A. Scoring and Critiques:

1. **Are review criteria weighted? Approach appears to be weighed more heavily than other criteria, like innovation and impact.**
   There are no set weights for each criterion in grant review. Reviewers should use their own judgment to weigh criteria for a particular application. The weights could be different for different type of applications. For example, Innovation may weigh more in R21 type applications than in R01 applications. The reviewer is free to determine the appropriate weight between the various criteria for each application as s/he sees fit. Every committee member will weigh the criterion scores in whatever manner that s/he thinks most appropriate.

2. **What instructions/orientation do reviewers receive regarding scoring?**
   All reviewers are provided with the **Guide for Scoring System and Procedure (http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf).** There are score descriptions in this Guide for reviewers. Reviewers also receive instructions on scoring and other review issues on a weekly basis. A special pre-meeting teleconference may also be held for reviewers in order for the SRO to address any review related questions they may have including scoring. NINR SROs have a PowerPoint presentation before each review meeting to remind reviewers of how to use the scoring system. Reviewers are encouraged to ask the SRO any questions on scoring before and during the meeting.

   Scoring is not simply a quantitative exercise of counting the number of strengths and weaknesses. It may be that a particular strength or weakness predominates; therefore, the score that best reflects that particular factor should be chosen. For example, in determining the overall impact score, it may be that the approach is sound, the environment is suitable, the investigators are well qualified, but the significance and innovation of the application are low. This may result in a number of strengths and only a few weaknesses, but the weaknesses qualitatively outweigh the strengths; therefore, the application should receive a below-average score. The list of score descriptions provides an orientation to the scale, but each reviewer needs to weigh for themselves how to reach the final score. This same reasoning can apply to the scoring of individual criteria.

3. **It seems that narratives are not always consistent with numeric ratings? Are reviewers provided guidance to maintain consistency between ratings and information provided in reviews?**
   SROs use **Guide for Scoring System and Procedure (http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf)** to train reviewers before the review meeting. This critical document is enclosed in the Reviewer Folder and is referenced if a question arises about overall Impact and/or criterion scores during the meeting. For example, score 3 as described as Excellent should be very strong with only some minor weaknesses (addressable and won't substantially lessen impact). On the other hand, score 9 (poor) indicates very few strengths and numerous major weaknesses that will severely limit impact.

   At NINR reviews, SROs always ask reviewers **to revise** their narrative critiques to match each criterion and overall impact scores after review discussion during the Edit Phase after meeting.

4. **To what extent do study section members change scores based on discussion and/or one 'strong' reviewer?**
   The review panel Chair and SRO moderating the review always make sure all scientific opinions are presented and discussed before the final voting. All reviewers will vote their conscience based on what they hear from the discussion. The final score is the average of all scores from the entire review panel.

5. **Is guidance and oversight given to reviewers emphasizing that emotional comments a reviewer may offer are of little benefit to the applicant when included in the summary statement and may detract from the scholarliness of the review process?**
   SROs always instruct reviewers to refrain from the use of inflammatory language in the review critiques. SROs also instruct reviewers not to express their emotional feelings when presenting their critiques and only focus on the scientific content.

6. **How are reviewers differentiating the 'significance' and 'innovations' sections? That is, how well are applicants clear on those two sections and responsive to the new instructions?**
   Significance is a stand-alone assessment of the project's goals in the context of the relevant field, and to a large extent assumes that the investigator(s), approach and environment are adequate to allow for successful completion of the aims of the project even if later discussion of each of these review criteria identify problems.

   Innovation is assessed by whether the application challenges and/or seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions. The innovation of a study may involve its approach. Accordingly, reviewers may wish to consider approach when evaluating innovation. The concern comes when reviewers place excess weight on "feasibility" and "risk" at the expense of innovation.

   When reviewers assess the Overall Impact of an application they are expected to take into account the scored review criteria (significance, investigator(s), innovation, approach and environment) and the additional review criteria to judge the potential of the project to exert a sustained, powerful influence on the field.

   It is important that Significance and Overall Impact be evaluated within the context of the research field involved. NIH program staff and Institute leadership will evaluate each project's relevance to their Institute mission in making funding decisions.

B. <u>Shortened Application Forms:</u>

7. **Since the application page limit has been shortened, to what extent is the Approach section sufficient for reviewers to make an informed decision? What are the weakest components of the Approach section?**
   Shorter applications are intended to help focus both applicants and reviewers on the essentials of the science. This also has the additional benefit of decreasing information overload, and potentially enabling a larger number of reviewers to read each application and participate in the review in a more informed manner.

The NIH grant application is among the longest used by funding agencies and foundations worldwide. In the initial RFI on shortened applications, three quarters of those responding felt shorter application lengths would not be burdensome. So far, we have not had any issues from reviewers regarding the shorter Research Strategy/Approach section.

Often the weakest component of the Approach section is that applicants fail to address the potential problems and alternative strategies to their research approach.

