NIH Updates: *NCI*

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NIH NATIONAL CANCER INSTITUTE

March 5, 2026

Funding Disclosures

This presentation was supported by the National Cancer Institute

Please add "yes" or "no" to each table cell. If "yes", please turn cell background color to yellow.	Tobacco Industry	E-cigarette & nicotine product industry (excluding pharma)	Pharma Industry
The work being presented has received funding or other means of support from any of the following sources:	No	No	No
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NCI Budget Remains Stable

FY 2024 Operating Budget	FY 2025 Operating Budget	FY 2026 Operating Budget
$7.22 billion	$7.22 billion	$7.35 billion

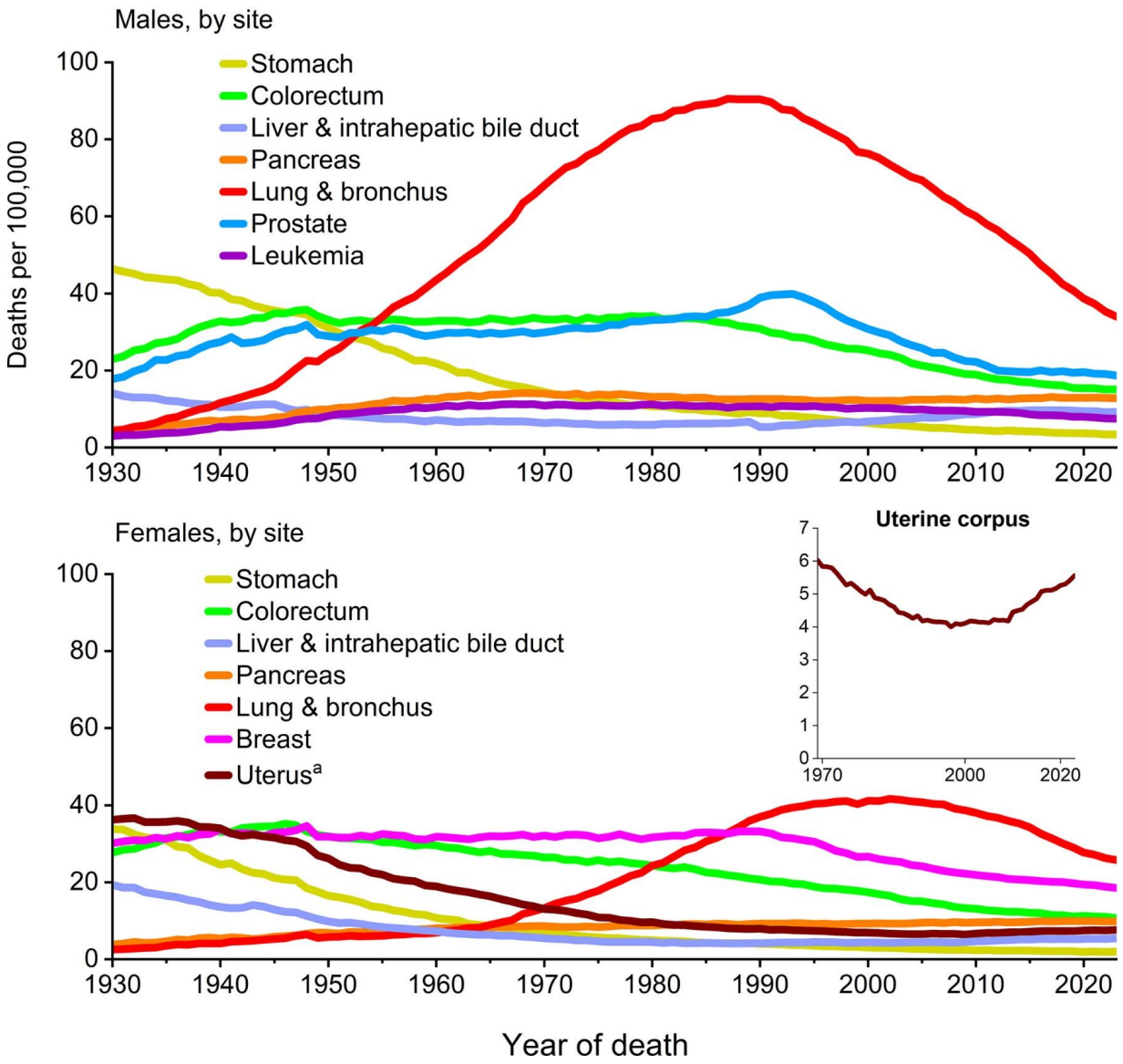
NIH Extramural Research Policy Changes

- Policies regarding large grants
- Basic experimental studies in humans (BESH) no longer considered clinical trials
- Multi-year grant funding
- International collaborations [foreign sub-awards]
- Unified NIH Funding Strategy

  Peer review remains critically important

  Reach out to your PDs! We care about you and we are doing our best to support you.

