About NIH Review Criteria

Applications submitted to the NIH consistent with the <u>NIH mission</u> are evaluated for scientific and technical merit through the NIH's, two-tiered peer review system. This requirement is mandated by the Public Health Service Act (e.g., Sections 406 and 492). The DHHS Uniform Administrative Requirements (45 CFR 75.203) specifies that the HHS awarding agency must provide public notice of application review information including the criteria and process to be used to evaluate applications.

Where Do Review Criteria Originate?

Congress authorizes NIH to award funds through authorizing legislation. Although the legislation may include a brief description of how applications will be evaluated, generally the details are developed in regulations. For example,

Mechanism	Regulation	
Biomedical and behavioral research	42 CFR 52h.8*	
National Research Service Awards (NRSA)	42 CFR 66.106 (direct), 42 CFR 66.206	
	(institutional)	
General (non-NRSA) training	42 CFR 63a.6	
Construction	42 CFR 52b.5	

Certain special initiatives may be authorized through legislation and/or may have additional review requirements detailed in regulations, for example:

Initiative	Regulation
National Library of Medicine Grants	42 CFR 59a.4 (resources), 42 CFR 59a.15 (regional
	<u>libraries)</u>
NIEHS Hazardous Waste Worker Training	42 CFR 65.5
NIH Health Center Grants	42 CFR 52a.5

Format

NIH review criteria that are used to evaluate grants, cooperative agreements, and fellowships are assessed by reviewers using the <u>NIH scoring system</u>, which differentiates three types of review criteria:

- *Scored Review Criteria*: receive individual criterion scores; contribute to the overall Impact Score.
 - The NIH uses the main points in the evaluation sections in regulation as the headings for the Scored Review Criteria that receive individual criterion scores. These criteria are applicable to each application submitted for that type of mechanism and receive individual criterion scores.
- Additional Review Criteria: do not receive individual criterion scores; contribute to the overall Impact Score

The NIH Peer Review regulations specify additional factors that are to be considered in the evaluation of applications for research grants. These include the adequacy of plans to include

both genders, minorities, children and special populations as appropriate for the work proposed, as well as the adequacy of the proposed protection for humans, animals, and the environment. Because these factors are not applicable to all applications in a mechanism category, they do not receive individual criterion scores.

The NIH cannot award grants unless certain factors are considered acceptable. For example, protection of human subjects, vertebrate animal welfare, and biohazards can impact funding decisions. Therefore, in addition to considering these factors in the overall Impact Score, reviewers are asked to rate these factors as Acceptable or Unacceptable, for NIH's further assessment as appropriate.

• Additional Review Considerations: do not receive individual criterion scores; do not contribute to the overall Impact Score.

The NIH uses Additional Review Considerations to seek the input of scientific experts concerning programmatic issues that do not directly reflect the scientific and technical merit of the work proposed, and therefore do not affect the scoring. For example, reviewers may be asked whether applications from foreign institutions present special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that are not readily available in the United States or augment existing U. S. resources.

Category	Affect Impact Score?	Criterion Scores?
Scored Review Criteria	Yes	Yes
Additional Review Criteria	Yes	No
Additional Review Considerations	No	No

Defining Questions

To the extent feasible, the review criteria use the same defining questions for all applications in a category. However, exceptions do exist, whereby the criteria are defined differently to reflect the science or intent of the funding opportunity announcement. For example:

Criterion	R01 standard questions	Research Resource (R24) questions
Significance	Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? 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?	How well does the proposed Coordinating Center address the needs of the research projects that it will coordinate? Is the scope of activities proposed for the Center appropriate to meet those needs? Will successful completion of the aims bring unique advantages or capabilities to the research projects?

In addition, certain types of Funding Opportunity Announcements (FOAs) may include additional FOA-specific questions. Typically, these additional review questions are found in Requests for Applications (RFAs) and Program Announcements with special receipt dates (PARs).