Interim Report on Recommendations to Simplify Review Criteria

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Introduction

This report summarizes a framework for review criteria and recommendations developed by the working group. The report was accepted by CSR's Advisory Council on March 30, 2020 with Council expressing strong support for the recommendations herein. **This represents a starting point for broader discussion with stakeholders.** Any changes to review criteria will involve broad consultations across NIH, including the Office of Extramural Research, Office of the General Council, NIH Institutes and Centers, and other NIH advisory and policy bodies. Additional input from the external scientific community would be sought. Complex issues remain, including extending this framework from R01 and R21's to clinical trials and to other funding mechanisms such as small business and training grants. Because of the complexity of issues and the need to consider perspectives of many stakeholders, the process of revising review criteria is not fast but is one to which CSR is committed.

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Recommendation 1. Reorganize review criteria to focus on key questions.

Reorganize the five core review criteria into three factors, *Importance of the Science*, *Feasibility and Rigor*, and *Investigator and Environment*. The intention is to better focus reviewers' attention on the key, big picture factors that should drive scores. Two factors pertain to the science that is proposed and are intended to capture judgements regarding conceptually distinct aspects of scientific merit; *Importance of the Science* versus *Feasibility and Rigor*. We want reviewers to think about the two basic questions: "Should it be done?" and "Can it be done well?". The third factor is *Investigators and Environment*. This factor asks reviewers to evaluate how the investigators and environment influence the likelihood that the project will succeed, that is, that it will be implemented well and will achieve its goals. Here, the question is "Will it be done?".

Applications would receive three factor scores plus an Overall Impact score. The individual criteria (significance, investigators, innovation, approach, environment) would not be scored. The factor *Importance of the Science* is derived from the criterion "Significance" and the conceptual aspects of "Innovation". The *Feasibility and Rigor* score is based on the criterion "Approach" and the technical aspects of "Innovation". The group sees rigor and reproducibility considerations as important aspects of "Approach". The Overall Impact score should reflect reviewers' overall judgement of scientific merit based on an integration of the three factor scores and will be used to prioritize applications.

Another potential benefit of this recommendation is that it could be advantageous in a partially-blinded review designed to reduce bias due to applicant demographics or home institution. For example, only *Importance of the Science* and *Feasibility and Rigor* might be assessed in stage 1, without identifying the investigator or institution, and *Investigator and Environment* could then be made available at a second stage of review.

Recommendation 2. Define each criterion and factor conceptually, rather than as a set of questions.

The idea is that a good definition can be applied across a wide range of science and methods, whereas questions, especially specific questions, tend to be more narrowly applicable and consequently need to be changed for specific types of applications. Select questions may, however, be useful.

Recommendation 3. Alter templates to focus reviewer attention on score-driving factors.

Alter the review template to remove headers for "Strengths" and "Weaknesses" below each scored factor, and instead provide headers for "Major Score-Driving Factors" and "Minor Points (optional)". Rather than have reviewers simply list strengths and weaknesses, which can lead to unnecessary focus on minor technical aspects of the proposal, the idea is to encourage reviewers to provide individual points on the factors that drive their score, be they positive or negative. The *Minor Points* field is optional and can be used to note scientific or technical considerations that the reviewer does not consider significant enough to drive their score.

Rather than specify a bulleted or narrative format, reviewers would be instructed as follows:

For factors 1, 2 and 3: "Using sentences or short narratives, explain the points that determine your score, clearly and concisely. Identify and weigh the most important strengths and weaknesses of the application with respect to [factor X]."

For Overall Impact: "Write a clear, concise paragraph that explains the basis for your score. Identify and weigh the most important strengths and weaknesses of the application."

The group notes that moving to web-based review templates will offer additional tools to get the correct balance between brevity and clarity in reviewer comments.

Recommendation 4. Clarify reviewer responsibility for evaluating the budget

to one of judging whether the proposed budget is appropriate given the proposed work. Reviewers should be asked to choose between these options:

Budget is appropriate to support the scientific activities proposed.

Budget appears excessive. Further justification is needed.

Budget appears inadequate and raises concerns about project feasibility.

A comments field would be needed to capture any specific points of concern, if raised. However, committees would have no responsibility to identify specific budgetary concerns or recommended changes.

Recommendation 5. Relieve reviewers of responsibility for the "additional review considerations" listed below.

These considerations should be evaluated by program staff for proposals likely to receive funding.

1. Biohazards
2. Foreign components
3. Select Agent Research
4. Resource Sharing Plans
5. Authentication of Key Biological and/or Chemical Resources

Rationale: Asking reviewers to evaluate these considerations dilutes their attention to scientific merit. It also risks inadequate review of the considerations. In general, reviewers have no special expertise in these areas. These are considerations where technical standards are appropriate and where detailed information is needed, information beyond what is reasonable in a research project grant application.

Recommendation 6. Convene an additional workgroup to consider simplifying review criteria for clinical trials applications.

