RFA-OD-19-022
Secondary Analyses of Existing Datasets of Tobacco Use and Health

Tobacco Regulatory Science
R21 Pre-Application Webinar
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NIH NATIONAL CANCER INSTITUTE

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Purpose

- Encourage the analysis of public use datasets that may inform tobacco regulatory actions in the United States (U.S.).
- Invite R21 applications proposing the innovative analysis of existing (publicly available) **nationally representative** U.S. cross-sectional and longitudinal data, to investigate novel scientific ideas and/or to generate new models, systems, tools, methods, or technologies that have the potential for significant impact on biomedical or biobehavioral research in areas relevant to FDA CTP
- Other publicly available data sets would be considered depending on the analyses to be conducted; however, nationally representative analyses will receive priority
  - Use of **non**-nationally-representative data will need justification
- Research results from this FOA are expected to generate findings and data that are directly relevant in informing the FDA's regulation of the manufacture, distribution, and marketing of tobacco products to protect public health

Datasets

May use any cross-sectional or longitudinal data pertaining to knowledge, attitudes, perceptions, behaviors, dependence, toxicity, and health effects

Example datasets including, but not limited to:

- Population Assessment of Tobacco and Health (PATH) Study
- National Youth Tobacco Survey (NYTS)
- Tobacco Use Supplement to the Current Population Survey (TUS-CPS)
- National Adult Tobacco Survey (NATS)
- National Health Interview Survey (NHIS)
- Behavior Risk Factor Surveillance System (BRFSS)
- Monitoring the Future surveys (MTF)
- National Survey on Drug Use and Health (NSDUH)
- National Health and Nutrition Examination Survey (NHANES)
- Health Information National Trends Survey (HINTS)
- National Longitudinal Mortality Study-Tobacco Use Follow-up (NLMS)

Using Existing Datasets

- Additional NIH data repositories can be found at https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html
- Datasets may be merged or linked to other existing datasets (e.g., geographic characteristics or policy information by region, state, or locality can be linked to existing national survey data)
  - **Example:** Tobacco Use Supplement to the Current Population Survey (TUS-CPS) dataset linkage to other CPS supplement datasets, such as the American Time Use Survey (ATUS)

Scientific Interest Areas

- Innovative analyses of extant data
  - new aims that are being addressed with existing data
  - new or advanced methods of analyses
  - novel combination and integration of datasets to investigate new research questions
- *Research using extant data that analyzes effects or outcomes that were not previously examined in the original scope of research is a priority for this announcement*
- For example, datasets collected for other purposes may be reanalyzed to identify patterns of tobacco use, perceptions of product harm, health effects from tobacco use
- Should consider the risk for spurious findings when conducting multiple analyses and/or using large datasets
- Applications **should not** propose to carry out currently ongoing data analysis or the maintenance and distribution of data sets

Priority Research Questions

Include, but not limited to:

- Identify and explain between-person differences and within-person changes in tobacco-use patterns, (e.g., frequency and duration of use by specific product type and brand, uptake of new products, and dual- and poly-use of tobacco products)
- Examine the role of electronic nicotine delivery systems (ENDS) in the initiation of and use of other tobacco products, including the increase in tobacco product(s) use, cessation of tobacco product(s) use, or relapse to tobacco.
  - Planned analyses should take into consideration product characteristics such as flavors and/or device types

Priority Research Questions (continued)

- Identify tobacco use behavior patterns associated with cigarette smoking and switching among tobacco products
- Assess between-person differences and within-person changes over time in attitudes, behaviors, exposure to tobacco products, and related biomarkers among and within population subgroups
- Examine the effect of different quantities and counts of tobacco products (i.e., number of cigars per package, number of snus pouches/portioned moist snuff per package) on trial, experimentation, and initiation among never tobacco-using youth and young adults and increased use/frequency, product switching, and delayed cessation among current tobacco users

Priority Research Questions (continued)

