

GUIDELINES FOR REVIEWERS' WRITTEN COMMENTS CAREER ENHANCEMENT AWARD FOR STEM CELL RESEARCH (K18)

The purpose of this funding opportunity is to encourage investigators to obtain the training they need to appropriately use stem cells in their research. The use of stem cells in biomedical research offers the potential for significant advances in the next decades, provided investigators not only understand this potential, but are equipped to take advantage of the possibilities. Human embryonic stem cells (hESC) have only recently become available and most investigators are not prepared to handle, maintain, or properly study hESCs. Likewise, the potential of human adult or cord blood, and even animal, stem cells for understanding, treating, and curing human disease is great. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed training will have a substantial impact on the pursuit of these goals.

The K18 award is intended to provide 6 months to 1 year of research support although 2 years will be considered. Refer to the NIH program announcement on the enclosed CD for more details. The format outlined below should be followed in preparing your comments for each K18 application assigned to you to review. As you prepare your critique, please include sections addressing each of the review criteria (detailed below), including the applicant, the qualifications of the stem cell expert, the research training plan, the research plan, the environment and institutional commitment, the quality of the training in the responsible conduct of research, and the budget. In addition, please note any issues pertaining to human subjects, animal welfare, and biohazards. Include additional headings when they seem appropriate to the review. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria.

The Primary (1) and Secondary (1) reviewers should each address all of the review criteria outlined below. The Secondary (2) or Discussant reviewer will prepare a brief written critique. A short paragraph highlighting the strengths and weaknesses of the application or bulleted lists of strengths and weaknesses are both examples of acceptable critiques written by the Secondary (2) or Discussant reviewer. If you prefer to prepare a full critique equivalent to a Primary (1) or Secondary (1) reviewer, you also have that option. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to receive a high priority score. These criteria are listed in logical order and not in order of priority.

Overall Evaluation

In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of enhancing the candidate's research career and how these factors determine your overall merit rating of the application.

Applicant

- Evidence of excellence in academic, research, and, if appropriate, clinical activities
- Potential to become, or continue as, an outstanding investigator, teacher, resource person, and leader in research programs related to the mission of the appropriate NIH Institute or Center.
- Quality and breadth of prior scientific training and experience.
- Degree and extent of previous research support and publications, considering the applicants academic level.

Stem Cell Expert (Sponsor)

- The stem cell expert's qualifications as well as prior experience and record of fostering academic growth and productivity.
- The expert's history of research productivity and peer-reviewed research support.
- Adequacy of active support for the proposed research project, if applicable.

Research Training Plan

- Quality and feasibility of the applicants training plan, including plans after completion of the award.
- Relationship of the research training plan to the applicants previous research focus as well as the applicants future research plans.
- An assessment of the value of the proposed training experience as it relates to enhancing the applicants capabilities as an independent investigator.

Research Plan

- Scientific and technical merit of the research question, design, and methodology.
- Relevance of the proposed research project to the applicants own research interests.
- Appropriateness of the research plan to the applicants career level and as a vehicle for developing the research skills described in the career development plan.

Environment And Institutional Commitment

- Adequacy of the research facilities and training opportunities for support of this award at the host institution, which may be the applicant institution, or at another institution.
- Clear evidence from the applicant's institution that the applicant will be given sufficient release time (Program Announcement page 2 at least 50%) to complete the proposed training and research project .
- Level of commitment from the applicant's institution in supporting the applicant's future plans to use stem cells in her/his research.

Training In The Responsible Conduct Of Research

Quality of the proposed training in the responsible conduct of research that has been, or will be, completed.

Protection of Human Subjects from Research Risks

Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications" which is included on the CD.

Data Safety Monitoring Plan

If a data and safety monitoring plan is required, indicate if it is adequate.

Inclusion of Women, Children, and Minorities Plans

Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. Determine whether children (**individuals under 21 years of age**) have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned.

Vertebrate Animal Welfare

If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury. The five items described under Section F of the PHS Form 398 research grant application instructions should have been addressed by the candidate. This includes (a) a detailed description of the use of animals in the proposed research including the identification of the species, strains, ages, sex, and numbers of animals required; (b) the rationale for using animals and the appropriateness of the species and numbers of animals to be used for the proposed research; (c) a complete description of the veterinary care of the animals being used; (d) an assurance that discomfort, distress, pain, and injury to animals will be limited to that which is unavoidable in the conduct of scientifically sound research and that analgesic, anesthetic, and tranquilizing drugs will be employed where appropriate to minimize discomfort, distress, pain, and injury; and (e) a description of any euthanasia method to be applied. Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards

Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.

Budget

Comment on the appropriateness and justification of the budget request within the context of the goal of the award. The candidate's salary must be based on a full-time, 12-month appointment and may not exceed the allowable NIH maximum salary per year. Up to \$50,000 per year is allowed for tuition, fees, and books related to career development; consultant fees to the sponsor, research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time. Justify any proposed changes.

Model Organism Sharing Plan

All NIH applications that plan to produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Please comment on the adequacy of the sharing plan, taking into consideration the organism, the timeline, and the applicant's decision to distribute the resource or deposit it in a repository. Your assessment of the sharing plan will not be factored into the priority score of the application. Your comments will be captured in an administrative note.