Tobacco Regulatory Science Program (TRSP)
Career Development Awards in Tobacco Regulatory Research
K01 and K99/R00

Application Information
June 22, 2018
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NIDA Training Director
## Types of Funding Opportunity Announcements (FOAs):

<table>
<thead>
<tr>
<th>Type of FOA</th>
<th>Description</th>
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| **Parent Announcements** | - Broad FOAs allowing applicants to submit an investigator-initiated application for a specific activity code  
- Many NIH institutes and centers (IC) participate  
- Usually ongoing (3 yrs)  
- Use standard due dates |
| **Program Announcements (PAs)** | - FOAs issued by one or more Institutes and Centers to highlight areas of scientific interest  
- Encourage applications for a new or ongoing program  
- Usually ongoing (3 yrs)  
- Use standard due dates  
- Types of PAs:  
  - PAS: with set-aside funds  
  - PAR: special receipt, referral, and/or review considerations |
| **Requests for Applications (RFA)** | - FOAs issued by one or more Institute or Center to highlight well-defined areas of scientific interest to accomplish specific program objectives  
(Make sure the science you are proposing fits the scope of the RFA!)  
- Indicate the amount of set-aside funds  
- Indicate anticipated number of awards  
- Usually single due date  
- Institute/Center usually convenes review panel |

Mentored Career Development Award: K01

PURPOSE: provide support and protected time to continue training and conduct research, in order to transition to an independent research position.

• Pursuing a new research area that warrants additional mentored research experience; or in need of substantial augmentation of current skills

• In need of three, four, or five years of mentored support

• Can devote a minimum of 75% of full-time professional effort

• Appropriate and committed mentor(s)

• Appropriate and feasible training, career development, and research plans

• Goal to pursue NIH R01
NIH Pathway to Independence Award: K99/R00

PURPOSE: to increase and maintain a strong cohort of new and talented, NIH-supported, independent investigators.

This program is designed to

• to facilitate a timely transition of outstanding postdoctoral researchers from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions, and

• to provide independent NIH research support during junior faculty stage to help launch competitive, independent research careers.
NIH Pathway to Independence Award: K99/R00

K99 Phase (1-2) years – mentored phase
- Obtain additional research training
- Mentoring to transition to independent faculty position

R00 Phase (3 years) – independent phase
- Transition is dependent upon
  - Offer of a tenure-track or equivalent position
  - Competitive start-up package
  - K99 phase progress and R00 research plans
  - Transition is reviewed internally (NIH)
# Career Development Awards for Tobacco Regulatory Science

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<tr>
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<th><strong>K01</strong></th>
<th><strong>K99/R00</strong></th>
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<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Supervised career development for individuals with <strong>doctoral degrees</strong> leading to <strong>research independence</strong></td>
<td>Facilitates timely transitions from mentored <strong>postdoctoral training</strong> to <strong>independent</strong> (faculty) research position/independent research program</td>
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| **Budget (yearly)** | Salary: up to $90k  
Research: up to $60k | K99: up to $90k salary + $60K research expenses, travel  
R00: $249k total (salary, research expenses, travel) |
| **Project Period** | 3-5 years  | K99: up to 2 years, R00: 3 years |
| **Renewable**  | No  | No |
| **Foreign Inst.** | No  | No |
| **Eligibility** | Never received major grant: R01, P01, etc. | Have not completed 4 years of postdoctoral research training at time of application or resubmission; never received R03, R21, R01, etc. |
| **Mentor**     | Required, non-reimbursable | K99: required, non-reimbursable; R00: independent |
# Scored Review Criteria

<table>
<thead>
<tr>
<th>Career Development Awards</th>
<th>Research Grants</th>
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<tbody>
<tr>
<td>Candidate</td>
<td>Investigator(s)</td>
</tr>
<tr>
<td>Career Development Plan/Career Goals &amp; Objectives/Plan to Provide Mentoring</td>
<td>Innovation</td>
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<tr>
<td>Research Plan</td>
<td>Significance</td>
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<tr>
<td>Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)</td>
<td>Approach</td>
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<tr>
<td>Environment &amp; Institutional Commitment to the Candidate</td>
<td>Environment</td>
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How to Decide Which RFA to Apply to: Clinical Trial Required vs. Clinical Trial Not Allowed

If you can answer “YES” to the following four questions, apply to the “Clinical Trial Required” RFA:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Studies intended solely to refine measures are not considered clinical trials. Studies that involve secondary research with biological specimens or health information are not clinical trials.
Resources to Clarify Information About Clinical Trials

• Interactive Decision Tool: https://grants.nih.gov/ct-decision/
• Case Studies: https://grants.nih.gov/policy/clinical-trials/definition-clinical-trials.htm
• FAQs: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm
Understanding the Application, Review, and Award Cycle

Review and Award Cycles – EXAMPLE for K01

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<tr>
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<th>DATE</th>
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<tr>
<td>Letter of Intent</td>
<td>30/60 days prior to application due date</td>
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<tr>
<td>Application Due Date</td>
<td>2018: July 19 &amp; November 8</td>
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<tr>
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<td>2019: July 19 &amp; November 8</td>
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<tr>
<td>Scientific Merit Review</td>
<td>2018: October</td>
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<td>2019: February &amp; October</td>
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<td></td>
<td>2020: February</td>
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<tr>
<td>Summary Statement Release</td>
<td>30 days after review</td>
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<td>Advisory Council Review</td>
<td>January 2019</td>
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<td>Earliest Start Date</td>
<td>April 2019</td>
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Tips for Success

• **Read the instructions.**
• Address all areas of the application (biohazards, attachments).
• Email the Program Officer/Scientific Review Officer if you have questions.
• Advisory Committees with application Letters of Support versus Letters of Recommendation/Reference submitted online for K99/R00 applications.
• **My Bibliography links/passwords.**
• Address all areas of rigor and transparency completely.
• Post-submission materials: NOT-OD-17-066
Utilize Resources on the TRSP Webpage

https://prevention.nih.gov/tobacco-regulatory-science-program/funding-opportunities

TRSP Research Priorities

Studies supported by TRSP

RFA link

FAQs

K01 vs. K99/R00