

NIH-FDA Tobacco Control Regulatory Science

Administrative and Budgetary Requirements

Pre-Application Webinar
June 22, 2018; noon-1:30pm

Career Awards in Tobacco Control Regulatory Research
(Mentored K01 and K99/R00 mechanisms)

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Career Awards in Tobacco Control Regulatory Research

- The NIH, via support from the FDA Center for Tobacco products (CTP), intends to fund approximately 6-10 career award applications for each of the four separate Funding Opportunity Announcements (FOAs) discussed during this webinar.

Career Awards in Tobacco Control Regulatory Research

FOAs published, as of June 4, 2018:

- [RFA-OD-18-005](#), Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (**K01 - Independent Clinical Trial Not Allowed**)
- [RFA-OD-18-006](#), Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (**K01 - Independent Clinical Trial Required**)
 - [RFA-OD-18-007](#), Pathway to Independence Award in Tobacco Regulatory Research (**K99/R00 - Independent Clinical Trial Not Allowed**)
 - [RFA-OD-18-008](#), Pathway to Independence Award in Tobacco Regulatory Research (**K99/R00 - Independent Clinical Trial Required**)

Career Awards in Tobacco Control Regulatory Research

Important dates to remember for RFA-OD-18-005:

[RFA-OD-18-005](#), Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (**K01 - Independent Clinical Trial Not Allowed**)

Letter of intent (LOI) due dates:

- **First round:** The LOIs are due 30 days prior to the first application date.
- **Subsequent rounds:** The LOIs are due 60 days prior to the first application due date.

Application due dates:

- July 19, 2018, November 8, 2018, July 19, 2019, November 8, 2019, by 5pm local time of applicant organization.

Earliest start dates:

- April 2019, July 2019, April 2020, July 2020

Career Awards in Tobacco Control Regulatory Research

Important dates to remember for RFA-OD-18-006:

[RFA-OD-18-006](#), Mentored Research Scientist Career Development Award in Tobacco Regulatory Research (**K01 - Independent Clinical Trial Required**)

Letter of intent (LOI) due dates:

- **First round:** The LOIs are due 30 days prior to the first application date.
- **Subsequent rounds:** The LOIs are due 60 days prior to the first application due date.

Application due dates:

- July 19, 2018, November 8, 2018, July 19, 2019, November 8, 2019, by 5pm local time of applicant organization.

Earliest start dates:

- April 2019, July 2019, April 2020, July 2020

Career Awards in Tobacco Control Regulatory Research

Important dates to remember for RFA-OD-18-007:

[RFA-OD-18-007](#), Pathway to Independence Award in Tobacco Regulatory Research (**K99/R00 - Independent Clinical Trial Not Allowed**)

Letter of intent (LOI) due dates:

- **First round:** The LOIs are due 30 days prior to the first application date.
- **Subsequent rounds:** The LOIs are due 60 days prior to the first application due date.

Application due dates:

- July 19, 2018, November 8, 2018, July 19, 2019, November 8, 2019, by 5pm local time of applicant organization.

Earliest start dates:

- April 2019, July 2019, April 2020, July 2020

Career Awards in Tobacco Control Regulatory Research

Important dates to remember for RFA-OD-18-008:

- [RFA-OD-18-008](#), Pathway to Independence Award in Tobacco Regulatory Research (**K99/R00 - Independent Clinical Trial Required**)

Letter of intent (LOI) due dates:

- **First round:** The LOIs are due 30 days prior to the first application date.
- **Subsequent rounds:** The LOIs are due 60 days prior to the first application due date.

Application due dates:

- July 19, 2018, November 8, 2018, July 19, 2019, November 8, 2019, by 5pm local time of applicant organization.

Earliest start dates:

- April 2019, July 2019, April 2020, July 2020

Career Awards in Tobacco Control Regulatory Research

Project periods for each career award opportunity:

[RFA-OD-18-005](#) and [RFA-OD-18-006](#) (K01s):

- Project period may not exceed 5 years.

[RFA-OD-18-007](#) and [RFA-OD-18-008](#) (K99/R00s):

- 1-2 year project period as a mentored K99 candidate, followed by up to a 3 year project period (R00 phase), as an independent scientist.

Career Awards in Tobacco Control Regulatory Research

PI eligibility and appointments:

K01 PI eligibility:

- PI must have a full-time appointment at the applicant institution. Intramural candidates are **not** eligible.

K99/R00 PI eligibility:

- PI must have a full-time appointment at the applicant institution.
 - Intramural candidates **are** eligible.

Career Awards in Tobacco Control Regulatory Research

Allowable costs:

Both K01 and K99/R00:

- Salary up to \$90,000 + associated fringe benefits
 - Research support costs up to \$60,000
 - F&A costs are 8%

K99/R00 only:

- R00 phase may not exceed \$249,000 annually, to include salary, fringe benefits, research support allowance, and applicable F&A costs

Career Awards in Tobacco Control Regulatory Research

Post-Award Information for both K01s and K99/R00s:

- Mid-period progress reporting due every 6 months, following the project/budget start dates
- All FDA-funded awards are excluded from carryover authority; therefore, prior approval is required (see terms on award notice)

QUESTIONS and/or CONCERNS?

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