

Hematology Grants Workshop

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Uppermost among the many concerns of young researchers is acquiring funding for beginning a career as a clinician-scientist. This chapter is targeted specifically at those individuals considering an academic physician-scientist career and those on the verge of becoming independent researchers.

In Section I, Drs. Poncz and lannone discuss the Mentored Career Development Award (K08). They summarize the application process, high-

I. THE NIH RESEARCH CAREER AWARDS (KO8 and K23): MECHANISM FOR MENTORED CAREER DEVELOPMENT

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Both the KO8 and K23 Mentored Career Development Award (MCDA) grant mechanisms are excellent means for beginning an academic career as a clinician scientist. The K08 is intended for individuals whose research is primarily laboratory based, while the K23 is for physicians whose focus is patient-oriented research. MCDA grants are strongly supported by the NIH-NHLBI as a mechanism for assisting junior faculty in achieving independence as clinician scientists through formal didactics and mentorship from senior scientists. An MCDA grant provides the recipient an opportunity to have an extended period (up to 5 years) of protected research time and is an excellent indication that the recipient has demonstrated a strong commitment to academic medicine, has begun research in a focused area of interest, and has feasible career development and research plans. In this session, the details of how to successfully apply for an MCDA will be discussed. Unlighting the critical components of a successful application and what the review process entails.

In Section II, Dr. Werner discusses what applicants need to know about the NIH Institutes' program, review, and grants management function; the different NIH staff whom applicants should contact during the various stages of the grants process; and the important sections and key phrases in NIH Program Announcements for career development awards.

like an RO1 application, an MCDA is a mentored grant application. Not only is the proposed science evaluated, but even more importantly, the following elements are evaluated: the candidate, the mentor, the career development plan, the potential of the proposed research to train the applicant for an independent career, and institutional support for the candidate.

Candidate

In the application, the candidate must demonstrate her or his potential to develop into an independent researcher and a commitment to do so. The candidate must also provide a description of how an MCDA will enable her or him to accomplish the proposed career development objectives and to achieve their short-term and long-term goals. Thus, letters that support the applicant's clinical accomplishments as well as her/his research skills are important. Previous productivity of the applicant's pre-fellowship and during her/his fellowship years is important, as would be evidenced by having one or more first-authored research publications. If there are no publications, a strong body of preliminary data generated by the candidate may be acceptable. Abstracts, clinical reviews and second-authored research papers carry less weight.

The applicant can be too early in her or his academic career and may be more appropriate for support either by an individual NRSA or on a T32 grant. Additionally, the applicant may also be too qualified. Having a long track record of publication may suggest that the applicant would not benefit from additional

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mentoring or formal didactics by the MCDA mechanism. Most successful candidates are either finishing their fellowship years, are instructors or are early in their assistant professor positions. The applicant should check with the NHLBI to see what grant mechanism would be most appropriate for her or him.

The applicant needs to document a commitment to medical research. Previous efforts at the college level, and efforts during medical school are among the ways one can demonstrate one's commitment. Often, personal stories of an unusual nature may help the candidate convince the reviewer of her or his outstanding potential. Previous research exposure, especially previous obtainment of an MD/PhD dual degree or a masters degree in a health-related field, certainly shows a commitment to a research career by the applicant. These applicants may be able to get by with a smaller body of preliminary data and can often successfully apply for an MCDA earlier in their fellowship years.

However, the MD/PhD candidate often is held to a higher standard. She/he should have publications from the thesis years, and should propose research that leads to additional growth in direction or research skills that go beyond those gained during the thesis effort. Sometimes less than five years of support may be justified for these applicants as they need less mentoring and have a track record of publications that should allow earlier success at obtaining an RO1. Additionally, a strong letter of support from the thesis advisor normally accompanies such applications

Career Development Plan

The applicant should also detail what they wish to accomplish during their mentored research experience. Ideally, the career development plan would describe how the applicant, in the course of conducting mentored research, would gain the knowledge and skills necessary to become an independent clinician-scientist. This may involve formal training through additional class work. If these classes provide new knowledge/skills and are directly applicable to the applicant's career goals, this formal training would be a positive component of the application. However, inappropriate class work or too much class work can be harmful to the application. Note that every applicant must receive training in the responsible conduct of research and this should be clearly stated in the application. The career development plan should include a description of the structure (including the frequency and nature) of the mentoring experience. This component of the MCDA application is often a critical component of a well-designed MCDA and is described in greater detail below.