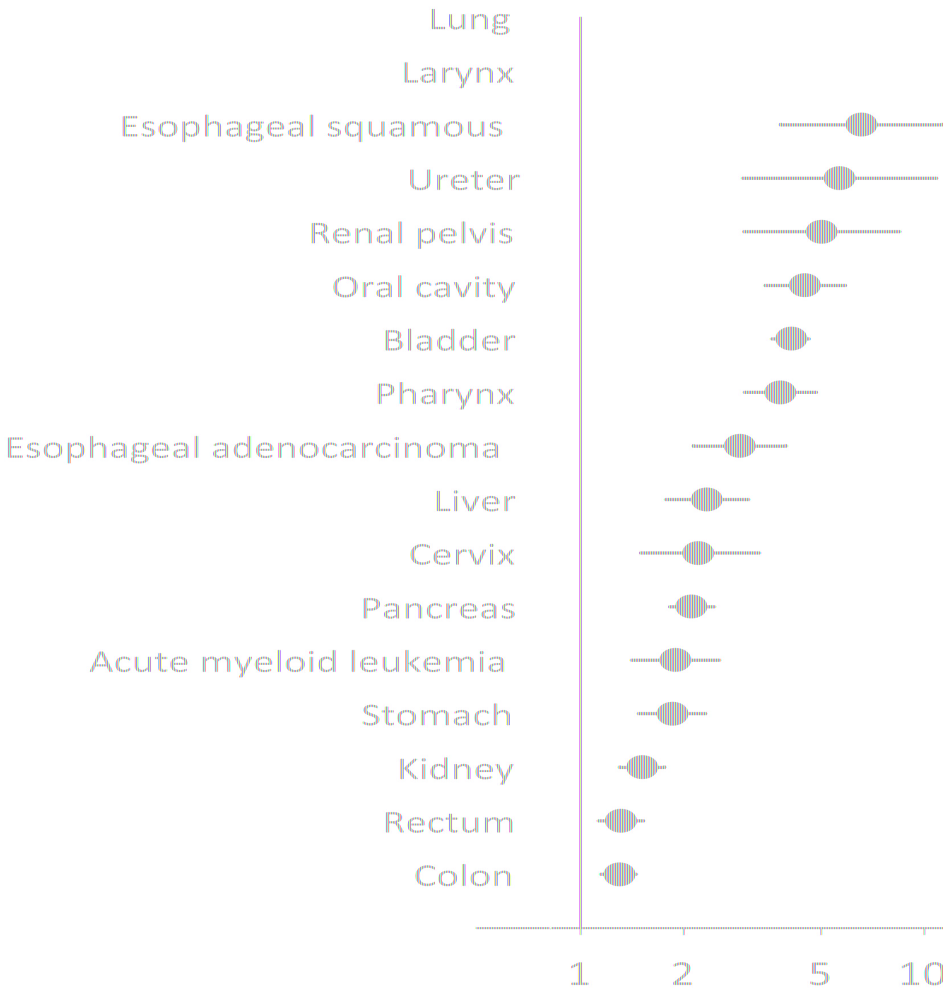
Cancer Statistics 2026



Cancer site	Deaths	% of deaths
Lung	**124,990**	**20.0%**
Colorectal	55,230	8.8%
Pancreas	52,740	8.4%
Breast	42,670	6.8%
Prostate	36,320	5.8%
Liver	30,980	4.9%

