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-03-053, published in the NIH Guide to Grants and Contracts on January 9, 2003 and on the Office of Extramural Research Home Page.

http://grants.nih.gov/grants/guide/pa-files/PA-03-053.html

For many years the National Institutes of Health has made a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of our nation's research scientists, but which have not been major recipients of NIH support. Funds have been added to the NIH budget specifically for the Academic Research Enhancement Award (AREA) program since 1985. AREA grants are for the support of small-scale health-related research projects conducted by faculty in institutions that are not research intensive. These grants create a research opportunity for scientists and institutions, otherwise unlikely to participate extensively in NIH programs, to contribute to the nation's biomedical and behavioral research effort.

The objectives for the AREA Grant program are:

- strengthening the research environment at institutions that are not research intensive;
- exposing students (including undergraduate, and/or professional/graduate students) at such institutions to research;
- providing support for meritorious research.

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.
- The AREA program continues to utilize "on time" procedures with regard to information on the budget and Other Support (i.e., certain information will be requested only when needed after scientific merit review and before award).

Typically, AREA applications are reviewed by scientific review groups (study sections) that review a "critical mass" of AREA applications. Frequently at least one of the reviewers is from an AREA-eligible school. Streamlined review procedures (designation and discussion of only the top half of the applications) may be used for the review of AREA applications.

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. In carrying out the scientific and technical merit review of AREA applications, the scientific review group will base its recommendation and score (if the application is scored) on the overall impact of the application on its field of study by considering the five review criteria and the overall evaluation..

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.

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, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

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 investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? PLEASE DO NOT INCLUDE descriptive biographical information unless important to the evaluation of merit.

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments benefit from unique features of the scientific environment or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support? Is the applicant school/academic component suitable for an award in terms of strengthening the research environment? PLEASE DO NOT INCLUDE description of available facilities or equipment unless important to the evaluation of merit.

OVERALL EVALUATION: In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the five review criteria and the objectives of the AREA grant program. Recommend a score reflecting the overall impact of the project on the field, weighting the review criteria, as you feel appropriate for each application. An application does not need to be strong in all categories to be judged likely to have a scientific impact and, thus, deserve a high merit rating. 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. Assessment of the overall impact should be made in the context of the very small budgets permitted to AREA applications.

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.

GENDER, MINORITY AND CHILDREN SUBJECTS: 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.

ANIMAL WELFARE: 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.