Parent K99, the NIDCR Award and the MOSAIC Award. There are a number of different K99 Awards. The parent doesn't have U.S. citizenship requirement. The NIAID Physician Scientist also does not, and only requires 50 percent effort. The NIDCR -- same deal, no U.S. citizenship requirement, although it still requires 75 percent effort. Then the Brain Research through Advancing Innovative Neurotechnologies is supported by a lot of different NIHICs, and this does require U.S. citizenship and permanent residence. And then there's one recent Maximizing Opportunities for Scientific and Academic Independent Careers, the MOSAIC one. This too requires citizenship and permanent residence. And then in the R00 phase, individuals have to have already an independent tenure track or equivalent, their own lab, limited teaching and clinical responsibilities so they can still do the 75 percent effort. And then what happens is, the quality of the tenure track offer is administratively reviewed by each NIHIC before the R00 is awarded. Although the R00s have actually been pretty successful.

And if we go to the K01, K08 and K23 FOAs, each with different requirements -- there are independent FOAs, three different types of FOAs. One for the PD-PI to conduct an independent clinical trial, another to have clinical trial research experience but don't permit an independent clinical trial, and the other one is to permit basic experimental studies with humans. And if it's not actually a clinical trial, for example, where testing of a drug is involved, but it is ones where the individuals can do certain basic experimental studies with humans. So it's important that everybody check on these different ICs, which ICs are actually signed on to which of these particular FOAs.

So if you look at the timeline for K Applications, the submission date, or the receipt date, is always due February 12th, June 12th or October 12th. If someone puts in a K Application that doesn't get funded, they can resubmit, and that resubmission date is March, July and November. And then this just shows you the review and the council dates, and when the award may be given.

So if we thinking about writing an effective K Application, a few important things -- really important to start early, and I'll talk about some of the strategies that can be used to do that. Develop a strategy, plan your application. Really know the application criteria -- requirements, sorry -- and the review criteria.

So one of the things that I've typically said, and I have to say that most of the individuals in my former lab who applied for a K Award were very successful. Start at least six months prior to the application due date, or you can begin planning even sooner. Get an NIH Commons account at least a month before the application deadline. It's important that everybody know who's writing a K Award, or planning to submit one, is that there is a new requirement for an ORCID ID for K Award applicants effective with receipt dates after January 25th, 2020, and that can be done within eRA Commons. And it's not difficult to do. Definitely know your organization, this is at the institution. Your organization's authorized an organizational representative to assist with. you know, what is required with the application. And then the other thing, the K Awards really require having someone submit a letter of reference. Really important to notify the individuals that you're asking to submit a reference early, give them plenty of time to submit letters of reference. Ensure they know you have your CV, and if possible, the aims of the grant.

So the other one is, develop a strategy. Assess your career situation and needs. Is there added value to a K Award, and not another funding mechanism? Definitely know which NIH Institute or Center funds K Awards in your research area. And then one of the most important things is to schedule a phone call with the NIH Program Officer that you're thinking is at the NIH Institute or Center, is the individual who will know about your research area training needs and career development, to be sure that they say, yeah, this definitely is the Institute or Center that you should be applying to. Assess the field and the competition. See what's being funded by NIH. Some of the really important things are identify mentors and collaborators. So every K Award requires a primary mentor, but I have strongly recommended for all of my former K Award applicants that they have more than one mentor. And that's important, in case something doesn't work out right with the mentor, or if you need a mentor who is providing a skill that your primary mentor doesn't have.

Discuss the mentors, discuss your plans early, your project in career development to be sure they're on board. Consider strengths and areas for growth. Can you fill any gaps and gain experiences with proposed mentor collaborators? And then identify essential resources and supports, and consider if this is available within your organization, or if possible could be obtained elsewhere.

And then planning the application -- this is probably one of the most important aspects of the K Award. Coordinate with your mentor or mentors. The K application is a collaboration, but probably the most important thing -- and this is something I definitely did for all of my former K Award applicants -- is put together a review committee to assess planning and provide critical feedback. And do this a good period of time before the submission deadline for the K Award. Draft a short description of the specific aims, and discuss these with the committee with the chalk talk, diagrams, central hypothesis. And don't write the entire grant before input is received on the aims. And then the other part is that be sure the project id distinct from the mentor's research, especially if that mentor has an R01. It can definitely be related, and that the mentor has supported the future independence.