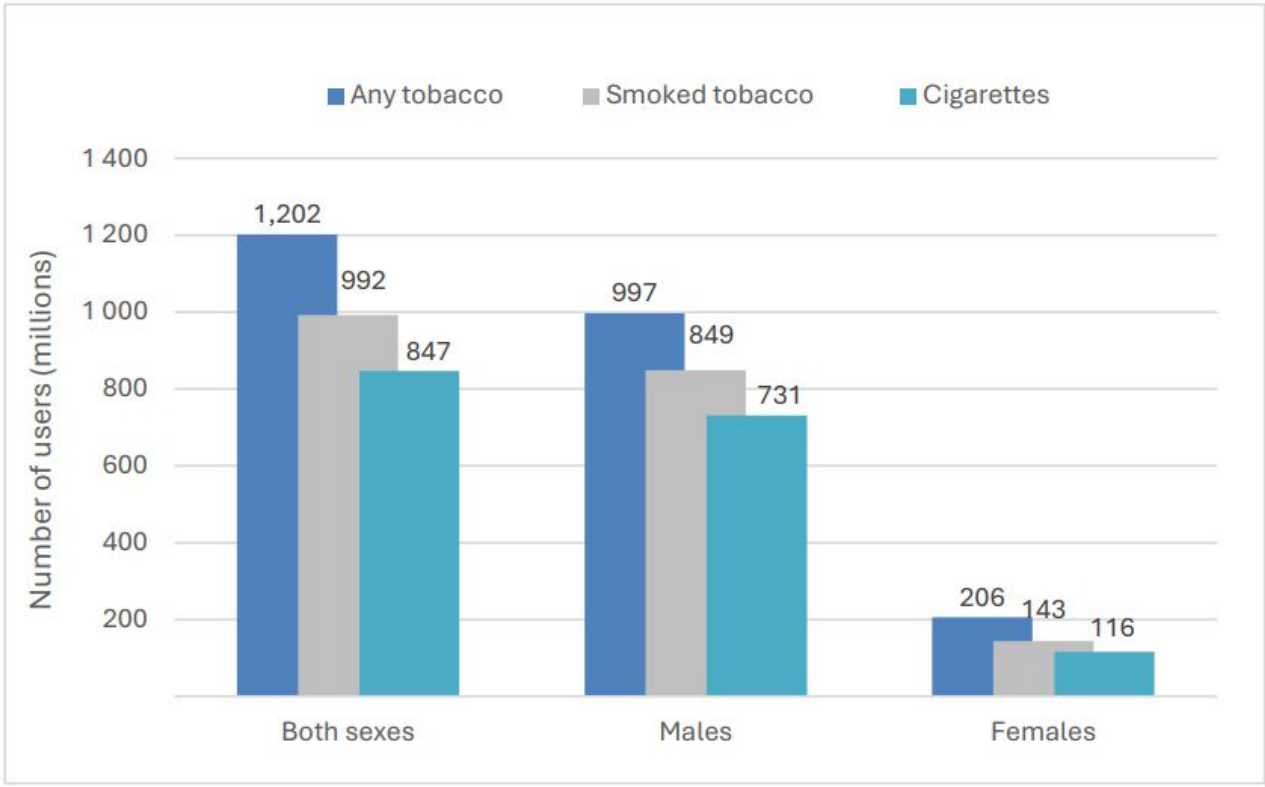
https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.70043

