Pre-Application Webinar for Tobacco Regulatory Research Career Awards
June 22, 2018

RFA-OD-18-005 (K01 Independent Clinical Trial Not Allowed)
RFA-OD-18-006 (K01 Independent Clinical Trial Required)
RFA-OD-18-007 (K99/R00 Independent Clinical Trial Not Allowed)
RFA-OD-18-008 (K99/R00 Independent Clinical Trial Required)

Helen I Meissner, ScM, PhD
Director, Tobacco Regulatory Science Program
Tobacco Regulatory Science Program (TRSP) Background

- Emerged as a result of a partnership between FDA’s Center for Tobacco Products (CTP) and NIH
- Has NIH oversight responsibility for trans-NIH activities with CTP (FOAs, grantee mtgs., etc.)
- TRSP represents an addition to the NIH tobacco research program and does not replace or diminish any existing tobacco research activities at any of the Institutes or Centers.
Tobacco Regulatory Science Program (TRSP)

Located in the NIH Office of Disease Prevention (ODP), the Tobacco Regulatory Science Program (TRSP) coordinates the trans-NIH collaborative effort with the Food and Drug Administration’s (FDA) Center for Tobacco Products (CTP) to conduct research to support its regulatory activities over tobacco products. Established in 2013 through an interagency partnership with the FDA’s Center for Tobacco Products, TRSP coordinates the collaborative research effort across the NIH with the FDA CTP.

With the passage of the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the FDA acquired the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health. Within the framework of the Tobacco Control Act, the NIH and FDA formed this partnership to foster tobacco regulatory research. The NIH has the infrastructure for the solicitation, review, and management of scientific research, and several NIH Institutes and Centers have long supported tobacco-related research as part of

What’s New

- FDA Announces Comprehensive Regulatory Plan To Shift Trajectory of Tobacco-Related Disease, Death
- Tobacco Regulatory Research Measures Available in the PhenX Toolkit

FOAs and Webinars

- New! Reissuance of K Mechanism FOAs
- Application Due Dates:
  - July 19, 2018, November 8, 2018,
  - July 19, 2019, November 8, 2019
- K Mechanism Pre-Application
AGENDA

- Research to Inform Regulatory Actions – Ami Bahde (CTP, FDA)
- Application – Michele Rankin (NIDA)
- Review – Weijia Ni (CSR)
- Grants Management – Amy Bucheimer (NIDA)
- Questions and Answers

Slides will be posted to website
http://prevention.nih.gov/tobacco