Because of the complexity of review criteria as currently implemented for clinical trials applications, we recommend that CSR appoint an additional workgroup, consisting of some members of the current group plus additional members with clinical trials expertise. That group would be charged with extending the framework for review criteria described in this interim report to the clinical trials arena. Expertise of the group should reflect the variety of types of clinical trials ranging from large, interventional safety and efficacy trials, to mechanistic, to those defined by the NIH as BESH (Basic Experimental Studies involving Humans).

Proposed Implementation

Below is a proposed language for reviewer guides/critique templates were recommendations 1-3 to be implemented. It was created focusing on non-clinical trial R01s.

Factor 1. Importance of the science (scored)

Assess how important it is to accomplish the proposed science. Try to evaluate the importance of this application not simply with respect to other very similar applications, but rather in the broad context of current scientific challenges and opportunities. Base your judgment of Importance on your evaluation of the application's Significance and Innovation.

a. ***Significance (not scored):*** Evaluate the scientific value of the knowledge likely to be gained through the proposed studies. Consider the impact of the facts it may establish, the methods, models and concepts it may develop or discredit, how that knowledge may shape future science, understandings of basic biology, physiology, or pathophysiology, disease and its prevention or treatment. Significance of the science must be distinguished from the significance of the disease, biological or physiological process, or broad scientific problem that frames it. Significance of the scientific knowledge is what matters.

b. ***Innovation (not scored):*** Evaluate the novelty and creativity of the ideas, methods, techniques, resources or other scientific products that would be developed by, used in, or that would emerge from the proposed work. Consider the extent to which novel ideas, data, and methods, etc. would be valuable in advancing biomedical science or in enhancing health.

Work that is not highly significant must not be rated highly important. Innovation is often critical and is generally desired, yet studies can be highly significant and important without being highly innovative.

Using sentences or short narratives, explain the points that determine your score, clearly and concisely. Identify and weigh the most important strengths and weaknesses of the application with respect to *Importance of the Science.* [followed by text box]

Factor 2. Feasibility and rigor of the methods (scored)

Evaluate the proposed work with respect to scientific design, methods, techniques, and analytic plan, the rigor of thought and approach reflected therein, and the likelihood that findings would be replicable. Assess whether the proposed design and methods are likely to yield scientifically robust findings, that is, is it scientifically feasible.

a. Approach (not scored): Evaluate the quality of the study design, methods, models, data collection, and plan for analysis and interpretation. Evaluate the extent to which the research approach will yield clearly interpretable, robust, rigorous and reproducible data. Evaluate how well the plan demonstrates technical competence and feasibility, and whether

it demonstrates the capacity to adjust methods appropriately to address problems and new challenges that emerge in the work. Evaluate the quality of plans for data analysis. Focus on major issues that strengthen or detract from the feasibility and quality of the work. Less important technical flaws or omissions, especially those that capable team of scientists are capable of correcting should carry less weight.

b. Innovation (not scored): Evaluate the novelty and creativity of approach, methods, and techniques with respect to how well they would help advance science in this field.

Projects need not be strong on both to justify a strong score. Work that is methodologically and technically sound may score well even if not innovative. Innovations, conceptual or technical, can powerfully advance a field and may have potential that justifies a good score even in the presence of technical uncertainties. Using sentences or short narratives, explain the points that determine your score, clearly and concisely. Identify and weigh the most important strengths and weaknesses of the application with respect to F*easibility and rigor of the methods*. [followed by text box]

Factor 3. Investigators and environment (scored)

Evaluate the likelihood that the proposed project will be executed well, the aims met, that the project will be productive and rigorous, and that scientifically valuable outcomes will result. Base the score on your evaluation of the investigator(s) and the institutional environment as detailed below.

a. Investigators (not scored): Evaluate the scientific background, expertise, skills of the PI and team of investigators with respect to the proposed science. Assess evidence of their intellectual and scientific capabilities. Strong investigators will creatively overcome obstacles and flexibly adapt to unexpected findings, thus improving the likelihood that the proposed project will be accomplished and will produce important new ideas, knowledge, tools, techniques, scientific or health resources. **Evaluate investigators in the context of their career stage**; different indicators and standards are appropriate for early, mid-career, and senior investigators.

b. Environment (not scored): Evaluate the extent to which the scientific environment, institutional support and capabilities, equipment, facilities and other resources available to the investigators will contribute to successful execution of the proposed project.

Give each criterion the relative weighting you believe appropriate. Projects need not be strong on both to justify a strong score. Using sentences or short narratives, explain the points that determine your score, clearly and concisely. Identify and weigh the most important strengths and weaknesses of the application with respect to *Investigators and Environment*. [followed by text box]

4. Overall Impact Score

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Judge the overall scientific and technical merit of the application. Considering the importance of the science, the feasibility and rigor of the proposed approach, and the capabilities of the scientists involved, assess the likely contribution of the project to advancing fundamental knowledge about the nature and behavior of living systems, or the application of that knowledge to enhancing human health. Write a clear, concise paragraph that explains the basis for your score. Identify and weigh the most important strengths and weaknesses of the application. [followed by text box]