Profound impact of tobacco on cancer

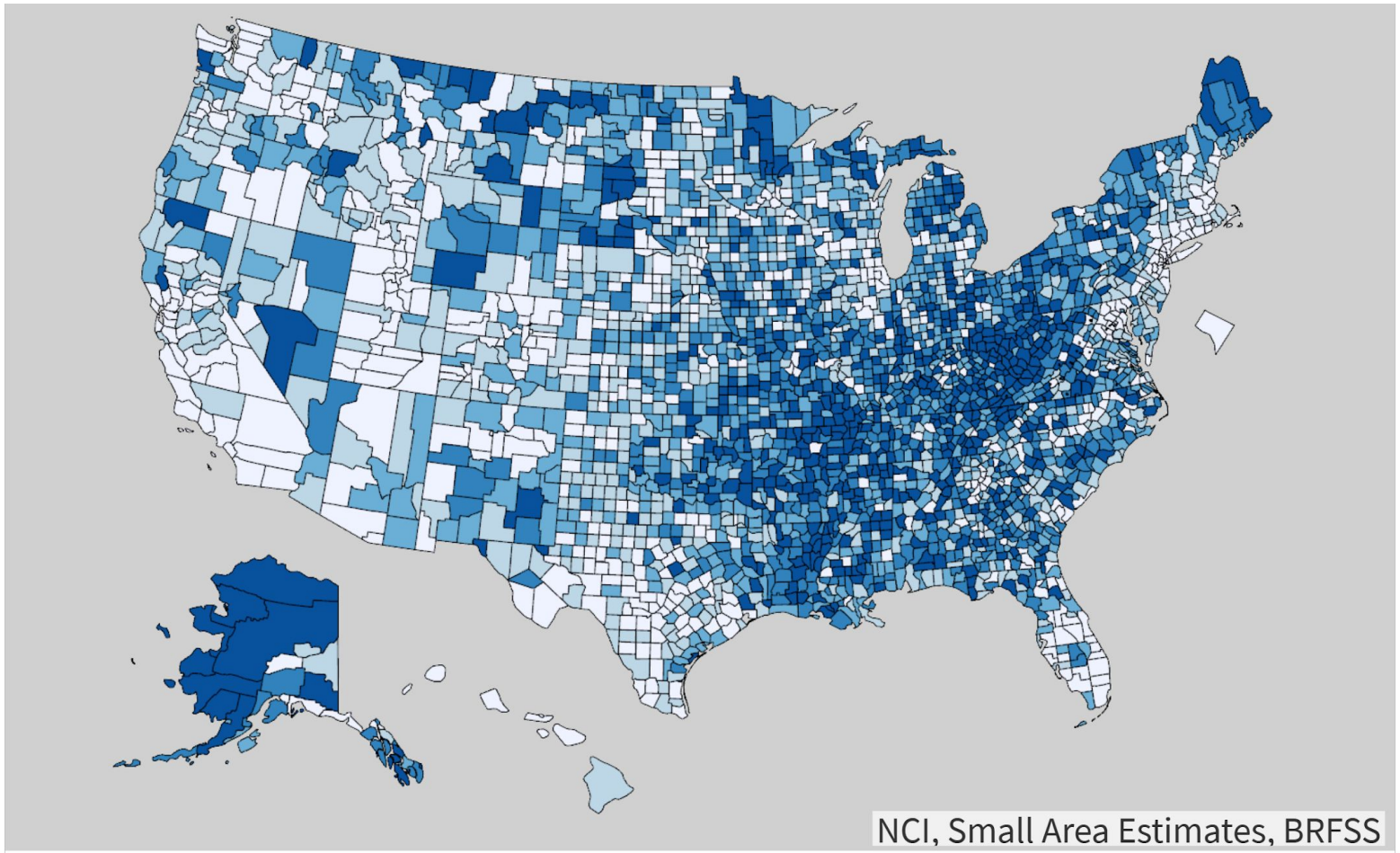


Freedman et al, IJE, 2016

Fig.7: Global number of tobacco users (millions) by type of tobacco, 2024

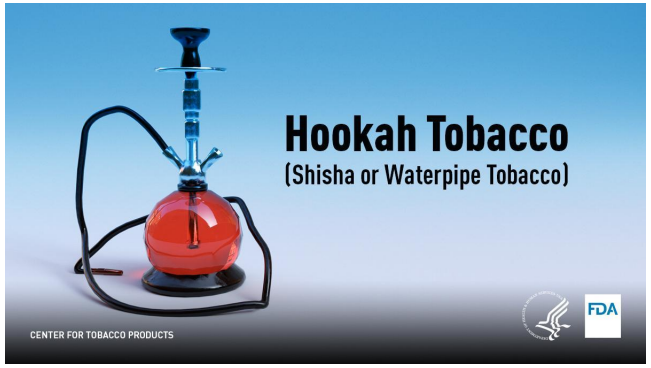


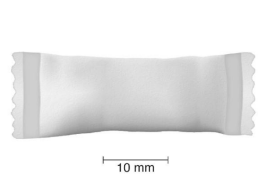
WHO global report on trends in prevalence of tobacco use 2000-2024



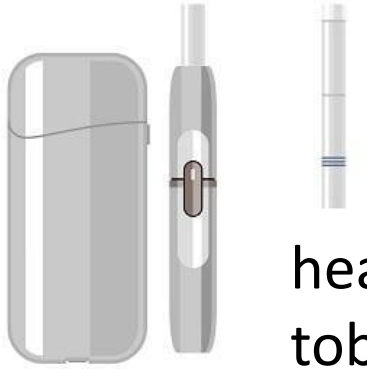
Current Smoking Prevalence (Age 18+)
Estimated Percent

1% - 10.5% | > 10.5% - 12.6% | > 12.6% - 14.3% | > 14.3% - 16.2% | > 16.2% - 33.8%





