P30 GUIDE FOR REVIEWERS

Recovery Act Limited Competition: Supporting New Faculty Recruitment to Enhance Research Resources through Biomedical Research Core Centers

EXECUTIVE SUMMARY

NIH Recovery Act Limited Competition: Supporting New Faculty Recruitment to Enhance Research Resources through Biomedical Research Core Centers (P30)

- Supported by funds provided to the NIH under the American Recovery & Reinvestment Act of 2009 ("Recovery Act" or "ARRA"), Public Law 111-5

- Supports the hiring of newly-recruited faculty to develop research projects within the context of Biomedical Core Centers, defined as a community of multidisciplinary researchers focusing on areas of biomedical research relevant to NIH, such as centers, departments, programs, and/or trans-departmental collaborations or consortia.

- Designed to enhance innovative programs of excellence by providing scientific and programmatic support for promising research faculty and their areas of research.

- Institutional awards that provide funding to hire, provide appropriate start-up packages, and develop pilot research projects for newly independent investigators, with the goal of augmenting and expanding the institution's community of multidisciplinary researchers focusing on areas of biomedical research relevant to NIH.

- Visit FOA at http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-005.html.

INSTRUCTIONS FOR WRITTEN CRITIQUE AND PRELIMINARY SCORES

Written Critiques

Please use the following guidelines when preparing written comments on the P30 grant applications assigned to you for review.

- You must format your critiques to follow the structured template provided. This can be downloaded from the files provided by your SRO and/or from the CD. You may also download the critique template from http://grants.nih.gov/grants/peer/reviewer_guidelines.htm.

- Each core criterion and additional review criteria are represented in the reviewer template and should be commented on, listing the strengths and weaknesses of each in a bulleted sentence format.

- The goal is to provide the maximum and most pertinent information in a concise manner.

- After considering all of the review criteria, briefly summarize the strengths and weaknesses of the application in the Overall Impact section of the template.

- Assigned reviewers must upload critiques before entering an overall impact/priority score.

- Criterion scores should be entered in IAR before the review meeting.

- Assigned reviewers may submit criterion scores only after their critiques have been uploaded. At the SRO's discretion, discussants who are assigned to the application and SRG members who are not assigned to the application may submit criterion scores without critiques.

- The criterion scores may be changed during FINAL SCORING on your electronic or paper Voter/Scoring Sheet, or following the review meeting during the EDIT phase.

- Please do not write your criterion scores on the critique template.

Preliminary Scores

- Each scored review criterion for the Individual Research Projects should be given a score using the nine-point rating scale.

- The criterion scores for the applications should be entered in the meeting IAR Web site in the NIH Commons before the review meeting using the same page that is used for submitting the preliminary impact/priority score and critique. Do not enter scores on the critique.

- The criterion scores may be changed following the review meeting during the EDIT phase.

- In the READ phase of the meeting reviewers may submit their scores and critiques, but may not edit them. Core criterion scores can be submitted only after your critique has been uploaded into IAR.

- The criterion scores will appear in the summary statement as part of your critique.

- The overall impact/priority score on a 1 to 9 scale should reflect your assessment of the likelihood for the project or program to exert a sustained, powerful influence on the research field(s) involved, in consideration of the standard review criteria and the additional review criteria (as applicable for the project/program proposed).

Review Criteria

Overall Impact/Priority

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers are asked to consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

These individual criterion scores are considered part of your critique, although they are not entered on the critique, and generally will not be discussed at the review meeting. They may be changed in the EDIT phase in Commons.   An application does not need to be strong

in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

How will the new Core Center contribute to building a community of multidisciplinary researchers focusing on a common research problem and enhance the ability of the institution/organization to conduct research in the specified area(s) of science? Will new faculty members hired under this initiative conduct research projects and receive career development support that will foster independent research careers and lead toward applications for future independent research project grants to further the mission of the Core Center?

Investigator(s)

Does the PD/PI have the ability and institutional authority to provide scientific and administrative leadership and direction for the Core Center, and to work with Core Center investigators to develop relevant research projects?

Innovation

Does the application identify critical research program needs and seek creative ways to incorporate Core Center resources, new tenure-track faculty and new research projects to help address those needs?

Approach

Are the plans for recruiting and appointing new investigators within the Core Center adequate and appropriate for furthering the scientific mission of the Center? Will the research activities and resources of the proposed Core Center assist in the development and strengthening of intra- and inter-institutional relationships across the academic health center or university, or with other institutions? Is the plan for evaluation thorough and rigorous? Are the proposed scientific goals of the Core Center, as well as the plans to achieve those goals, feasible, innovative and of high scientific/technical merit? Are potential problems, alternative strategies, and benchmarks for success presented? Are the proposed plans and criteria to select relevant research projects and monitor their long term success of sufficient strength, feasibility and appropriateness, including whether there is an adequate strategy for selecting projects that leverage resources and complement the Core Center's mission and strengths?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Is the current infrastructure well described and is it conducive to conducting research projects that are relevant to the research mission of the proposed Core Center? Will the research activities within the Core Center help to foster career development for newly-independent investigators, and lead toward applications for future independent research project grants that further the mission of the Core Center? Are the institutional support, equipment and other physical resources available to the investigators adequate for the development and implementation of relevant research projects? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there evidence that new faculty members hired under this initiative will have at least 75% protected research time during the duration of this award? Will new faculty members be given appropriate joint appointment(s) and access to facilities, resources and graduate students from other components in the institution/organization, or

collaborating institutions? Are shared institutional resources being made available to investigators within the Core Center?

Additional Review Criteria

As applicable for the project proposed, reviewers are asked to consider the following additional items in the determination of scientific and technical merit, but not to give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. 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. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO 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.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

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.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Inclusion of Women, Minorities and Children

When the proposed project involves clinical research, reviewers are asked to evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

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".

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.

For additional information to assist you in making these determinations, please refer to http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf and http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Worksheet.pdf.

Gender Inclusion Code

G1 = Both genders

G2 = Only women

G3 = Only men

G4 = Gender composition unknown

Minority Inclusion Code

M1 = Minority and nonminority

M2 = Only minority

M3 = Only nonminority

M4 = Minority composition unknown

M5 = Only foreign subjects

Children Inclusion Code

C1 = Children and adults

C2 = Only children

C3 = No children included

C4 = Representation of children unknown

Vertebrate Animals

Reviewers are asked to evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to: http://grants.nih.gov/grants/olaw/VASchecklist.pdf.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Budget and Period Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

Select Agents

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). Select agent information is available via http://grants.nih.gov/grants/policy/select_agent/.