Mentor and Mentoring Plan

The quality of the mentor is almost as important as the applicant. The mentor should engender confidence that she/he would be able to guide the applicant into a successful career as an independent clinician scientist. Thus the mentor must be a productive investigator in the area being pursued by the applicant. The mentor should also have strong research grant support. It is hard to envision how the mentor will help support the applicant if she/he does not have the financial means to allow the applicant to complete her/his project. Lack of research funds may also reflect poor productivity by the mentor and is a serious warning sign to the reviewer.

The mentor should also have a strong training record. Both the number of trainees and what they are presently doing are important. Often this is best presented in tabular form. This required track record often eliminates young investigators as a single mentor. However, if a more experienced co-mentor is included, scientists earlier in their careers can effectively serve as more proximal mentors. Whether the young investigator is more appropriately designated the mentor or comentor depends on what is best for the applicant. The publication record and the grant support of the young mentor may be more closely scrutinized than someone with an established training record. The record of the established co-mentor in terms of publications in the area of the application, grant support, and previous trainees also need to be well documented. The co-mentors willingness to serve as such and the degree of time commitment must be clearly delineated in their letter.

Mentors should convey, in the Mentor's Statement, their enthusiasm and knowledge of the applicant's career development and provide a careful record of how the applicant's career will be nurtured in very specific detail. This involves a careful presentation of the informal and formal education that the applicant will undergo. The frequency of meetings with the applicant informally and formally, and how often the applicant will meet with the advisory committee and what the goals of this committee are need to be presented. Longterm issues of how the proposed research effort will be used to advance the applicant's career should be addressed in detail. Often this involves how the applicant will have an opportunity to develop her/his individual career niche separate from the mentor. It is very important that the mentor's vision and that of the applicant's are concordant. For example, if the applicant details specific course work, this should also be mentioned by the mentor.

An advisory committee is almost always an important component of a mentored research experience. The details of the structure of the committee and the goals of this committee should be clearly stated. Ideally, its members have strong publication records in areas related to the applicant's proposed research and have strong history of mentoring. Inclusion of their NIH CV is useful. Letters indicating their willingness to serve on the advisory committee should be included. These letters should state the willingness of the members to serve on the committee, the frequency of meetings and the goals of these meetings so as to convince the reviewer that the committee will function as stated. Offsite committee members can be problematic. These members should be included in addition to a strong local committee. The details of the advisory committee as described by the applicant and mentor must coincide with statements in the letters from committee members.

Environment and Institutional Commitment

The candidate should describe how the institutional environment would enable the successful attainment of the proposed career development plan and research. There must also be a clear commitment on the part of the candidate's institution to support the proposal by providing the necessary time and resources. The Institutional letter of support is critical in establishing this commitment to the candidate's proposal. This letter should show familiarity with the applicant's past and proposed future, but most importantly, should provide a clear commitment to the candidate as evidenced by providing protected research time and release from duties that will interfere with the proposed research. An institutional letter of support that shows a true commitment to the applicant by providing additional resources given up front (e.g., research support and individual laboratory space) are very well received and enhance the applicant's chances of being considered an outstanding candidate.

Most problematic can be an Institution's commitment in terms of a real academic title. Ideally, the applicant often is about to attain or just obtained an assistant professor level position. Often the commitment is for an instructor position. Certainly an assistant professor position is better received because it is a formal part of the academic structure, and it shows a clear commitment to the applicant. Instructorship or a nontraditional title such as assistant research scientist are fairly nebulous positions and show little commitment by the Institution to the applicant. Further documentation of the level of commitment is required under these circumstances. Statements that the applicant will be promoted to assistant professor upon the receipt of the MCDA may be rational and reasonable from the Institution's perspective, but do not show strong support for the applicant. Strong support would be a letter by the Institution indicating that this promotion would occur independent of receipt of this award.