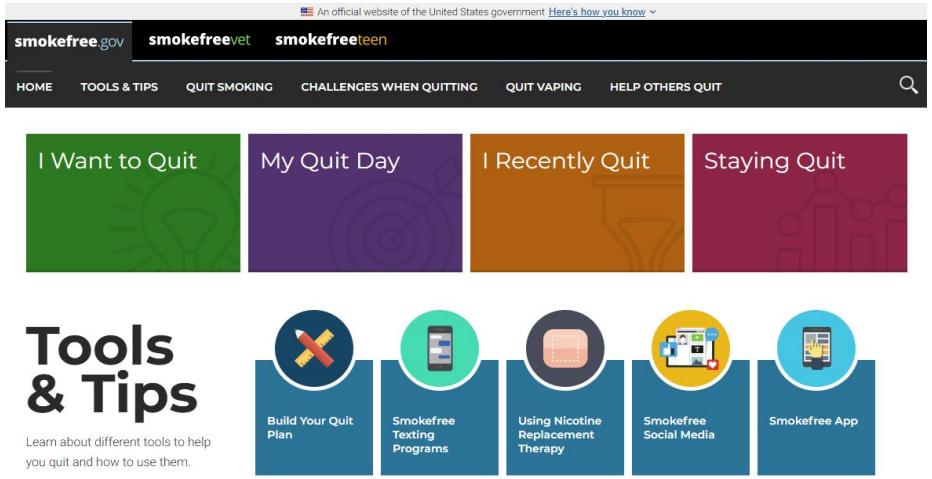
nicotine pouches



heated tobacco

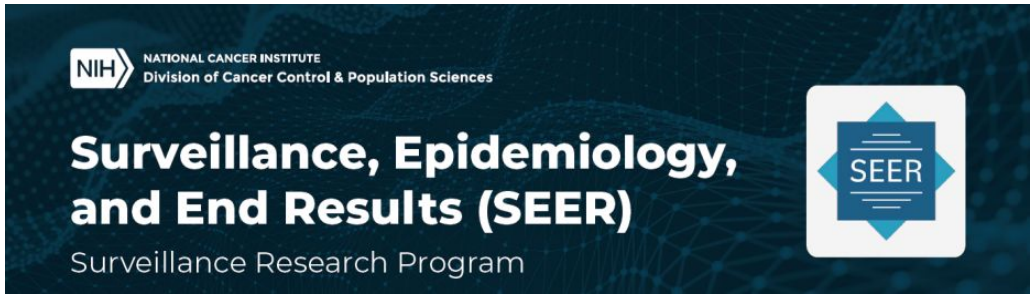
Smokefree.gov

- Smokefree.gov is a suite of **web- and mobile-based smoking cessation resources** that provide evidence-based information and support to people who want to quit smoking and/or vaping
  - Resources include:
    - Mobile-optimized websites (3)
    - Text-messaging based intervention programs (7)
    - Smartphone app (1)
    - Social media accounts (4)



- Smokefree.gov resources reach **~8-9 million** people per year
- Freely available to the public

Surveillance



https://seer.cancer.gov/statistics-network/explorer/application.html

Tobacco Use Supplement
Current Population Survey
2022-2023

Health Information National Trends Survey
hints
HINTS 7 (2024)

PATH
Population Assessment of Tobacco and Health
A collaboration between the NIH and FDA
Wave 7 (2022-2023)

