

Some hints on obtaining a K01 for post-docs and junior faculty

Timeline by Greg Siegle, Ph.D.¹
Hints by Greg Siegle, Ph.D.¹ & Judith Ford, Ph.D.²
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¹Western Psychiatric Institute and Clinic, University of Pittsburgh School of Medicine
²Yale University School of Medicine

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The Countdown... Sample Time Line:

At least D-7
months

- Collect & read through previous K's to get a flavor for the style they're written in.
- Read through the NIH guide for how K's are evaluated so that you know how to orient the award for a positive review. Review categories unique to the K including: candidate, environment, career, mentor, research plan. The primary guide can be found at <http://grants.nih.gov/grants/guide/pa-files/PA-00-019.html>
- Read the additional guidelines given to NIH reviewers who are commenting on a K-award at <http://cms.csr.nih.gov/NR/ronlyres/0660C631-CE8D-4324-B192-AC8BD4DA9429/10404/K01ReviewGuidelines051106.pdf>
- Plan to be a reviewer for other people's K's through your research committee or any other available venues. This is helpful as it can force you to say what you like and don't like in grants that aren't too close to home yet.
- Start thinking about the topic & project you want to examine in your K.
- If you need more pilot data, consider collecting it early. It is nice to have the 6 months prior to the K for writing rather than frantic pilot data collection plus writing.
- Start considering who you want for a mentor and contact them. This is not as easy a decision as it may sound – it's often useful to have someone as your mentor who was not your post-doctoral mentor. It shows that you're growing in a new direction. Some useful (i.e., fundable and practical) qualities for mentors include: a track record of mentorship, a big name in the area you're transitioning to (remember, the K is about moving into new territory), and a personality you think you could deal with for 5 years.
- Read the excellent NIH website on getting grants at http://grants1.nih.gov/grants/grant_tips.htm
- Check out the excellent resource: "Career development center for postdocs and junior faculty" at <http://nextwave.sciencemag.org/cdc/index.shtml>, particularly their "how to write an R01" toolkit and advice from "The GrantDoctor: Advice for

- Grant Seekers."
- D-6 months:
- Order Bill Gerin's book "Writing the NIH Grant Proposal: A Step-by-Step Guide" (ISBN: 9781412915328)
 - write an abstract & 2 page précis of your research plan
 - Get reviews of the abstract and proposal from your mentor, close faculty, other post-docs or junior-faculty, specifically, if possible, other k-awardees.
 - Take stock of the sections that will be necessary for your K. Use the Table of Contents from the SF424 augmented with relevant sections for Career awards as your guide. The packet can be obtained from: http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000 and supplemental instructions for K-awards http://grants.nih.gov/grants/guide/url_redirect.htm?id=52000
 - Discuss the proposal with a program person at NIH to see whether it's likely to fly. Also discuss the type of award it should be (K01, K08...). The program person for NIH K-awards for each branch of NIH is listed at http://grants.nih.gov/grants/guide/contacts/parent_K01.html and http://grants.nih.gov/grants/guide/contacts/parent_K23.html
- D-4 months
- Finish a first draft of the career development plan
 - Contact potential consultants to see if they'd be willing to consult with you. Ask them for letters of support & their biosketches. It's often useful to offer to write 1) the "personal statement" section for their biosketch and 2) a first draft of a letter for them. Hints on writing letters and biosketch sections are appended below.
 - Contact individuals to write letters of reference for you. They shouldn't be your consultants. I'm told that it may be useful for at least one of them to be at your institution.
 - Find out when your local grants office needs to know you'll be submitting something, and what they'll need from you when. Different institutions function quite differently, but it's often useful to give them lots of heads up and to begin discussing the budget with them early.
- D-3 months
- Finish a first draft of the research plan
 - Pass the career and research plans by your mentor, and other postdocs and k-awardees.
 - Send a draft to your program person at NIH
 - Send first drafts of letters to your K consultants who've asked for them. In writing first drafts of letters, feel free to be very positive about yourself and your research – they can always edit out anything they don't agree with.
- D-2 months
- Start meeting with grants people about getting the budget into shape.
 - Talk with your NIH program person. Ask for their suggestions and what committee it should go to. Have them help you write a cover letter so that it gets to that committee.
 - Look up the committee you're targeting on the web and see who's on it. Tailor the application to the committee members likely to review it (i.e., cite them and have their interests in mind).
 - Distribute K to your research committee, or if you don't have a research committee, distribute it to some faculty who've written grants before. Ideally you'll want to obtain ~3 reviews. It's useful to scrap pride as a concept and go for the toughest most brutal reviews you can get *before*

sending the grant out to NIH. If they're done in-house there's less for the NIH reviewers to pick on.

