



Center for
Scientific Review

Tobacco K01, K99/R00 Applications Peer Review Process

**Pre-Application Webinar for RFA-OD-18-005, -006, -007, & -008
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NIH Clinical Trial

RFA-OD-18-005: K01 CT not allowed

RFA-OD-18-006: K01 CT required

RFA-OD-18-007: K99/R00 CT not allowed

RFA-OD-18-008: K99/R00 CT required

Definition: A research study in which **one or more human subjects** are **prospectively assigned to one or more interventions** (which may include placebo or other control) to **evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

Scored Review Criteria

Overall Impact

- Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Candidate

- Does the candidate have the potential to develop as an independent and productive researcher? Do the letters of reference show evidence that the candidate has a high potential for becoming an independent scientist?
- If proposed, does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study? Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

Career Development Plan

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence? Are plans to integrate the candidate into the tobacco regulatory research community and present the research findings to the research community appropriate?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

Scored Review Criteria (cont.)

Research Plan

- Are the proposed research question, design, and methodology of significant scientific and technical merit? Does the project address an important issue or a critical barrier in the field? Is there a strong scientific premise for the proposed project? Is there evidence of a rigorous study design?
- If clinical trials are proposed, will the clinical trial experience contribute to the research project?

Mentor(s), Collaborators, etc.

- Are the mentor's/collaborator's research qualifications in the area of the proposed research appropriate?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

Environment & Institutional Commitment

- Is the institutional commitment to the career development of the candidate appropriately strong? Are the research facilities, resources, and training opportunities adequate and appropriate?
- If clinical trials are proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Additional Review Criteria

These are not given individual scores but will be considered in the overall impact score

- **Time Line (Clinical Trials only)**
- **Protections for Human Subjects**
- **Inclusion of women, minorities and Children**
- **Vertebrate Animals**
- **Biohazards**

Additional Review Consideration

As applicable, reviewers will consider the following items, but will not give scores for them, and they are not considered in the overall impact score

- **Training in the responsible conduct of research**
- **Select agent research**
- **Resource sharing plans**
- **Budget and period of support**

Peer Review Principles

- **Review will be conducted by Special Emphasis Panel**
- **Conflicts will be excluded**
- **Most reviewers will be from outside the government (Federal employees cannot exceed 25% of the members)**
- **Standard NIH review procedures will be used, and every applicant will receive written feed back (a “summary statement”)**

Impact/Priority Scores

- **For reviewers, the NIH score scale is 1-9, in integers, 1 being best, highest impact**
- **All eligible reviewers on the panel will give an overall impact score for each discussed application. The average score is multiplied by 10, and rounded to the nearest integer, giving the priority scores from 10-90, 10 being the best overall score**
- **Not Discussed applications (about 50%) will not receive priority scores**

Review Contact

If you have additional questions specifically about the review process for these applications, please contact:

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