Research Plan

The proposed research effort is another important component of the application. It is of value that the applicant prepares this section, but even more important is that the mentor has reviewed this section and has helped guide the applicant in its preparation. Too often the mentor declares that the applicant prepared the research section, and this appears quite apparent with the science sections being either too short or too long, not sufficiently mechanistic with testable hypotheses, presenting the preliminary data in a poor fashion or not properly organizing the application by accepted standards. This lack of mentoring at the first step of the MCDA process reflects badly on both the mentor and the applicant.

On the other hand, the application should not be that of the mentor. Certain language clues such as repeatedly referring to published data from the mentor's laboratory group as "we" when the applicant was not yet in the laboratory or showing as preliminary data published data from the mentor's group that didn't involve the applicant reduce enthusiasm for the applicant. The inclusion of preliminary data derived by the applicant is of paramount importance. Occasionally the work of others in the mentor's group is appropriate to quote, but it is best to clearly indicate its origin.

While there are many caveats on how to optimally present one's research plan, most of these issues are beyond the scope of this presentation. However, one common defect is poor presentation of preliminary data and other figures. Here are some important guidelines: Minimize presentation of figures of data done by others. The applicant's figures should be clear. Extra copies of colored figures and gray scale figures should be given to the reviewers, but make sure that the data are so clear that even copies are interpretable. This often means avoiding shrinking figures down to the minimum interpretable size. Always show important controls. The most common mistake is to leave out data necessary to convince reviewers that equal loadings were done in each lane. Label the figures. Figure legends are very useful. Refer to each figure shown. Figures can utilize a lot of the allotted space, but often are worth the price. Space can be made up by avoiding excess space preand post-figure and in the organization of the written part; however, one should realize that larger font size and line spacing makes the grant more readable to the reviewers. Finally, many times a figure depicting the proposed central thesis or model can be worth presenting early in the application.

Planning for the Application Deadline

It is important to set aside 2-3 months of full-time effort for the preparation of the MCDA. A major portion of this time commitment is necessary to have the needed time to coordinate all the various components of the application as well as giving the mentor time to help with revisions. Many applications will have the applicant's view of his mentored experience at variance with what others are saying. For example, if the applicant proposes certain didactic courses, the mentor should also propose these courses. If the mentor says that the advisory committee will meet twice a year, it is problematic if the applicant says three times a year and the members of the committee either fail to mention frequency or say another order of frequency. The applicant needs to have letters of support (and probably CVs) from collaborators acknowledging the specific assistance that the applicant proposes exist.

Revised Applications

Finally, not every worthy applicant gets funded on the first round. One has three chances to be funded. It is important to carefully read the comments from the reviewers and respond to each concern in The Introduction to Revised Applications section. Note that the reviewers that may be assigned to a specific resubmitted grant may not necessarily be the same the second time as the first time. It is possible that new weaknesses may be discerned or that a proposed solution by a previous reviewer is now seen as problematic. The members of the review committee are highly experienced at reviewing such applications and make a strong effort to give special consideration to third-time submissions. However, some applications may not be supportable because of sufficient concerns with the applicant, the mentor, the design of the mentoring experience, the institutional support or the proposed effort. The applicant is urged to read each review, realizing that these reviews may provide important insights into issues related to their chosen path and invaluable insight into career direction. Those funded should also read the reviews carefully as they may provide important insights that may help on their quest towards their next career goal, the achievement of their first RO1 application.

II. NIH MENTORED CAREER DEVELOPMENT AWARDS

Ellen M. Werner, PhD*

One of the more daunting tasks for new researchers who apply for NIH funding is learning how to navigate the NIH with its different organizational units, acronyms, policies, websites and grants announcements. Often, the lag time between submission of a grant and receipt of the notice of grant award requires patience on the part of the applicant, and the applicant's Department Chair and Office of Sponsored Research. The purpose of this paper is to provide readers with an overview of NIH, an understanding of the grant process and its timeline, and the resources that are available to help new investigators plan and submit successful grant applications. URLs are inserted in the text as links to more detailed information.

NIH consists of twenty-seven Institutes and Centers, and the NIH Office of the Director: http://www.nih.gov/icd/.