- Set up a meeting with your chairman to discuss the K, and send him or her 1) a cover letter, 2) a draft, 3) your CV. It's also courteous to prepare a draft of a support letter.
 - If you haven't fulfilled all your university's requirements for eligibility for submitting grants (esp. on-line research ethics courses, conflict of interest forms...), make sure you do. And make sure your mentor's fulfilled them too.
 - If you haven't written your NIH biosketch, do that. Note that the NIH biosketch format requires an ERA Commons ID. These are generally dispensed by someone at your university – often the grants office will know how to get one if no one else does.
- D-1 month
- Make suggested revisions
 - Pass it by at least your mentor & one other faculty member again.
 - Acquire syllabi for the courses you've proposed, for inclusion as appendices
 - Work with your mentor on your letter of support. There's no law or taboo against their taking an active role in the preparation of this document. Rather, you may have seen more K's than your mentor, and thus may have a better idea of what such a letter should include.
 - Bug consultants for their letters & biosketches
 - Reread the guidelines given to NIH reviewers who are commenting on a K-award (<http://cms.csr.nih.gov/NR/rdonlyres/0660C631-CE8D-4324-B192-AC8BD4DA9429/10404/K01ReviewGuidelines051106.pdf>) and review your own award. Doing a written critique of your own work can be sobering.
 - Work with your grants office to deal with your budget. Make sure that all necessary subaccounts and subcontracts (e.g., for the MR center if you're scanning) are in place. As part of this process, give them a signed face sheet. Make sure that "New Investigator" is checked.
- D-1 week
- Work with staff to package the whole business and get stuff sent off to the grants office for signatures
 - Write your cover letter. Note: Your program person can help you construct this letter so it's directed towards the most appropriate committee and to his or her branch.
 - Copy your appendices (up to 5 reprints, course syllabi, & your department's facilities description from the grants office – it may be a million pages but allegedly helps)
- D-2 days
- Make sure you have all your consultant and reference letters
 - Make sure you have all your budget papers. This may take legwork. If need be, consider hand carrying it through these steps rather than have the grants office do it for you.
- D-1 day
- Submit the grant!

Other hints:

Consultant letters

Take care as you draft letters for your consultants and mentors to say about you. The letters are a big part of reviewers' determination of your consultants' belief in and commitment to you.

- Do not be modest – your consultants should know you, be enthusiastic about you and your project, and demonstrate that they are committing the proposed resources to help you.
- Chris Martin has used the following sections in his letters:
 - Involvement with mentee
 - Summary of mentee background
 - Mentee's appropriateness for a K01
 - Correspondence of career development plan and research proposal
 - Endorsement of collaborators
 - Commitment of mentor's resources
 - Description of mentor's resources
 - Support for mentee
- The NIMH guidelines for a career award reference letter state that the letter involves an evaluation of the candidate with special reference to:
 - potential for conducting research
 - evidence of originality
 - adequacy of scientific background
 - quality of research endeavors or publications to date
 - commitment to health oriented research
 - need for further research experience and training

Your Biosketch

- Use your personal statement for a *scientific* (not the rest of your life) biography of where you've been and what your professional aims are. Ideally, it should lead directly to the proposed project and from it.
- In your personal statement, differentiate yourself from your sponsor – you should be working towards a career different from theirs.
- You should have at least 3 published or in-press publications and ideally more than 1 first-author to be competitive. If you don't have at least 2 publications, this is something your sponsor should address in their letter, ideally with a plan for increasing publications.

Biosketch Personal Statements from consultants

The NIH biosketch requires that PI's, mentors, and consultants include a personal statement. It is helpful to write this section for your PI. Here's a template I've used.

"The proposed research involves XXX. I have expertise in all of these areas, including XXX, a long history investigating XXX, experience with XXX, and formative work in XXX. My work in this area began in XXX. I currently direct the XXX lab which is devoted to these themes. I have successfully administered major grants in this area and currently serve as PI or Co-I on multiple NIH grants using XXX. I have a strong track-record of mentorship and co-mentorship for K-awardees. Currently I mentor XXX junior faculty, XXX of whom have K-awards. My post-doctoral and junior faculty mentees have regularly transitioned to prestigious appointments. I have and can provide the necessary resources to support XXX's training goals."

