ACADEMIC RESEARCH ENHANCEMENT AWARD (AREA, R15) GUIDE FOR ASSIGNED REVIEWERS' PRELIMINARY COMMENTS

Note: Additional information about the AREA program can be found in Program Announcement PA-06-042, published in the NIH Guide to Grants and Contracts on October 26, 2005 and on the Office of Extramural Research Home Page.

http://grants.nih.gov/grants/guide/pa-files/PA-06-042.html

The purpose of the Academic Research Enhancement Award (AREA) program is to stimulate research in educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation's research scientists, but that have not been major recipients of NIH support. These AREA grants create opportunities for scientists and institutions otherwise unlikely to participate extensively in NIH programs, to contribute to the Nation's biomedical and behavioral research effort. AREA grants are intended to support small-scale health-related research projects proposed by faculty members of eligible, domestic institutions.

The objectives for the AREA Grant program are to:

- benefit investigators through the opportunity to conduct independent research;
- benefit the grantee institution by strengthening the research environment through AREA grants; and
- benefit available students through exposure to and participation in research in the biomedical and behavioral sciences.

Reviewers should keep in mind a number of Supplemental Instructions for this program.

- AREA applications must be submitted with budget of one to six modules of $25,000 for up to 36 months.
- Additional biographical information is requested regarding the experience of the Principal Investigator in supervising students in research.
- Specific information about the applicant institution relative to the goals of the AREA program is to be provided along with the usual information on the "Resources" page.

FORMAT FOR WRITTEN REVIEWS

Please use the following guidelines in preparing written comments on AREA applications assigned to you for review. **NOTE: Your written review should not bear personal identifiers since unaltered comments will be sent to the principal investigator**.

CRITIQUE: Include as little descriptive information in this section as possible. Please address, in five individual sections, each criterion listed below. In addition: for competing continuation (renewal) applications, include an evaluation of progress over the past project period; for amended applications, address progress, changes, and responses to the critiques in the summary statement from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. These comments on progress and response to the previous review should be provided in a separate paragraph and/or under the appropriate criteria.

Review Criteria: The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple Program Directors/Principal Investigators (PD/PI)s, is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PD/PIs?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the PD/PI(s) and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Multiple PD/PI Leadership Plan: For applications designating multiple PD/PIs, a new section of the research plan, entitled "Multiple PD/PI Leadership Plan" (section 14 of the Research Plan Component in the SF424 R&R or Section I of the Research Plan in the PHS 398), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs must

be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the Notice of Grant Award (NOGA).

Overall Evaluation: Summarize the major factors from the five review criteria above that contribute to or detract from scientific merit. In addition, evaluate whether the proposed project addresses the objectives of the AREA grant program which are to (1) provide support for meritorious research, (2) strengthen the research environment of schools that have not been major recipients of NIH support, and (3) expose available undergraduate and graduate students in such environments to meritorious research.

Protection of Human Subjects from Research Risks: Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

Inclusion of Women Plan:
Inclusion of Minorities Plan:
Inclusion of Children Plan:
Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults

2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender unknown	Minority representation unknown	Representation of children unknown
5		Only Foreign Subjects	

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.

Vertebrate Animals: 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: Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

Additional Review Considerations

Budget: Evaluate direct costs only. The support requested in each application may be up to $150,000 in direct costs expended over a period of up to thirty-six months. Budget requests must be in modules of $25,000. Modular grant application, review, and award procedures apply. Under the provisions of the Just-In-Time procedures, detailed justification of budgetary items and information on other support are not required. Within these limitations, comment on whether the budget request is appropriate.

Model Organism Sharing Plan: The NIH policy on sharing of model organisms for biomedical research was announced in the May 7, 2004 issue of the NIH Guide (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html). Starting with the October 1, 2004 receipt date, all new and competing-renewal NIH grant applications that plan to produce model organisms will be expected to include a sharing plan. Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of $500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

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