FY 25 TCRB Grants – Type of Research

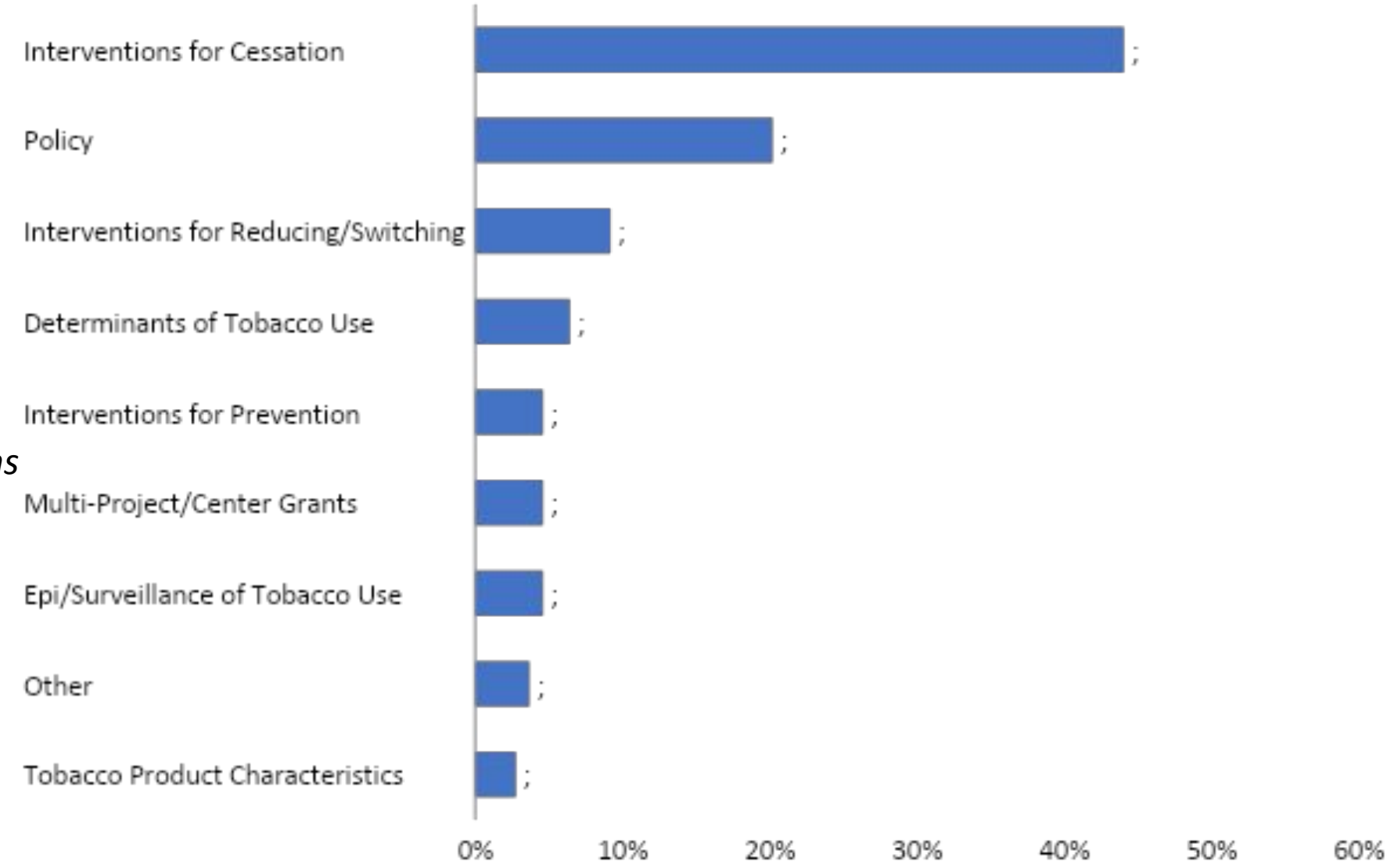
109
Active Grants*

**Excluding no cost extensions*