Budget:

- Budget for as much money as you can. That is, cover as much of your salary as possible on the K (since you're not allowed to get other salary-covering grants during the first years of the award period).
- Plan to spend the full available \$50,000 per year. If nothing else, that amount nearly covers salary for 2 RA's.
- The part of the budget section where you describe the team members is *not* a formality. Rather, it's the first thing reviewers read! Also, because there is no specific section in the grant in which you'll brag about how cool your consultants are (e.g., what they've accomplished that's not directly about you), this is the section to do it in. It's good to boast here about how you and your consultants 1) are experts, 2) have worked together productively in the past, and 3) are capable of pulling this off. Make sure each consultant has a specific role, and that their contributions can be differentiated from the others. If your project is affiliated with an existing center, infrastructure, or team (e.g., the late-life center) mention this in the budget section.

Abstract

- Plan to spend time on the abstract. It's often neglected by K-award applicants or inconsistent with what they actually propose. Yet, it's the first thing reviewers read, and frames their impression of the rest of the application.

Career Development Plan:

- Spend equal time on the career development and research plan. They're weighted equally in the review. Sometimes the career development plan is weighted higher.
- The K is supposed to be a *transition* grant. Make sure it sounds like you need a training grant to do the proposed work.
 - If you already have access to funding for work very similar to what you're proposing, chances are reviewers will figure this out. They read biosketches carefully. Plan to address it.
- The biography section should reflect how your past work and professional development have led to the work you propose in the K. Funded grants I've read sound like the applicant's whole life has led up to doing the work they propose in their K.
- Be specific about how often you'll meet with your consultants, exactly what courses you'll take, and how all of this time supports your goal.
- There are guidelines in the SF424 packet for necessary Career Development sub-sections. Use them.
- Except in rare cases, have a statistician as a consultant or acknowledge a statistical support group in your budget justification.
- For applicants doing proposing to learn neuroimaging... Reviewers like to see a few specific items. 1) Have a physicist on board as a consultant, ideally one associated with the center where you're scanning. 2) Have an MR-statistician on board. 3) Propose to take a course or workshop in neuroimaging – to either obtain or hone your skills as a scanning maven.
- For applicants doing clinical trials.... Reviewers like to see a clinical trialist on your consultant-mentoring team – someone who's done many more and larger trials than you.
- For applicants planning to work with clinical populations who do not have clinical training.... This is likely to come up on review. It's truthfully a hard road in review and your chances may be diminished. Plan to speak about how you'll deal with this with program – they've seen it before. Also, plan to address it carefully in a few ways. 1) spell out whether you want to be a clinical researcher (i.e., the person working with patients) or a clinical collaborator (always have a clinical researcher on your team). If it's the former,

plan to say why you don't need formal (degreed) clinical training for what you want to do. Reviewers are biased to think poorly of clinical evaluations being done by people with no degreed clinical training, so if you need clinical evaluations, having a clinical collaborator is very useful.

- Some of my post-K-receipt observations... Whole courses are hard to find time for once you've got your research in full swing. Consider proposing workshops and time limited training instead. Also, too many regular meetings with consultants can become burdensome, particularly if you don't have much to talk about. A few well-placed visits can go a long way.

Research Plan:

- Keep it extremely feasible. More feasible than you think you have to. K's are often hit for being "too ambitious."
- Have no more than 3 specific aims. Reviewers want to see a simple story.
- Have pilot data. Making links between your previous work and the work you propose in the K establishes a flow of continuity through your career development and allows you to use your previous research as pilot data. (You can probably spin just about any work you've ever done to sound like pilot data for the award.) More is better.
- Near as I can tell, the award is about you getting the training that will help your career to go in an interesting direction. The project is a chance to use that training. As such, it's probably useful to make sure that you're incorporating your training into your research plan, e.g., if you propose to learn a statistical technique, include that technique in your proposed analyses.
- Title and Abstract
 - Needs to communicate clearly what you propose to do.
 - It may determine which study section it will go to (so gear it to go where you want – use relevant buzz words)
 - It may determine who is asked to review your proposal (so tailor it to your committee)
 - Reviewers will rely heavily on the abstract when providing a summary in front of the committee (so give them good things to say)
- Specific aims.
 - Have no more than 3 specific aims. Reviewers want to see a simple story.
 - Keep it extremely feasible. More feasible than you think you have to. K's are often hit for being "too ambitious."
 - Your specific aims should fit on 1 page. Do this with enough white space that it's easy for reviewers to read.
 - A good format is an introductory paragraph that lays out the rationale, a short clarifying paragraph, and then your aims, indented with hanging margins to be clearly readable, followed by a summary sentence saying why the work will change lives.
 - Clearly state your hypotheses or questions. Make sure they are testable and that you can test each of them within the confines of your grant.
 - It's a good idea to boldface the aims and if you have space, to use wider (e.g., hanging) margins for this section so that people can write comments.
 - Ideally, you'll want pilot data for each of your specific aims. If you have questions you want to test for which you have no pilot data and which may be difficult to get, these should be described as secondary aims.
 - Re: direction... For NIMH currently, it's useful to make sure you address a highly prevalent mental health problem that is clearly important, and to note that you've