The other part is, don't propose too much. Avoid an over-ambitious project, but it should be novel and significant. The hypothesis should be testable, and the aims doable with the resources requesting. The scope of the hypothesis and aims should match the available time and resources, and the research and career development objectives should be matched. Some examples of this, if your research direction is involving RNA sequencing, then really important to go into a bioinformatics workshop and courses. Same with novel imaging approaches -- be sure that there are call facilities that you can actually take advantage of. Be sure that you've got an expert collaborator, even if that's different from the primary mentor, and those individuals can even be at another institution.

Then when we think about the application requirements, this is what is required: the candidate's qualifications, career goals and objectives, the mentors, collaborators and consultants, the institution's environment and commitment to the candidate. And then the specific aims and the research strategy -- and I'll go through these now.

So a few tips as you write -- make life easy for reviewers, write clearly and concisely. Label all components clearly, and make sure figures and legends are readable. I had experience in study sections when I was still in academia, and there were a number of situations where the figures were tiny, the font was tiny. The other is, avoid too much information, a figure can be very useful as long as it's a very clear figure. And then guide the reviewers with graphics as much as possible, and be sure that before the grant is submitted that you edit and proofread.

Then the other thing is, write a compelling argument why your career will be advanced to independence by receiving a K Award. Important to write for both experts and non-experts in the field, because most of the review panel only reads a specific aims page, and that's really the one that everybody should be able to look at and grade. Then cite the published work of experts with leading articles in the field, because again, some of my review experience was that the reviewers would say, why is my paper not actually cited here, because this is one that is very relevant to this particular application.

Then the candidate's qualifications, there are two things. Everybody has to put in a biographical sketch, which is education, training, contributions to science, a personal statement, your research experience and other qualifications for this K Award. And then the research support -- what research projects you've had, your mentors and colleagues attesting to qualifications at the research team. But then some of this should be included in the candidate's background portion, because again, not all reviewers actually look at the bio-sketch and the background. So ensure that key information is provided, even if it repeats the bio-sketch. A commitment to an academic research career, interactions, collaborations, research achievements, experience and other relevant experience that you've had -- leadership, teaching and mentoring.

Then the career goals and objectives -- the important part to put into this is new or enhanced research skills you will gain. Other activities to enhance your research career, for example, courses, workshops, techniques, teaching, mentoring, including "soft skills" by management and leadership. If you've changed research direction before you submitted this K Award, discuss the reasons and justify how it's going to enhance research career development, and provide a career development timeline, including plans to apply for subsequent grant support. The other part in this, again, is part of my prior experience -- career development can include a visit to another laboratory to learn new technologies or approaches. And it also involves networking for the future, so that is something that most of my former K Awardees actually did.

So then the primary sponsor should really be committed to the candidate's career. In their statement, they must explain how they will tangibly contribute to the applicant's career development. Discuss what the planned research and career development activities, regular interactions with the applicant. Document sources and amounts of anticipated support for the applicant's research project, which may be beyond the research funding that is provided with the K Award. And then probably the most important part in this mentor statement is that the mentor should discuss the plans for transitioning the candidate to independence by the end of the K Award, and provide details of their previous experience as a mentor and the outcomes of former mentees.

And then the Institutional Environment and Commitment. This should really document a strong, well-established research program related to the candidate's interests. Experienced faculty, facilities and resources, opportunities for intellectual interactions -- journal clubs, seminars, presentations. And then Research Centers or Program Projects which may provide resources and interactions to promote the candidate's success, commitment to the candidate's career development. And then another important part is adequate office space, lab space, time and support to the candidate for the period of the K Award, so this statement really requires these issues.

So if we go back to the specific aims of the project -- typically, what I'd recommend is that there should be a central hypothesis, and then each of the aims should be a sub-hypothesis. It's to solve a specific problem and address a critical barrier to progress in the field, and to challenge an existing paradigm or develop new technology. All members of the review panel may read this page -- I think I've said this before -- so it's really important. State the problem, why you can solve it, what's new and the hypothesis and sub-hypothesis related to each aim. And then end with why completing the aims would be a major contribution to the biomedical field, clinical practice, and to career development. A summary figure helps -- it used to be that the summary figures would put in the specific aims. Now that's not allowed, but a summary figure immediately after the specific aims would be fine.