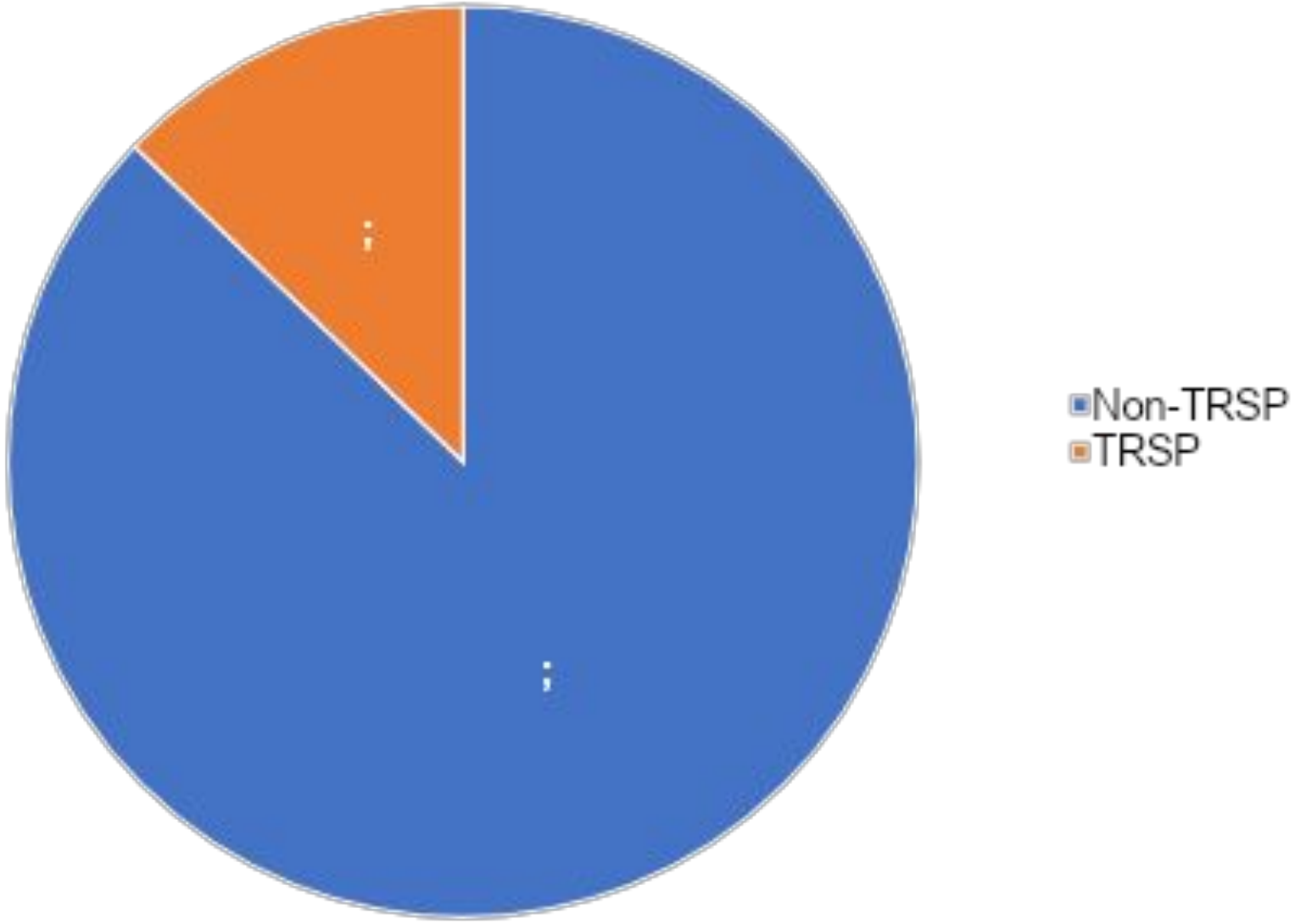
$84,360,226
Total Costs

31
New Grants**

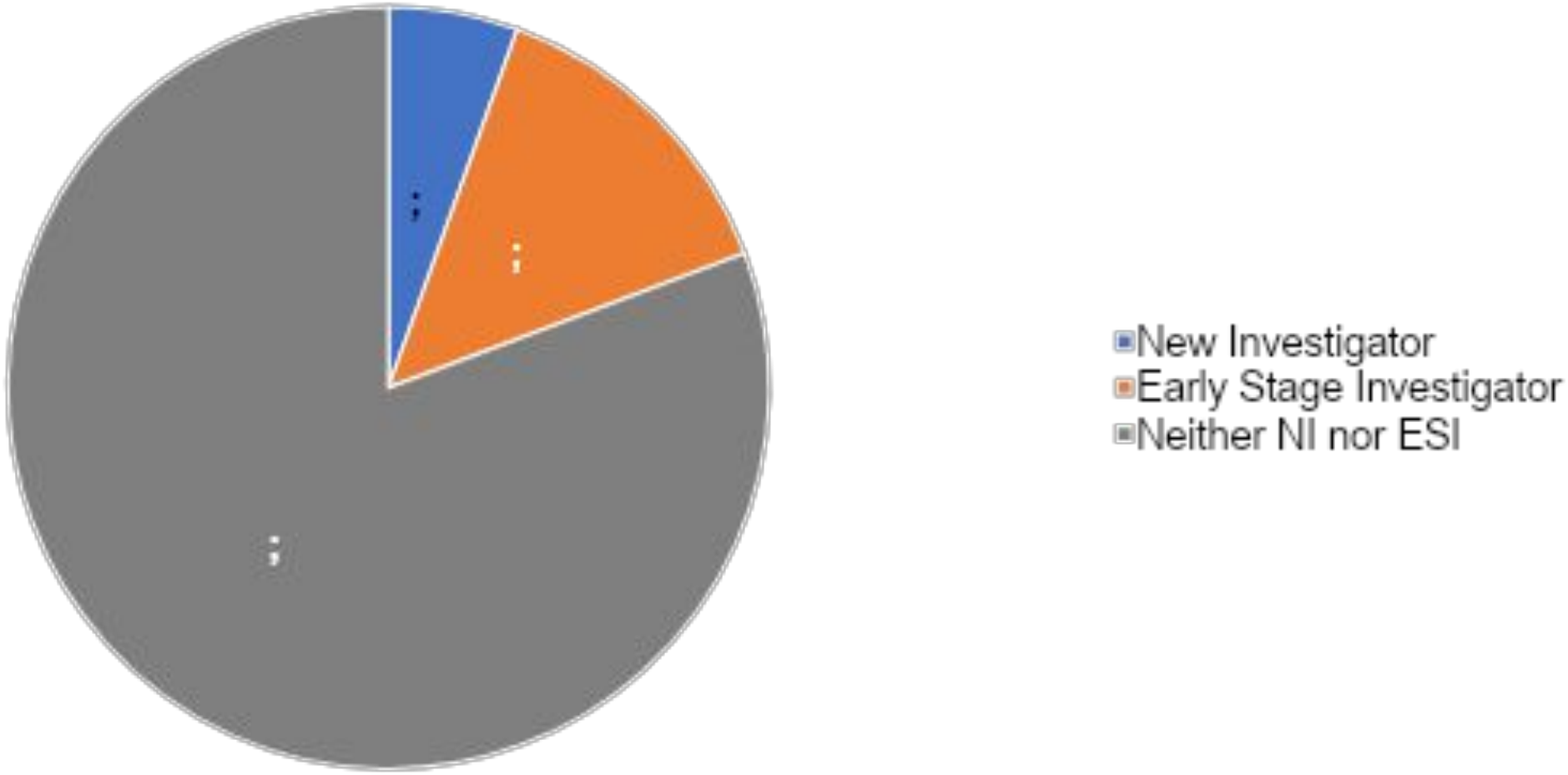