done so. It's also useful to clearly show how you are likely to have high impact on this problem.

- The specific aims should not be dependent on each other; if hypotheses for Specific Aim 1 are not confirmed, it should still be useful to examine Specific Aim 2. That is, don't make your aims a "house of cards"
- Significance (this is where you'd put the background necessary for understanding the application)
 - Clear clinical implications and how the world will get from your application to the clinic
 - Review of relevant literature
 - Straightforward theory you are testing with direct tests of the theory
 - The goal of included background is to make a strong case in the reader's mind for why your topic is important and why your question is interesting. You don't have to really motivate your specific hypotheses until the preliminary data.
 - Give road signs to help the reviewer help follow your argument.
 - If possible follow the organization of the specific aims.
 - Review just enough relevant literature to get the readers on board with what you're doing and to let them know you know the field. Reviewers will not be experts in your area; this section should give such individuals *just* what they need to know.
 - Consider citing literature by members of the study section likely to review your grant.
 - Reviewers appreciate citations in text to authors names (not reference #'s)
 - Be accurate in your citations – you can lose points if you don't.
 - Make sure to include recent studies in your review.
 - At the end, summarize what is known and where gaps in the knowledge base are.
 - It's useful to say what important information will be gleaned both if your hypotheses are confirmed and if they are *not* confirmed.
- Preliminary data.
 - Have preliminary data that demonstrates the feasibility of your method and show that your hypotheses are promising.
 - Show figures of the data you've collected. The figures should be easily readable, correctly labeled/annotated, referenced in the text, and described in a figure heading. Be sure that descriptions of the figures match what's in them.
 - Making links between your previous work and the work you propose in the K establishes a flow of continuity through your career and allows you to use your previous research as pilot data.
 - It's often useful to organize your preliminary data in terms of your specific aims.
 - At the end of the preliminary data, the reader should have an idea of exactly what your questions are, what your hypotheses are, and what your design is likely to be. There should be no surprises in the design.
 - Highlight how the data was collected or analyzed in conjunction with your consultants so as to build up the impression that you have a good research team.
- Research Design
 - The design should follow clearly from your background and preliminary data. It should be clear how each of the specific aims are addressed by the design.
 - Feel free to have a relatively small manageable design. It doesn't have to be huge (often smaller is better).
 - Recap the overview (reviewers may not read in 1 sitting).
 - Put in a time-line. A chart is useful in justifying a 5-year study.
 - Be specific about the # of subjects to be included, inclusion and exclusion criteria. (Note: Avoid inconsistencies!)

- Carefully describe your methods.
- Predictions with graphs are favorably reviewed. If you can't do this, the design may be too complicated.
- If you're doing a clinical trial (careful, these are often seen as ambitious in a K-award), make sure to include "usual" clinical trials features that are looked for upon review.
 - Describe the planned dose of the treatment and how you arrived at it.
 - Plan to analyze
 - received dose of the treatment (for pharm, ideally levels of whatever the active ingredient are; blood levels for pharma, skill level for cog training, expertise at technique for therapy),
 - adherence to treatment protocol,
 - attrition and not-missing-at-random data,
 - side effects profiles,
 - effects of initial severity on outcome (i.e., measuring change without accounting for initial severity).
 - Talk about how you will deal with missing data (e.g., multiple imputation). In particular, if end-points are missing, talk about your plans for whether or not you will use estimated values. Note that "last-observation-carried-forward (LOCF)" has fallen out of favor, particularly for mechanistic trials.
 - If you are analyzing who got better, make sure to define response, remission, or whatever criterion you are using for "got better", and to justify that decision.
- Checklist for specific important features reviewers will look for:
 - conceptual/theoretical rationale for your predictions.
 - proposed analyses that specifically address your aims and hypotheses.
 - Something about type I error control if there is more than one possible dependent variable
 - Power analyses for each of your aims. Note that power should be for the specific tests that you propose. So if you propose to use mixed effects models, you should not report power for t-tests. You should justify where you are getting effect sizes used in estimation.
 - Limitations
 - Design alternatives/roads-not-taken section - often very well received and heads off negative comments before they're made. Showing awareness of your limitations is a good thing. Just don't argue too persuasively against yourself...
 - Timeline – what will you do in what years.
- Conclusion
 - Briefly summarize what you're proposing
 - End on an optimistic note. It's the last thing reviewers will see of your grant.
- Appendices
 - The appendix is NOT part of the electronic materials sent to reviewers.
 - Do not put your glossary of terms in the appendix.
 - Include articles that will help reviewers to understand the details of the project.
 - Don't expect all reviewers to read the appendices. They may not even be required to look at them.
 - If you're developing a treatment, I've heard that it's useful to submit the actual treatment manual (25-150 pgs) as an appendix. This is not a substitute for describing the intervention in the grant.

