

RFA-OD-19-021

Maximizing the Scientific Value of Existing Biospecimen Collections (R21 Clinical Trial Not Allowed)

Pre-Application Webinar

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Office of Disease Prevention

Purpose

- To stimulate exploratory research relevant to the mission of the Food and Drug Administration (FDA) - Center for Tobacco Products (CTP) using existing (publicly available) biospecimens currently stored in repositories in the United States.
- To maximize the scientific value of these stored collections and to provide researchers with an opportunity to generate preliminary data for subsequent research proposals.
- To generate data for use in subsequent grant applications
- Research Projects must address the research priorities related to the regulatory authority of the Food and Drug Administration (FDA) - Center for Tobacco Products (CTP)

Biospecimen Collection Examples

- Population Assessment of Tobacco and Health (**PATH**) Study biospecimen collections: <https://www.icpsr.umich.edu/icpsrweb/content/NAHDAP/pathstudy-biospec-index.html>
- National Health and Nutrition Examination Survey (**NHANES**) biospecimen collections: <https://www.cdc.gov/nchs/nhanes/index.htm>
- Prostate, Lung, Colorectal and Ovarian (**PLCO**) Cancer Screening Trial collections: <https://biometry.nci.nih.gov/cdas/plco/>.
- National Heart, Lung, and Blood Institute (NHLBI) Biospecimen and Data Repository Information Coordinating Center (**BioLINCC**) Biorepository: www.biolincc.nhlbi.nih.gov

Relevant Biospecimen Requirements

- Must conduct at least one new lab measurement, but can combine that with pre-existing measurements.
- Nationally representative collections will receive priority.
- If using a non-nationally representative collection, application must include why the collection is unique and why it contains elements not available in a nationally representative data set.
- Request for biospecimens from the collection must be initiated at least 30 days prior to the application due date. Confirmation must be included in the grant application.
- Biospecimens may be pooled with biospecimens from another collection, but this should be justified.

Research Objectives and Scope

Research examples include but are not limited to:

1. Compare biomarkers of tobacco exposure and potential harm related to use of noncigarette tobacco products across surveys.
2. Identify and develop biomarkers of harm and exposure unique to new and emerging non-cigarette tobacco products (both tobacco specific and flavor specific), including but not limited to e-cigarettes.
3. Examine the effect of chronic exposure to waterpipe tobacco smoke/hookah on biomarkers of inflammation and other harm.
4. Utilize urinary specimens to analyze biomarkers of tobacco exposure not currently measured by other national studies in urine.
5. Utilize blood specimens to analyze biomarkers of tobacco exposure not currently measured by other national studies.

6. Examine alterations in genetic and epigenetic markers associated with exposure to tobacco products.
7. Examine the health effects of transitioning from combusted to non-combusted tobacco use, using biomarker outcomes.
8. Prospectively compare biomarker expression profiles to self-reported tobacco products use 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.
9. Assess between-persons differences and within-person changes over time in attitudes, behaviors, exposure to tobacco products, and related biomarkers among and within population sub-groups or by risk factors.
10. Identify and examine biomarkers of harm and exposure between dual and polytobacco users, including but not limited to electronic nicotine delivery systems (ENDS) and combusted tobacco products.

All Aims must fall within CTP's regulatory authority

Non-Responsive Research Topics

- Applications that do not use existing data/biospecimens
- Applications focusing on non-tobacco products
- Short-term studies of the acute effects of reduced nicotine content cigarettes
- Studies of short-term health effects and/or acute toxicology/clinical pharmacology testing of early generation ENDS products.
- Applications outside of the regulatory authority of CTP

Scientific Research Contacts

Applicants are **strongly encouraged** to speak to scientific contacts listed in the RFA regarding responsiveness.

NCI: Rachel Grana Mayne, PhD granar@mail.nih.gov

NLHBI: Lisa Postow, PhD lisa.postow@nih.gov

NIAAA: Abraham P. Bautista, PhD bautista@mail.nih.gov

NIDA: Mary Kautz, PhD kautz@nida.nih.gov

NIEHS: Fred Tyson, PhD tyson2@nih.gov

Letter of Intent

Due: August 9, 2019
June 8, 2020
January 7, 2021

Include:

- Number and title for this funding opportunity
- 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)
- **Specific aims- strongly recommended**

Send to TRSP@mail.nih.gov

Applications

- **Due:**
 - October 8, 2019
 - August 7, 2020
 - March 8, 2021
- Budgets are limited to **\$200,000** in direct costs any one year, and **\$275,000** total direct costs for the entire project period.
- Grant awards to this FOA will be up to two years in length

More information

- Contact scientific contacts
- TRSP@mail.nih.gov
- Frequently Asked Questions:

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