8. **Changes in application format and review are evolving. Is it fair to say that reviewers and grant writers are trying to make sure they are executing their respective roles to the best of their ability and meeting NIH requirements?**
   There have been many changes to application forms and many notice updates for NIH grant applications recently. Now both application format and review guidelines have been finalized and we will do our best to inform the scientific community about these changes. Recently, NINR conducted Grantsmanship workshops on application and review changes at four nursing research regional meetings and received very positive feedback from the nursing scientist community.

C. Application Submission and Resubmission:

9. **After applications have been reviewed, we are informed they will not be funded since they are not well matched to an agency priority area—could pre-screening on this be done so that the application is routed to a different agency for funding consideration?**
   Before submitting an application, the PI and critical key personnel (such as sponsor/mentor for F/K applications) should read the corresponding FOA very carefully and understand the mission of related NIH institute/center. The cover letter should be used to indicate the study section and IC preferred by the applicant. The PI is encouraged to provide several ICs for funding consideration with one as the primary IC assignment.

   NINR program directors and SROs always check applications for NINR scientific mission fit as soon as they are assigned to NINR by CSR receipt and referral. If a mismatch is identified, the application will be reassigned by CSR to a different IC. Applicants should also check their applications' assignment and alert the NINR staff if changes are needed.

10. **What is the distribution of grants reviewed by funding mechanism?**
    It varies review round to review round.

11. **What is the percentage of grants reviewed that can be considered (a) basic research, (b) clinical research?**
    The majority of NINR reviewed grant applications are considered clinical research.

12. **Is there the possibility of a process by which second submission application, which receives a strong, but not funded score, could be amended for a 3rd review?**
    NIH plans to increase the success rate of new and first resubmission applications by decreasing the number of resubmissions or amendments that are allowed. This policy applies to all types of applications submitted to NIH including small

business (SBIR and STTR), fellowships, career awards, etc. Under this new policy, applications can only be revised and resubmitted once. NIH does not anticipate making exceptions for any type of application. By reducing the number of resubmissions, the goal is to permit funding of larger numbers of new and first resubmission applications and thereby to allow investigators to spend less time revising and resubmitting and to begin their research projects in a timely fashion.

If the application is not funded after second submission (A1), the PI is expected to submit a new application that is significantly and substantially different in content and scope with more significant differences than are normally encountered in a resubmitted (amended) application.

There are a few other ways to resubmit an unfunded A1 without SIGNIFICANT CHANGES in content: change the grant activity code (for example, from R01 to R21) or respond to an RFA (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html). Outside NIH, the National Health Council with many foundation organizations takes advantage of NIH peer review and is willing to consider some unfunded, but meritorious applications for funding. The website is http://healthresearchfunding.org.

13. **Frequently on the second submission (A1) the application is reviewed by different reviewers. Thus, the investigator responds to input from first reviewers but is presented with new issues based on new reviewers. Since it is now "two times and you are out" this makes it difficult, as reviewers can be diverse in their critiques. In some cases we have responded to critique with changes to address and scores have been worse.**
The resubmission status of an application is considered as an additional scoring review criterion. The responsiveness to the previous review critiques is considered during the determination of scientific and technical merit, and can influence the overall impact score. For NINR reviews, we always try to keep at least one or two reviewers from previous review to review the resubmitted application to maintain consistency.

The primary review consideration should always be the quality of the research that is proposed. Responsiveness to weaknesses identified by previous reviewers may well improve the quality of some aspects of the application, but may or may not improve the overall impact. For example, if the reviewers of a resubmission application do not feel that the significance has changed, then they might not give an improved impact score simply because the technical approach has been cleaned up.

D. Reviewer and Study Section Performance Evaluation:

14. **Is there a metric to quantify the performance of individual reviewers?**
At this time there are no plans to capture and display that data.

15. **Is there a metric to quantify the performance of a study section?**
At this time there are no plans to capture and display that data.

16. **Critique is influenced by reviewers who claim some information is missing in the grant that is actually in the application, so score is adversely affected. This may have to do with the fact that reviewers are frequently assigned 12 or more**

applications to review. This takes a considerable amount of time (3-4 hours per grant application is not too generous an estimate) to do a thoughtful thorough review and with accuracy. I know recruiting reviewers is a struggle for NIH, but more people might be willing to review if they knew they would have a smaller review assignment. This could potentially improve the level of scientific review.

This is very good question on the reviewer workload issue. For NINR review meetings, we try to keep the maximum review assignments for each reviewer under 7. We always keep the reviewer workload in mind and try to balance the workload for every reviewer in all NINR review meetings.

Applicant appeal of review outcome may be based on Factual error(s) by one or more reviewers that could have altered the outcome of review substantially. NINR SROs always carefully check factual errors in preliminary critiques and summary statements. If any errors are found, the SRO will contact reviewers to correct them and make sure no wrong information is presented in both review meetings and summary statements.