Style

- Your proposal will be read by 3 people, some of whom may be only *relatively* familiar with your topic.

- They are your advocates before the committee.
 - Make them like you.
 - Help them understand what you propose.
 - Don't annoy them with inconsistencies, typos, errors, arrogance, narrow margins and a small font.
- Pick a topic that you can "pitch" in 30 seconds or less. The primary reviewer of your proposal has only a few minutes to make that same pitch to the committee.
- If you use abbreviations, have a glossary. I recommend using as few abbreviations as possible. None is preferable, even if you use terms a bunch. You have just a few abbreviations to keep track of – reviewers are reading many applications in one night, all with their own terminology.
- In the reference section, include *all* authors of referenced papers.
- Remember: Font, line spacing, wide margins, figures, charts, tables, avoid inconsistencies. Arial 11pt is the standard.
- Make it easy to read, enjoyable to read, pleasing to the eye, and be sure it makes sense. All this figures into the review, because if reviewers are frustrated or bothered by the format they may find reasons to criticize the grant. If they enjoyed reading it, they may be more likely to fund it.

Responding to Pink Sheets

- You have 1 page to reply to the critique. *Use every bit of it.*
- Do not continue your response in an appendix. *That is very annoying, and it may not get read.*
- Do refer the readers to exactly where your changes are (page numbers or sections). Repeat reviewers may simply look to see that you've made their requested changes. That said, do not simply refer the reviewer to a page in the text to find the changes you have made. *Explain the gist of how you responded.*
- Respond to EVERY item in the review if possible.
- Following every revision request blindly though is not recommended either. It is the reviewer's job to suggest what's wrong. It's not their job to suggest how to fix it; what seems like a fix to one reviewer may be making the application less interesting to another reviewer. Even if they suggest how to fix it, look for the deeper critical comment and consider what fix would improve the application. So, for example, if it is suggested that a measure is unjustified, removing the measure may technically address this criticism, but a different reviewer who liked the measure, just not the rationale for it, may be disappointed. Adding better justification for the measure could have been a more palatable option.
- If you disagree, explain why. *"We disagree" doesn't work.*
- If the reviewer asks for more detail, do not just refer to a paper, especially if it is not appended.
- Revise the body of the proposal to be consistent with the changes you said you would make in the reply to the review. Demarcate important changes in the text. I like using a gray or red line outside the text via Word's Track Changes mode. Note that marking changes in color is fine – people rarely print applications for review anymore. *If possible avoid saying the changes are too extensive to denote.*
- If you made mistakes in the first submission, apologize.
- It is rarely useful to make changes on a revision that were not specifically identified as problems in the first submission, unless they were true design weaknesses.
- Get feedback from your project officer who heard the committee's discussion of your proposal.

Other:

- Have a good relationship with a staff person who can take care of putting stuff on forms for you. You shouldn't have to spend your time putting stuff on forms.

Good luck!

-- Greg

Sources

Much material for the "Other Hints" borrowed, with permission, from Judy Ford's excellent workshop:

Ford, J. (2004). *Moving from Excellent (2.0) to Outstanding (1.0)*. Meeting of the Society for Psychophysiological Research, Sante Fe.

Spirit of some comments taken from:

Bartels, S. & Smith, G. (2004). *Developing winning R01 services/interventions/neuroscience research proposals*. Geriatric Psychiatry Boot Camp.

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