Most grant-funding authority resides with the Institutes. The NIH Office of Extramural Research is the focal point for policies and guidelines for extramural research grants administration.

http://grants1.nih.gov/grants/welcome.htm#introduction http://grants1.nih.gov/grants/OER.htm

Individual Institutes are the primary organizational units for reviewing, funding and administering Training and Career Development grant applications, such as the Mentored Career Development Awards (MCDAs). At this year's ASH, there are three NIH Institutes, each with slightly different opportunities for MCDAs: the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK), and the National Cancer Institute (NCI). The websites for these Institutes link to specific information about their specific grants programs, including MCDAs. NHLBI:

http://www.nhlbi.nih.gov/funding/index.htm NIDDK: http://www.niddk.nih.gov/fund/fund.htm NCI:

http://www.nci.nih.gov/researchfunding/

Within each Institute or Center (IC), there are (1) intramural research programs; (2) Extramural Divisions and their scientific Programs; (3) a Review Branch; and (4) a Grants Operations/Management Branch. The latter three organizational units have distinct roles and responsibilities, which are important for applicants to

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understand when contacting the NIH during all phases of the application process.

Extramural Divisions and Programs plan, support and evaluate research and training in basic, applied, translational and prevention research, clinical trials, and demonstration and education projects. Review Branches are responsible for convening committees of extramural scientists who review grant applications and assuring integrity of the review process. Grants Operations/ Management Branches oversee budgets, assure adherence to NIH funding policies, and issue funds for grants that will be supported.

NHLBI:

http://www.nhlbi.nih.gov/about/org/index.htm http://www.nhlbi.nih.gov/about/dbdr/index.htm http://www.nhlbi.nih.gov/about/dea/index.htm NIDDK:

http://www.niddk.nih.gov/welcome/org/toc.htm http://www.niddk.nih.gov/fund/divisions/KUH/ KUHintro.htm

- http://www.niddk.nih.gov/fund/divisions/DEA/ DEAintro.htm
- http://www.niddk.nih.gov/fund/divisions/DEA/ review_branch/revhomenew.htm

NCI:

http://www.nci.nih.gov/aboutnci/organization/ http://deainfo.nci.nih.gov/

Steps in Applying for an MCDA

There are three main phases in the application process: application; review; and post-review. The following outline describes the steps and lists the resources to use during each of these phases.

Application Phase

Step 1. Find the appropriate Institute and Mentored Career Development Award mechanism

It is important to review each Institute's mission statement prior to applying for a MCDA to decide which Institute's scientific areas best fit your proposed research. This might not be an obvious decision since there is some overlap in NCI's, NIDDK's and NHLBI's scientific areas, especially in the basic sciences, and since all Institutes are increasingly promoting interdisciplinary and multidisciplinary research.

NHLBI:

http://www.nhlbi.nih.gov/about/org/mission.htm NIDDK:

http://www.niddk.nih.gov/welcome/mission.htm NCI:

http://www.nci.nih.gov/aboutnci/overview/mission

Identifying the most appropriate MCDA (e.g., K01, K08, K23, K18, K25) for your research and career de-

velopment purposes will enable you to determine whether the Institute you have selected funds that award and if you, preliminarily, meet all eligibility requirements. The second URL is the NIH Career Award Wizard and particularly helpful at this stage. http://grants1.nih.gov/training/extramural.htm http://grants1.nih.gov/training/kwizard/index.htm

You will need to verify that you meet all eligibility criteria, including any Institute-specific special requirements. Reading the NIH program announcement for the grant selected by the Career Award Wizard, and then documents that link off the Institute's Training Website will prepare you for Step 2.

