



**Center for
Scientific Review**

Peer Review Process

Lauren Fordyce, PhD
Scientific Review Officer
Center for Scientific Review

Key Dates for Application Review

- Application Due – July 14, 2022*
- Scientific Merit Review – January 2023
- Advisory Council Review – May 2023

*According to the RFA, no late applications will be accepted for this Funding Opportunity Announcement.

Application must be completed at the time of submission

- No changes can be made after submission; missing or corrected materials CANNOT be submitted after the deadline
- NIH Post-Submission Material Policy (NOT-OD-19-083) – limited type of materials can be submitted
 - Must be submitted 30 days prior to the meeting
 - Must be submitted by your Authorized Organization Representative (AOR)/Signing Official (SO)
 - Reviewers are not obligated to read post submission materials.

CONFLICTS OF INTEREST

We make all efforts to avoid any real or perceived conflicts (as defined by NIH policies).

- Out of Meeting Conflicts
- Out of Room Conflicts
- **Out of Meeting Conflicts are excluded from participating in the review meeting:**
 - Anyone involved in or listed as involved personnel on any of the applications
 - People from the tobacco industry

CONFLICTS OF INTEREST

Out of Room Conflicts are excluded from the review of a specific application

- Collaborators/Former collaborators (last three years)
- Mentors/Mentees (10 years or forever) of anybody involved in your application
- Everyone from an Institution where any of the application's involved personnel works (this can sometimes include those writing Letters of Support)

Scored Review Criteria

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission](#) are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact - Overall

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 following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria - Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important issue or a critical barrier in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge and/or technical capability be improved? How will successful completion of the aims affect the concepts, methods, and technologies related to the manufacture, distribution, and marketing of tobacco products?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those 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?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research in the field of tobacco science as it relates to the manufacture, distribution, and marketing of tobacco products? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, or instrumentation 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?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Scored Review Criteria (same as listed in FOA)

- **Overall Impact**

- Reviewers provide an overall priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) in consideration of the following review criteria and additional review criteria

- **Significance**

- Does the project address an important issue or a critical barrier in the field? If the aims of the project are achieved, how will scientific knowledge and/or technical capability be improved? How will successful completion of the aims affect the concepts, methods, and technologies related to the manufacture, distribution, and marketing of tobacco products?

- **Investigator**

- **Innovation**

- Does the application challenge and seek to shift current research in the field of tobacco science as it relates to the manufacture, distribution, and marketing of tobacco products? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, or instrumentation 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?

- **Approach**

- **Environment**

Scored Review Criteria (Clinical Trials)

- Additionally for Clinical Trials there are specific questions within the core review criteria that will need to be addressed including:
 - PD/PI expertise and experience organizing, managing, and implementing clinical trials
 - Is the study design justified and appropriate? Are the study populations appropriate and well-justified?
 - Are potential ethical issues adequately addressed? Is the process for informed consent and assent appropriate?
 - Data management and statistical analysis
 - Does the Environment include the appropriate infrastructure for managing a clinical trial?

Additional Review Criteria (TCORS)

These are not given individual scores but will be considered and weighted in the overall impact score of the application

Additional Review Criteria - Overall

As applicable for the TCORS proposed, 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.

The overall TCORS will be evaluated as an integrated research effort. The review will assess the level of merit of the TCORS as an integrated effort, including the following criteria:

Center Coordination and Synergy:

- Is the Integrative Theme of the proposed Center clearly evident across Research Projects?
- Are TCORS Scientific Domains clearly specified?
- Is there evidence of the proposed Center's coordination/collaboration across the TCORS components (Cores, Research Projects)?
- Are there advantages of conducting the proposed research as a center program rather than through separate research efforts? Will the research efforts taken together have more impact on the field than each separate project conducted in isolation? Will the research proposed in individual projects be enhanced by the Center?
- Are timelines and milestones in-place that will allow an evaluation of progress to be made?

Research Potential to Inform Regulatory Decision Making:

- Does the applicant clearly describe how Center Research Project outcomes and findings would inform potential regulatory decision-making?

Career Enhancement Plan:

- Can the proposed career enhancement core adequately provide the expertise, resources, and institutional commitment to students and investigators and move them towards independent careers in tobacco regulatory science? Have they provided adequate plans for networking and collaboration?

Additional Review Criteria (TCORS)

- Center Coordination and Synergy
- Research Potential to Inform Regulatory Decision Making
- Career Enhancement Plan

Standard Additional Review Criteria

Standard aspects of NIH application:

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources

Thank you!

Please review Section V. “Application Review Information” in the RFA/Funding Opportunity Announcement for more details about the specific review criteria