

## NCI Discussion Luncheon

Notes from presentations by Lester Gorelic and Dorkina Myrick by Misha Rand and Channing Der

### T32 Pre/Postdoctoral Training Grants in cancer biology

- Require a cancer focus and the goal is to turn out cancer researchers - to “provide the broadest exposure to all aspects of cancer”.
- Predoctoral: postdoctoral trainee ratio: all new T32 submissions must have a predoctoral: postdoctoral training ratio of 25:75 ratio. This focus on postdoctoral training is based on the expectation (although statistically rigorous analysis has not been done) that since postdoctoral fellows have already committed to a career in cancer biology, there is a greater likelihood that they will stay in cancer biology research than predoctoral fellows who are just starting their research training. This policy was formulated by the NCI Cancer Training Branch, but was implemented only after approval by an external advisory group of established cancer researchers. Existing T32 programs will not be required to meet this ratio. However, the NCI does encourage PI’s of ongoing predoc/postdoc T32’s with ratios less than this optimal to begin to shift their programs to this ratio. However, the failure of a competing renewal application to meet this ratio will generally not prevent the application from being accepted for review. In 2006, 170 T32s supported 1200 trainees, with a predoctoral: postdoctoral fellow ratio of 35:65.
- 85% of T32’s focus on cancer biology, with the remaining 15% of T32 grants supporting research training in areas such as epidemiology, pharmacology, imaging, and cancer prevention. A significant number of T32 grants are focused on the training of individuals in specific oncology disciplines. However, this is research training, primarily in basic science cancer research, and was not clinical training which cannot be supported by a T32 grant. Additionally, T32’s do support clinical research according to the NIH definition of clinical research; but not clinical training.
- Preceptor composition: 50% of faculty with independent support for cancer research (which does not need to be NCI-funded grants); the remaining 50% should have independent research support “reasonably relevant to cancer”. NCI is fairly liberal in applying the “relevant” criteria.
- Faculty preceptors – need to have a strong research and mentoring track record; it is not a good idea to have K-awarded faculty. Less established investigators could be included as faculty on a T32 grant but generally not as primary mentors. However, this should be done sparingly and only if the junior faculty are teamed up with a more established investigator who would initially serve as the primary mentor until the junior person is able to establish a successful research/mentoring track record. Diversity in preceptors is NOT an important factor. The key is a successful track record in mentoring and research. The number of faculty included in a T32 program needs to be appropriate for the program objectives and should provide prospective trainees with an adequate pool of potential faculty from which they will select their mentors. Generally, there should be at least a 3:1 ratio of potential mentors to trainees.
- If there is a turnover in faculty during the last funding period, this needs to be explained in the renewal application. The problem with excessive faculty turnover is that reviewers become concerned about the long term continuity and viability of the program.
- Program director strengths – this person should be well-recognized in research, and have strong experience in administration.
- Executive committee – one that is really functioning is very important and must be well-defined. The responsibilities of the executive committee, as they relate to the management and ongoing evaluation of the T32 program, and how the committee interacts with the PI, need to be clearly defined.
- The criteria for selection of trainees need to be well-defined, especially for predocs.
- External review committee – not a requirement, but the strong programs typically have them.
- Make sure the application is complete - incomplete application suggests that the PD is too busy, and will therefore not be able to provide adequate oversight of the program

- The success rates for new competing applications are generally lower than for competing renewal applications. The success rate in fiscal year 2006 for new T32 submissions (14%) was approximately one-half of that for competing renewal applications (27%).
- What is considered success in the outcome of past trainees – not strictly based on becoming an independent academic researcher – as long as the former trainee is still doing biomedical research, this is considered success. Reviewers now are more lenient on this issue (it use be, that if a fellow goes into big pharma, that this was considered bad). So, based on this, a person who becomes an editor at Cancer Cell, or does technology transfer, works at the FDA, monitors clinical trials, is NOT considered successful outcomes of training.
- Plans for recruitment of individuals underrepresented in biomedical research into T32 grants - In the past, underrepresented referred to ethnic and racial groups. By the end of the 2007 calendar year, the requirements for plans and reporting on progress in this area will be expanded to include individuals who are socioeconomically disadvantaged or disabled; and information on progress made towards recruiting individuals from these additional groups into T32 programs will be required for all competing renewal T32 programs. Finally, the plan will be named the “Recruitment and Retention Plan to Enhance Diversity”.
- If you have a potential minority candidate for your T32 grant, but do not have an available “slot”, you can apply for an administrative supplement (currently called a CURE supplement) to the T32 grant to add the candidate to the grant as a trainee. The NCI contact for this type of “CURE” supplement is Dr. Nelson Aguila ([aguilah@mail.nih.gov](mailto:aguilah@mail.nih.gov)).

## **K awards**

- With the exception of the NIH K08, all of the K’s in our grant portfolio can be used to support individuals with Ph.D.’s. However, for the NIH K23 and K24, the Ph.D. degree must be a clinical Ph.D.; for the K07 and K05, the Ph.D. can be in a number of scientific disciplines as long as the proposed career development plan focuses on cancer, prevention, control, behavioral and the population sciences; and the K25 focuses specifically on quantitative scientists including engineers who generally do not have clinical doctorates.
- Finally, even the NCI use of the K12 (which historically had supported only clinical oncologists) has an optional track for Ph.D.’s pursuing a career in patient-oriented research. The K99/R00 is the only NCI-supported K-award primarily for Ph.D. scientists pursuing a career in basic science human cancer research.

## **K99/R00 Pathway to Independence Award**

- Basically the replacement for the previous NCI Howard Temin award, which was specifically for more advanced and truly outstanding postdocs who were at the “cusp” of independence. The new K99 award replaces the NCI Howard Temin (K01) Award. The Howard Temin Award was the only NCI K-award that focused specifically on basic science cancer research and that supported extramural basic science Ph.D. researchers. The Howard Temin Award was originally very highly competitive/selective and was intended to support the best of the basic science postdoctoral researchers. Subsequently, the level of selectivity of awardees was relaxed to permit more Ph.D. basic science cancer researchers to have access to an NCI-supported Career Award. The NCI is committed to supporting a minimum of 20 K99/R00 awards annually, which is the approximate number of Temin Awards issued in fiscal year 2006. The first round of 20 K99/R00 awards was made in fiscal year 2007
- Provides two years of support for additional mentoring followed by 3 years of support as an independent investigator, thereby facilitating a “seamless” transition from the mentored stage of career development to the independent phase.
- The NCI restricts the scope of the research supported by a K99/R00 to basic science research in human cancer systems. However, a researcher can propose during the initial stages of the K99/R00 studies in non-human cancer systems, e.g. mouse models, but must translate the findings of these

studies to a human cancer system sometime during the award period. The more recent iterations of the NCI Howard Temin Award had a similar eligibility requirement.

- One of the unique features of the K99/R00 that distinguishes this K from other K's is the absence of a requirement for applicants to be US citizens or to be able document permanent residence status. However, such individuals must be able to document that their visas will permit them to remain in the US until the completion of the 5 years of K99/R00 support.

### **K22 Career Transition Award**

- Provides protected time to postdocs as they transition into their first independent position or junior faculty within the first 2 years of their first independent position to develop their first independent cancer research program.
- The K22 was developed to protect the evolving research careers of physician scientists, patient-oriented researchers, and prevention and control scientists as they transition from their postdoc (mentored) positions to their first independent research positions; and also to provide for M.D.'s who at most might have a first 5 year dedicated research experience through a prior mentored K-award, an opportunity to gain as much research experience as the Ph.D.'s in order to make them as competitive with Ph.D.'s for R-grant funding. With a view to providing intramural (within government) basic science Ph.D.'s the same access as their extramural counterparts to an award similar to the Howard Temin Award, eligibility for the K22 was subsequently expanded to include intramural basic science Ph.D.'s.
- 3 years of research and salary support
- The NCI K22 also supports individuals who have been in their first independent research position for no more than 2 years.
- Most cancer biology focused. As of 2006 there were 24 active K22s with: 67% supporting cancer biology research.