NIH Program Announcements for all MCDAs are available at:

http://grants1.nih.gov/training/

careerdevelopmentawards.htm

Institute-specific requirements are available at: NHLBI:

http://www.nhlbi.nih.gov/funding/training/redbook/ trgnprog.htm NIDDK: http://www.niddk.nih.gov/fund/training/ training.htm#Career NCI:

http://cancertraining.nci.nih.gov/

Step 2. Locate the appropriate Institute/Center Program Official

The Program Official is responsible for the programmatic, scientific, and/or technical aspects of a grant, and is also known as a Health Scientist Administrator (HSA). Use the above URLs for the Institute'sTraining Websites to find the HSA's name and contact information. It is essential that you contact the Health Scientist Administrator to determine if your proposed application topic fits into his or her program; to verify that you have selected the appropriate MCDA; to discuss your career development plans, mentor, research topic and training; and to ask whether there are any supplemental guidelines, helpful hints, and model applications. http://www.nhlbi.nih.gov/funding/training/redbook/

newintro.htm

When you have found the appropriate Program and Mentored Career Development Award mechanism, ask the HSA about requesting assignment to his or her program. The Health Scientist Administrator can submit an "Awaiting Receipt of Application" (ARA). (See Center for Scientific Review, below.)

Step 3. Plan your grant application, using available NIH and other resources

Be sure to join the NIH listserv to receive notices and announcements about changes in policies, applications forms, etc., that may affect your application. http://grants1.nih.gov/grants/guide/listserv.htm

There are many sources available to help with grantsmanship, instructions for completing the PHS 398 application kit, and completing required application sections on human subjects and use of vertebrate animals in research. The following list is a good starting point.

Quick Guide:

http://deainfo.nci.nih.gov/extra/extdocs/ gntapp.htm

FAQs:

http://grants.nih.gov/training/q&a.htm http://grants1.nih.gov/grants/funding/giofaq.htm

PHS 398 Application forms and instructions:

- http://grants1.nih.gov/grants/funding/phs398/ phs398.html
- http://grants.nih.gov/grants/funding/phs398/ section_4.html

http://grants1.nih.gov/grants/funding/phs398/ rcarefguidelines.pdf

Human Subjects:

- http://grants.nih.gov/grants/funding/phs398/ section_1.html#e_humansubs
- http://grants.nih.gov/grants/funding/phs398/ section_1.html#exemption_cat
- http://grants.nih.gov/grants/funding/phs398/ enrollment.pdf
- http://ohrp.osophs.dhhs.gov/humansubjects/ guidance/ decisioncharts.htm
- http://ohrp.osophs.dhhs.gov/humansubjects/ guidance/ hsdc93-03.htm
- http://www.niaid.nih.gov/ncn/clinical/ decisiontrees/ default.htm

http://grants1.nih.gov/grants/peer/ hs_review_inst.pdf

Vertebrate Animals:

http://grants.nih.gov/grants/funding/phs398/ section_1.html#f_vertebrate_animals http://grants.nih.gov/grants/olaw/olaw.htm

GrantsNet (AAAS): http://nextwave.sciencemag.org/

GrantsDoctor: http://nextwave.sciencemag.org/cdc/

How to write a grant application: http://www.niaid.nih.gov/ncn/grants/default.htm http://www.niaid.nih.gov/ncn/training/advice/ index.htm http://www.niaid.nih.gov/ncn/training/ default_training.htm http://www.niaid.nih.gov/ncn/grants/basics/ index.htm http://www.niaid.nih.gov/ncn/grants/ default_grants.htm http://www.research.buffalo.edu/spa/

ProposalFormsNIH.htm

http://nextwave.sciencemag.org/cgi/content/full/2002/10/ 23/8

Checklists for everything in the application phase: http://www.niaid.nih.gov/ncn/grants/charts/ checklists.htm

Step 4. Submit your application to the NIH Center for Scientific Review (CSR).

Applicants sometimes ask HSAs to allow submission of a grant after the published receipt date. HSAs cannot waive the receipt date.

Receipt dates:

http://grants.nih.gov/grants/funding/phs398/ section_2.html#c

"If a receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following workday."

When your application is received at the CSR, it will be reviewed by staff who will then assign it to an Institute and Program. If the HSA submitted an ARA requesting assignment of your application, it will likely be assigned to his or her program. A request, however, does not guarantee assignment to a particular Institute or HSA.

Assignment of your application: http://www.csr.nih.gov/events/AssignmentProcess.htm

Step 5. Center for Scientific Review sends notification of application assignment

The CSR sends you a notice to inform you of your application's assignment, and the names of the NIH officials. If your application was not assigned to the Institute/Center you requested, contact the HSA with whom you worked during the application phase. When your application is assigned to the appropriate Institute/Center program, it is in the Review Phase.