So a few tips on the hypothesis. Strong, testable hypothesis rather than simple advance in technology or collecting information. Aim two should be doable, meaningful, if aim one does not pan out. Ask questions that prove or disprove a hypothesis, rather than use a method or search for a problem or simply collect information. Then the methods are a means to perform your experiments. Your experimental results and appropriate statistical analysis will prove or disprove your hypothesis. The hypothesis must be testable during the K Award, and with the level of available resources.

So then if we go the research strategy, the significance is the importance of the problem you're trying to solve. How the study and anticipated results will improve scientific knowledge, technical capability or clinical practiced in one or more fields. And how existing concepts, methods, technologies, treatments or interventions may be impacted if the proposed aims are achieved. Then the innovation part is how your proposed research will challenge or improve current research or clinical practice paradigms, novel theoretical concepts, novel approaches, methodologies or interventions that may be used. And then advantages of existing approaches, methodologies, instrumentation or interventions.

Then the research strategy -- and it's really important to know that this is actually the scorable part of this grant application, which actually drives the overall score. The approach includes the methods and analyses to test the hypothesis and accomplish the specific aims, and requires attention to positive-negative controls, randomization where appropriate. The benchmarks for success anticipated to achieve the aims, potential problems and alternative strategies, and for early stages of development, describe strategies to establish feasibility and manage high-risk aspects of the proposed work. Then this is now a scorable element in the K Awards -- rigorous experimental design, power calculations, sufficient and biological variables, appropriate statistical tests and authentication of reagents.

So the scored criteria, the candidate research, academic and-or clinical record, commitment and potential to develop as an independent and productive researcher. And then the quality of the letters of reference -- and this is really important. The referees should know you. I definitely, when I've been on review panels, have seen situations where there's been a letter of reference that has just been a couple of sentences, and it's been from an individual who really has not been involved with the person who is applying for the K Award. So really important that when you get a letter of reference, you have someone you've worked with before. Career development plan, goals, objectives -- contribute substantially to the scientific development of the candidate; content, scope, phasing and duration of the plan in the context of prior experience.

And then the research plan, as I mentioned, this is really the one that drives most of the final score of the K Award application. But it's the scientific and technical merit of the research question, design and methodology. Strong premise, rigorous experimental design and statistics addresses relevant biological variables. And then really important -- the relevance of the proposed research to the candidate's career objectives. And is the research plan appropriate to the stage of research development and developing the research skills described in the career development plan?

And then for the mentors, consultants and collaborators, this is scored also, their qualifications, funding, mentor statement, a clear commitment and plan for the K Award recipient or applicant to go for career development and a pathway to independence. And the mentors and collaborators must have real roles, be clearly involved and have time to commit. For most of the K Awards, applicants and awardees that I have mentored, I've always requested that we have an additional mentor, just in case anything is needed that an additional mentor can assist with. Environment and institutional commitment to the candidate, assurance that a 75 percent effort will be devoted to research, capable faculty and research facilities, and then assurance that the candidate is considered an integral part of the institutional research program.

So then there are additional review criteria review considerations. This is the study timeline for clinical trials, protection of human subjects, inclusion of women, minorities and children, vertebrate animals, biohazards. And then additional review considerations, which are training in responsible conduct of research, select agent research, resource sharing, authentication of key biological chemical resources, and then the budget and the period of support.

And then rigor is definitely part of the score, so the scientific premise, significance, the approach in the research strategy and the consideration of relevant biological variables. And these are definitely contributors to the overall impact score. Currently the authentication of key biological or chemical resources is a new attachment, but it doesn't contribute to the score.

And then with this, I'll stop. I think it's really important for anyone who is listening to this talk to keep the joy in research. Writing a grant is fun. Trainees and mentees provide a scientific family forever, and certainly all of the trainees and K Awardees that I was a mentor for, I'm still having connections with them to assist them in their future academic careers. Then there are some websites here that can be contacted to actually look at certain issues that you may need to know more about. Then NIHTrain@mail.nih.gov is an email can individuals can actually send questions, if they have them.

With that, I will stop.