### **K25 Mentored Quantitative Research Development Award**

- Intended to provide for quantitative scientists to apply skills to basic science. This award provides up to 5 years of salary and research support to quantitative scientists (Ph.D.'s, engineers with a research qualifying degree) for career development in the first time application of their quantitative skills to biomedical research (in cancer for the NCI). Eligible applicants can range in experience from new Ph.D.'s to senior investigators. However, applicants must not have prior training in the biological sciences or significant prior experience in applying their quantitative skills to biomedical research.

### **F32 Individual Research Awards (postdocs)**

- Total support of 3 years, minus T32 time; restricted to US citizens or permanent residents.
- Successful funding is based on the quality of mentor, the lab environment, the research training plan, and strong recommendation letters.
- Documentation of training potential is also important. Regardless of the quality of the science, sponsors, etc., if the award will not provide additional training that the applicant does not already have, the application will fare poorly in review.
- The science is important, but primarily as a vehicle for providing the additional needed research training.
- Letters should rank 1's; reference letters too honest sometimes; do that with person, not with application
- 2006 22% 317 app, 71 funded

### **K08 Mentored Clinical Scientist Research Career Development Award**

- Open to individuals with any type of “professional” doctorate degree, including D.D.S., D.V.M.’s, Pharm.D’s, etc.
- Laboratory-based cancer research focused, applicant with only limited research experience. Can be used to support individuals with a wide range of prior research experience. However, the level of experience must be such that the candidate can still demonstrate the need for a focused 5 years of mentored research career development...
- The K08 (and the K23) can be used to support career development in translational research. For the K08 this could be achieved by devoting the first 3-4 years of the award to lab-based preclinical studies; and in the last 1-2 years translate the results of these studies into clinical trials. Additionally, since the focus of the K23 is patient-oriented research, a grantee could devote the first 1-2 years to the preclinical studies and then in the latter years of the award move these studies into clinical trials.
- Quality of mentor, career development plan; strength of institutional commitment.
- 75Ksalary support/30K research support
- 75% effort required. 5 year award leading to independent investigator status (and R-grant funding)
- 2006 81 applications, 22 funded.

#### **K12 Paul Calabresi Award for Clinical Oncology**

- The intent of the NCI K12 is to develop a cadre of patient-oriented researchers to work with basic research cancer researchers to design all phases of hypothesis-based clinical trials. The original focus of the NCI K12 was on the career development of clinical oncologists. More recently, the NCI has expanded the scope of the K12, retaining the original emphasis on clinical oncologists but introducing a “second track” for PhD basic scientists who are clearly dedicated to a research career focused on working with clinicians to design hypothesis-based clinical trials. Clinician candidates for appointment to a K12 should be in the latter stages of their fellowship training or junior faculty, and need additional mentored career development in basic science cancer research and patient-oriented (clinical trials) research. If the candidates need additional career development in only one of these aspects of cancer research, then they should apply for an individual mentored K-award (K08 or K23).
- The objectives of the K12 are achieved through multiple mentorship (at least one basic science researcher and at least one patient-oriented researcher for each candidate), required basic science patient-oriented research and didactic components; and an experience translating laboratory-based research findings into clinical trials,
- Success rates for the K12’s vary from year to year. In fiscal year 2006, 4 out of 11 (36%) applications were awarded. However, due to the special infrastructure requirements for a K12- e.g., large base of clinical trials types, specifically the hypothesis based Phase I trials- the number of institutions that could successfully support this type of program are likely to be limited).

**R25T:** cancer education and career development program – epidemiology, etc., need to justify why can’t be done with a T32