Review Phase

Step 6. The Scientific Review Administrator (SRA) is your contact person

During the review phase, any contact with an NIH official should be with the NHLBI/NIDDK/NCI SRA. Reasons for contacting an SRA include a recent publication, new preliminary data, or a transfer to a new institution.

Glossary of terms: http://www.drg.nih.gov/REVIEW/terms.htm

Step 7. Peer Review Meeting is held

Mentored Career Development Awards are reviewed

by the Institutes' Special Emphasis Panels (SEPs). "SEPS are formed on an ad-hoc basis to review applications requiring special expertise... Because of the multi-month period between submission and review of an application, applicants often wish to submit supplementary materials. However, each study section has policies for acceptance of such additional material (e.g. length; time of submission)."

http://www.drg.nih.gov/REVIEW/peerrev.htm

Step 8. Priority Scores and Summary Statements are released

About two weeks after the review, you will receive a mailing with your priority score. Priority scores are "numerical rating that reflects the scientific merit of the proposed research relative to the 'state of the science.'" http://www.drg.nih.gov/REVIEW/terms.htm

Mentored Career Development Awards are not "percentiled" since they are reviewed by an Institute's Special Emphasis Panel and not by a trans-NIH review panel. It is too early for the HSA to inform you if your application will be funded, although you can get an idea of the Institute/Center's past history of funding K awards.

http://grants1.nih.gov/training/outcomes.htm#funded

Approximately eight weeks after the review, you will receive a Summary Statement with a cover letter from the HSA. The summary statement is "a combination of the reviewers' written comments and the Scientific Review Administrator's summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations."

http://www.drg.nih.gov/REVIEW/terms.htm

Post-review Phase

Step 9. Recontact the HSA

It is appropriate to contact the HSA if you: have any questions about your summary statement, see a human subjects or animal use code on your summary statement, or need advice about submitting an amended application.

Step 10. Submit Just-in-Time (JIT) information

JIT information will be requested by and must be sent to the Institute's Grants Operations/Management Branch. Grants Operations/Management Branches are the financial management units at the Institute/Centers. All money-related questions should be referred to them. Reply to Human Subjects and/or Animal Use codes as soon as possible. If these issues are not resolved prior to funding, they will delay award of the grant. Work with the HSA to resolve these issues.

Step 11. The Institute's Advisory Council meets Institutes' Advisory Councils help the Institute Directors make funding decisions for the different grant mechanisms. However, funding decisions for MCDAs is based mostly on each Institute's budget and the availability of monies for K awards. If your application will be funded, the HSA will send you a letter with this information. However, it is not an official notice. That is issued by the Grants Operations/Management Branch in the form of a Notice of Grant Award (NOGA) that is sent via email to your institutional business official.

The NIH Welcome Wagon Letter contains information for new grantee organizations, but is also useful to new grantees:

http://grants1.nih.gov/grants/funding/

welcomewagon.htm

Remember that the turnaround time from submission of an application to award is anywhere from nine to twelve months.

http://grants1.nih.gov/grants/funding/ submissionschedule.htm

Step 12. Consider submitting an amended application If your application is not funded, you will have to decide about submitting an amended application. It is in your best interest to do this, but work with the HSA to be sure that you effectively address all the issues that were identified by the review panel. Ask the HSA if your application's funding might be deferred until later in the fiscal year (Note: NHLBI's receipt dates for revised applications are the same as for new applications.) Follow instructions for amended applications in the PHS 398. Note and address the issues identified in the Summary Statement, especially the section entitled "Resume and Summary of Discussion."

NIH Glossary of Terms http://grants.nih.gov/grants/glossary.htm http://www.csr.nih.gov/review/terms.htm NIH Acronym List http://grants.nih.gov/grants/acronym_list.htm NIH useful links http://grants.nih.gov/grants/useful_links.htm Tips: http://www.nigms.nih.gov/funding/tips.html

Finally, do not be discouraged if you need to submit one or two amended applications. Most initial MCDA applications will not be funded but success rates for first and second amended applications are excellent.