GUIDELINES FOR REVIEWERS' PRELIMINARY WRITTEN COMMENTS FOR BIOENGINEERING PARTNERSHIPS (BRP)

A BRP is a multidisciplinary research team applying an integrative, systems approach to developing knowledge and/or methods to prevent, detect, diagnose, and treat disease and understand health and behavior, and must include bioengineering expertise in combination with basic and/or clinical investigators. A BRP may propose design directed or hypothesis-driven research in universities, national laboratories, medical schools, private industry and other public and private entities. Each BRP should bring together the necessary engineering, basic science and/or clinical expertise to focus on a significant area of bioengineering research within the mission of the NIH. A BRP can vary in size and exhibit diverse forms of organization, participation, and operation. No single type of BRP fits the needs of every area. Rather, the size, structure, and operation of a BRP are determined by the proposed research. BRP applications may be reviewed either in a standing study section or in a special emphasis panel.

Please use the following guidelines when preparing written comments on bioengineering research grant applications assigned to you for review. The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In your written review, you should comment on the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

NOTE: Your written reviews should not bear internal personal identifiers because unaltered comments will be sent to the investigator.

You do not need to write a description. However, the primary reviewer will paraphrase the applicant's abstract at the meeting**.**

CRITIQUE: It is not uncommon for applications for bioengineering projects to focus on technology development rather than on proving or disproving a scientific hypothesis. Review criteria for all NIH grant proposals have been modified to include non-hypothesis driven research such as systems design, methods and instrument development. Please address, in individual sections, each criterion listed below. Include as little descriptive information in this section as possible.

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?

- If the specific aims of the BRP are achieved, will they provide significant advances in the selected area of bioengineering research?
- Is the research likely to have a significant impact on other areas of research?
- Will the technological advances have a significant impact on human health?

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 PDs/PIs, 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 PDs/PIs?

- Are the BRP engineering, scientific, and clinical approaches and methods adequately developed, well-integrated, and appropriate to the aims of the project?
- Is a timetable with adequate research milestones proposed?
- Are appropriate specifications and evaluation procedures provided for assessing technological progress?
- Is the plan for sharing or disseminating technologies developed or enhanced under this program announcement adequate?
- Is the plan for technology transfer involving each partnering organization adequate?
- Does the application describe arrangements that facilitate the fruitful participation of a partner at a distant site?
- If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

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?

- Does the BRP propose new approaches, explore new research paradigms, or represent new concepts that combine engineering, physical, and clinical sciences?
- Will the proposed approaches or concepts solve current scientific or technical problems in novel ways?

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 principal investigator and other researchers? Does the PD/PI(s) and 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, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

- Does the scientific and technological environment in which the work will be done contribute to the probability of success?
- Does the partnership create potential opportunities to foster trans-disciplinary communication and training across traditional scientific and technical boundaries?

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), 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: In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the project in terms of the five review criteria. Describe how the combination of proposed partners enhances the quality of the application.

ADDITIONAL REVIEW CRITERIA:

Partnership and leadership: Is the proposed partnership adequate for the research? Is there evidence that the partnership will be effectively managed by the PI or project manager? Is the partnership strategy well planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the developed technology?

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.

SCORE: Recommend a score reflecting the overall quality of the project, weighting the review criteria, as you feel appropriate for each application. An application does not need to be strong in all criteria to be judged of high quality 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*.

OTHER CONSIDERATIONS: These comments are useful to NIH but should not influence your overall score.

Administrative Note: (e.g., There is potential overcommitment and/or scientific overlap with other existing grants and/or pending applications.)

Budget: Evaluate the direct costs only. Do not focus on detail. For all years, determine whether all categories of the budget are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support.

Data Sharing Plan: Applications requesting more than $500,000 direct costs in any year of the proposed research are expected to include a data sharing plan in their application. Assess the reasonableness of the data sharing plan or the rationale for not sharing research data.

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.

Technology transfer: Is the proposed plan to integrate technology transfer from the partnering organizations adequate?

Revised 7/16/07