



Center for
Scientific Review

Tobacco Regulatory Science Small Grant Program for New Investigators

Peer Review Process
Pre-Application Webinar RFA-OD-15-004 (R03)
December 2, 2015

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Key Dates for Application Review

- Letter of Intent Due: January 4, 2016
- **Application Due: February 23, 2016**
- **Scientific Merit Review: June 2016**
- **Advisory Council Review: August 2016**
- Earliest Start Date: September 2016

Overall Peer Review Goal



To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.

Peer Review Process

- The applications will be reviewed in a Special Emphasis Panel composed of experts from mainly outside of the government.
- Standard NIH policies will apply for confidentiality and conflict of interest management.
- A Summary Statement, with written critiques, will be provided for every application.
- Every application will receive either an Impact (priority) Score or a “Not Discussed” designation.

Before the Study Section Meeting

- Each application is assigned to 3 or more reviewers 5-6 weeks in advance.
- Reviewers assess each application by providing:
 - A preliminary **Overall Impact**** score
 - 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 (5) review criteria and additional review criteria (as applicable for the project proposed).
 - Criterion Scores for each of the 5 Core Review Criteria
 - A written critique

****Reviewers use the standard NIH scoring scale of 1 to 9 (integers only), where 1 is the best score, reflecting the highest potential impact (see next page).**

9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

Scored Review Criteria (from FOA)

- **Significance** *modified for TRSP applications*
- **Investigator(s)** *unchanged from traditional NIH criteria*
- **Innovation** *modified for TRSP applications*
- **Approach** *unchanged from traditional NIH criteria*
- **Environment** *unchanged from traditional NIH criteria*

Scored Review Criteria, cont'd

Significance

- Does the project address an important ~~problem~~ **issue** or a critical barrier ~~to progress~~ in the field?
- If the aims of the project are achieved, how will scientific knowledge, and/or technical capability ~~clinical practice~~ be improved?
- How will successful completion of the aims ~~change~~ **affect** the concepts, methods, and technologies ~~treatments, services, or preventative interventions that drive this field~~ **related to the manufacture, distribution, and marketing of tobacco products?**

Scored Review Criteria, cont'd

Investigators

- Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project?
- If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Scored Review Criteria, cont'd

Innovations

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions **in the field of tobacco science as it relates to the manufacture, distribution, and marketing of tobacco products?**
- ~~Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, **or** instrumentation, or interventions proposed?~~
- **Will the outcomes of the project provide new information to further develop the knowledge base that informs the manufacture, distribution, and marketing of tobacco products in order to protect public health?**

Scored Review Criteria, cont'd

Approach

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Scored Review Criteria, cont'd

Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria (from FOA)

As applicable, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- **Protections for human subjects**
- **Inclusions of women, minorities, and children**
- **Appropriate use of vertebrate animals**
- **Management of biohazards**

Research Involving Human Subjects

Important Considerations

- Is the proposed study exempt from human subject review?
- Are there any apparent physical, psychological or social risks to the human subjects?
- Are the protections adequate?
- What are the potential benefits to the subjects and to mankind?
- Are the inclusions of minorities and both genders adequately addressed?

Research Involving Children

Children must be considered for inclusion in all human subject research supported by NIH

- Child is defined as an individual under age 21
- If children are included, Investigator must address:
 - age range
 - expertise of investigative team
 - facilities
 - sufficient numbers
- If children are not included, must justify exclusion

Inclusion of Women and Minorities

Proposed clinical research must include:

- Plans for the inclusion of minorities and members of both genders, as well as the inclusion of children.
or
- A clear and compelling justification indicating that inclusion is inappropriate due to the health of the subjects or the purpose of the research.

Vertebrate Animal Welfare

Important Considerations

- Proposed use of the animals, and species, strains, ages, sex, and numbers to be used
- Justifications for the use of animals and for the appropriateness of the species and numbers proposed
- Adequacy of veterinary care
- Procedures for limiting discomfort, distress, pain and injury
- Euthanasia in accord with American Veterinary Medical Association guidelines

Biohazards

Important Considerations

- Are the necessary special facilities available to protect the environment and research personnel from potentially hazardous conditions?
- Will biohazardous materials be handled appropriately?
- Have employees been trained adequately in safe practices?

At the Meeting

Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order.
- Discussions start with the application with the best average preliminary Overall Impact score.

Not Discussed Applications

- About half the applications will be discussed.
- Applications unanimously judged by the review committee to be in the lower half are not discussed.
- The panel will discuss any application a reviewer wants to discuss.

Scoring

- Score applications on five core criteria using a scale of 1-9
- Preliminary overall impact/priority score using 1-9 scale
- Discussed applications receive an overall score from each eligible (i.e., without conflicts of interest) panel member, and these scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.
- All applications will receive scores:
Not discussed applications will receive initial criterion scores from the three assigned reviewers.

Your Summary Statement

- Scores for each review criterion
- Critiques from assigned reviewers
- Administrative notes if any



If your application is discussed, you also will receive:

- An overall impact/priority score and percentile ranking
- A summary of review discussion
- Budget recommendations

When Preparing an Application

- Read instructions
- Never assume that reviewers will know what you mean
- Refer to pertinent literature
- Don't overstate the significance of your research
- State rationale of proposed investigation
- Include well-designed tables and figures
- Present an organized, lucid write-up
- Don't be overly ambitious
- Obtain pre-review from colleagues at your organization

Insider's Guide to Peer Review for Applicants:

<http://www.csr.nih.gov/applicantresources/insider>

Alignment

Criteria	Application
Significance	Research Strategy a. Significance
Investigator(s)	Biosketch Personal Statement
Innovation	Research Strategy b. Innovation
Approach	Research Strategy c. Approach
Environment	Resources Environment

What Reviewers Look for in Applications

- Significance and impact
- Exciting ideas
- Clarity
- Ideas they can understand -- Don't assume too much
- Realistic aims and timelines -- Don't be overly ambitious
- Brevity with things that everybody knows
- Noted limitations of the study
- A clean, well-written application

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Common Problems in Applications

- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions