Frequently Asked Questions Regarding Review of Restructured Applications

Q. With the shortened application, looks like I will need to spend more time searching for details in the literature, right?
A: No, more time in the literature should not be necessary, and applications should still be self contained. By switching to a shorter application, NIH is shifting emphasis, with more expectation of a strong rationale and potential for lasting impact on the field and less emphasis on demonstrated feasibility with every detail anticipated.

Q. How do I know what type of application I am reviewing and the page limits that apply?
A. Applicants are required to follow the instructions in the specific funding opportunity announcement (FOA) when completing their application. The FOA will dictate the activity code of the application (e.g., R01, R21, R43) as well as the specific page limits for the various sections if they differ from those specified in the SF424 R&R. Validations at eRA will assess compliance with the page limit requirements of some, but not all of the sections. Applications that contain inappropriate material in the animal, human subject, or resources sections included to circumvent the page limits should be brought to the SRO's attention.

Q. What are the major changes in the application?
A. The application has been reorganized to coincide more closely with the review criteria. For most of the activity codes (e.g., R01, R21 etc) the application has also been shortened (see slide 4).The Biosketch format has been changed to limit the number of publications listed and to include a personal statement about the investigators ability to accomplish the proposed work. The Facilities and Resources section has been modified to focus on the facilities and resources that specifically contribute to the accomplishment of the aims of the proposed research.

Q. What is the policy for enforcing compliance with page limits?
A. NIH Electronic Research Administration (eRA) has validation checks in place for the specific aims and the introduction. Electronic submissions that exceed the page limits in other sections will be flagged in the Division of Receipt and Referral. Applications and those that exceed the stated page limit for a required section will not be forwarded to review.

Q. Where in the application can I find preliminary data?
A. Preliminary data are included in the Approach section of the Research Strategy. They may be as a separate section within Approach or distributed throughout that section.

Q. Are there tips for providing meaningful comments in the critiques to support the scores?
A. Identify major strengths and weaknesses. Indicate why a particular issue is a strength or weakness. If the criterion score is >3, comment(s) under weaknesses are helpful and advised.

Q. What should I do if the principal investigator has not used the new form for the Biosketch?
A. Both old and new forms are permitted but may not exceed four pages. The biosketch should contain a personal statement, positions/honors and research support sections, and no more than 15 publications. Applications lacking a personal statement or citing more than 15 publications are still compliant as long as they do not exceed the four page limit.

Q. What should reviewers do when the Personal Statement in the Biosketch is missing?
A. Nothing, the Personal Statement is recommended but not an absolute requirement. Lack of a Personal Statement or inclusion of more than 15 publications will not impede the application moving forward to Peer Review, however, without the personal statement, reviewers might find it difficult to rate the investigator criterion.

Q. What are the new instructions for Facilities and Equipment section?
A. This information is used to assess the capability of the organizational resources available to perform the effort proposed. This section should identify the facilities to be used, their capacity, proximity and availability and should be limited to those resources directly applicable to the proposed work. Early stage investigators, should describe institutional investment in their success as an investigator, e.g., start-up funds and mentoring arrangements. In the case of multiple sites, the resources available at each site should be described. A description of special facilities used to handle biohazards or other potentially dangerous materials should be included. Major items of equipment already available for the proposed studies should be listed under Equipment.

Q. How should resubmission applications be handled?
A. No change in review of resubmissions has been made. The applications will be in the short format and will include an introduction. As before, the reviewers should address how well the investigator(s) responded to the concerns of previous reviewers. In most cases, applicants are allowed a single resubmission.

Q. If the application is a renewal, where do I find the progress report for the previous funding period?
A. The description of previous progress will be included in the Approach section of the Research Strategy. It may be presented as a separate section or incorporated into the individual specific aims.

Q. What do reviewers need to know about giving guidance to applicants?
A. Reviewers should keep guidance to applicants separate from their critiques. Reviews should focus on strengths and weaknesses of the application as submitted, not “mentoring” or redesigning experiments for applicants. However, if there are specific points that a reviewer wishes to covey to the applicant, they should put these comments in the last box of the critique template, “Additional Comments to Applicant”.

Q. How should reviewers consider application sections without page limits when they include information that should have been part of sections with page limits?
A. The information in the human subjects and vertebrate animals sections should be used to describe the individuals (humans or animals) to be involved in the study and the measures to insure the limitation of risks. The Resource Sharing section should focus on the plan for sharing, not how organisms or data were generated. These sections should not be used to describe detail of experimental design or rationale. Extraneous information should not be taken into account. The fact that this additional text was included should not affect the overall impact/priority score or criterion scores.

Q. Is there a requirement for IRB or IACUC approval for human studies or vertebrate animal studies to be “Acceptable”?
A. No, the review by NIH study sections is independent of institutional IRB and IACUC approval. Those institutional approvals may occur after the application is reviewed. Reviewers should evaluate for themselves whether the risks and enrollments for human studies or the five elements for animal studies are acceptable.

Q. Is there a requirement for consent of Institutional Signing Official (SO) for additional materials?

A. Yes, the SO must concur with submission of any supplemental material. This is most easily ensured by having the material sent to the SRO by the SO (submission of material by the investigator with a cc to the SO is not sufficient).

Q. How will restructured applications change the summary statements?
A. The changes in applications should not change summary statements. The format of the application and the review criteria have been aligned as a result of the enhancement process. Summary statements will continue to include individual reviewer critiques in the bulleted strengths and weaknesses format as well as individual criterion scores for each assigned reviewer.

Q. What is the difference between Impact and Significance?
Significance: Reviewers should consider the following questions: Does the project address an important problem or critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
Overall Impact: Reviewers will provide an overall impact 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 five review criteria, and additional review criteria (as applicable for the project proposed).

Q. What level of details reviewers should expect given the shorter page limits?
A. With shorter applications, it is important that reviewers don't expect the same level of detail that they've seen in the past. Emphasis should be on impact, strategy, experiment, etc. Refer to document on tips for writing bulleted critiques.

Q. How should reviewers use the "Advice to Applicants" section of the review critique template?
A. Reminder: this is an optional section, but could provide helpful information to the applicant. Gives reviewers the opportunity to provide guidance to applicants on issues that did not affect the score given by the reviewer. Reviewers can use this space to note that they found information in a non-page limited section that really belonged in a page-limited section.