- Examine the pattern of use of flavored tobacco products (what flavors are used at what point during tobacco use transitions) associated with: (1) transitions from never used to established use of tobacco products (including ENDS), and (2) transitions from established use of tobacco products (including ENDS) to complete cessation of all tobacco products
- Examine how measures of comprehension and understanding of tobacco product risk relate to tobacco product use
- Examine how tobacco product marketing, packaging, and/or labeling of newly deemed tobacco products (across various types of tobacco product categories) relate to patterns of product use, including dual use, transitions, and switching behavior—among youth, young adults, and adults

Priority Research Questions (continued)

- Examine health outcomes from various tobacco product types (**except** cigarettes)
- Examine the long- and short-term health effects of transitioning from combustible to non-combustible tobacco, and from non-combustible to combustible tobacco, using biomarker and/or health outcomes
- Compare biomarker expression profiles with self-reported use of tobacco products, and analyze measures associated with biomarkers of exposure that may inform risk associated with tobacco exposure for mortality/morbidity by age, sex, and race/ethnicity
- *Current FDA-CTP research priorities can be found here: https://prevention.nih.gov/tobacco-regulatory-science-program/tobacco-regulatory-research-priorities*

Scientific Interest Areas

- Applications may focus on one or more classes of tobacco products
- Identify vulnerable population, describe how the population is important to the research question.
- Vulnerable populations include:
  - Youth and young adults
  - Race/ethnicity
  - Low SES
  - Rural populations
  - People with mental health or medical co-morbidities
  - Military/veterans
  - The LBGTQ community
  - Pregnant women/women of reproductive age

Non-responsive Research Topics

- Areas that may be responsive to FDA CTP's tobacco regulatory authority but NOT responsive for the purposes of this RFA:
  - Applications that do not use existing data
  - Applications focusing on non-tobacco products
  - Graphic health warnings for cigarette packages and advertisements
  - Communicating harmful and potentially harmful constituents to the public
  - Impacts of marketing restrictions on adults
  - Studies of demographics and/or risk perceptions that describe only exposure to advertising without linking exposure to tobacco use behaviors

Special Considerations

- Data used for these research projects should meet ethical conditions as described in the RFA
- *The FDA CTP has adopted the* National Advisory Council on Drug Abuse (NACDA) *guidance regarding tobacco industry funding of applicants responding to this FOA*
  - https://www.drugabuse.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/council-statements/points-to-consider-regarding-tobacco-industry-funding-nida)
  - While this guidance was originally issued for NIDA applicants, it is relevant for all applications submitted under this FOA.

Scientific Research Contacts

- Rachel Grana Mayne, PhD, MPH **(NCI)**
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- Abraham Bautista, PhD **(NIAAA)**
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- Mary Kautz, PhD **(NIDA)**
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- Fred Tyson, PhD **(NIEHS)**
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Letter of Intent

- Not required, but strongly recommended
- **Due:** 60 days prior to the application due dates in RFA
- **Include:** Descriptive title of proposed activity; Name(s), address(es), and telephone number (s) of the PD(s)/PI(s); Name of other key personnel; Participating institution(s)
  - Draft specific aims - strongly recommended
- Send to TRSP@mail.nih.gov or can be mailed to address in RFA

Helpful Hints: Ensuring your application is responsive

- ***Strongly Recommended:***
  - Discuss your research and specific aims with the Scientific/ Research Contact from one or more Institutes relevant to your research
    - Particularly important if using a dataset not specified in the RFA
  - Contact the Scientific Research Contact(s) before submitting your LOI, if possible
  - Name the Scientific Areas of Interest for your proposed research both within your LOI ***and*** application
  - Submit the LOI early to allow time for feedback

For More Information

- Contact Scientific Contacts on the RFA
- Email TRSP@mail.nih.gov
- Read the **Frequently Asked Questions** document located on the TRSP website:

  https://prevention.nih.gov/sites/default/files/2019-07/FAQs-for-R21-SecondaryAnalyses.pdf

  - *Note that the FAQs will be periodically updated as additional questions are received*