***Type 1 or Type 2 Awards*



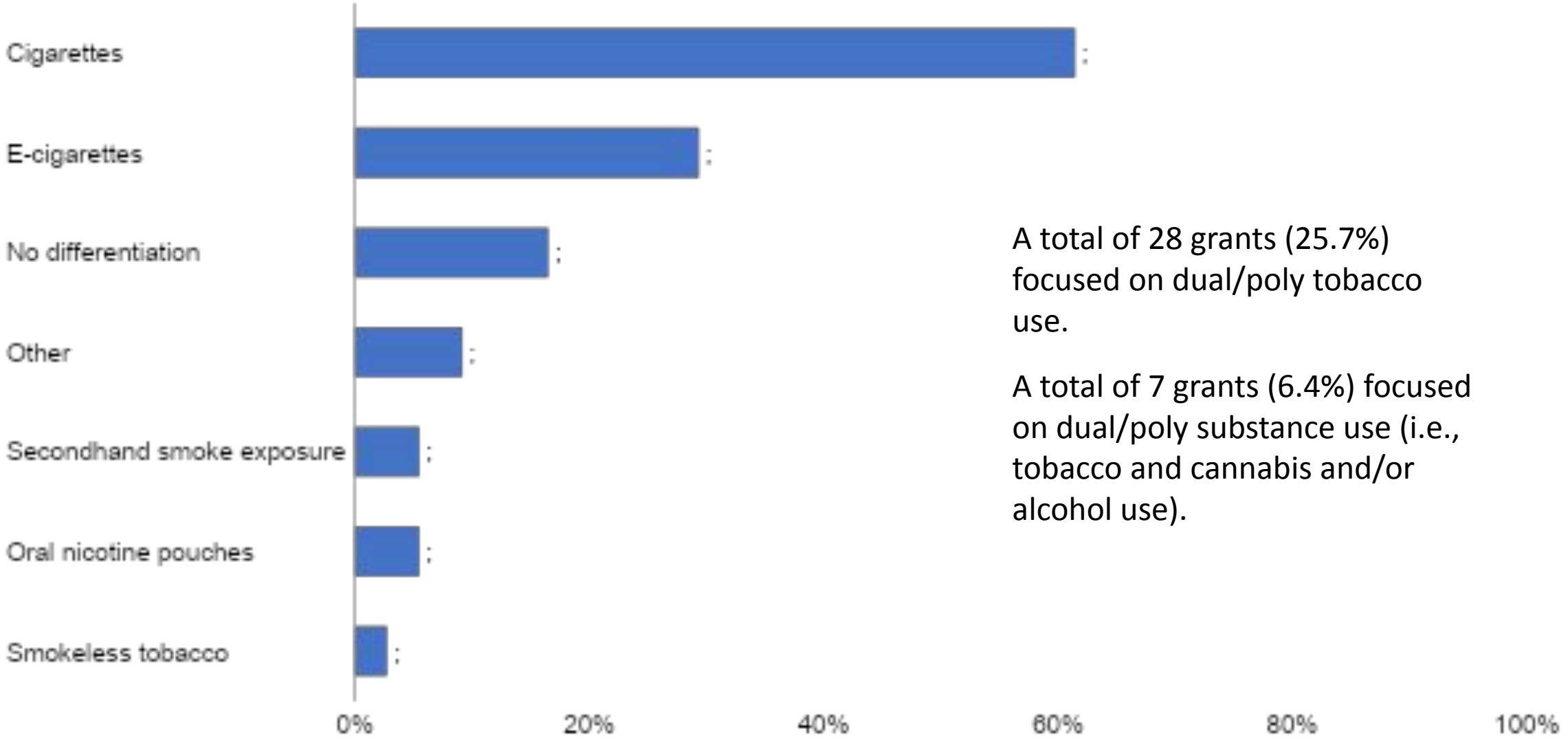
FY 25 Grants – Funding source



FY 25 Grants – Investigator Type



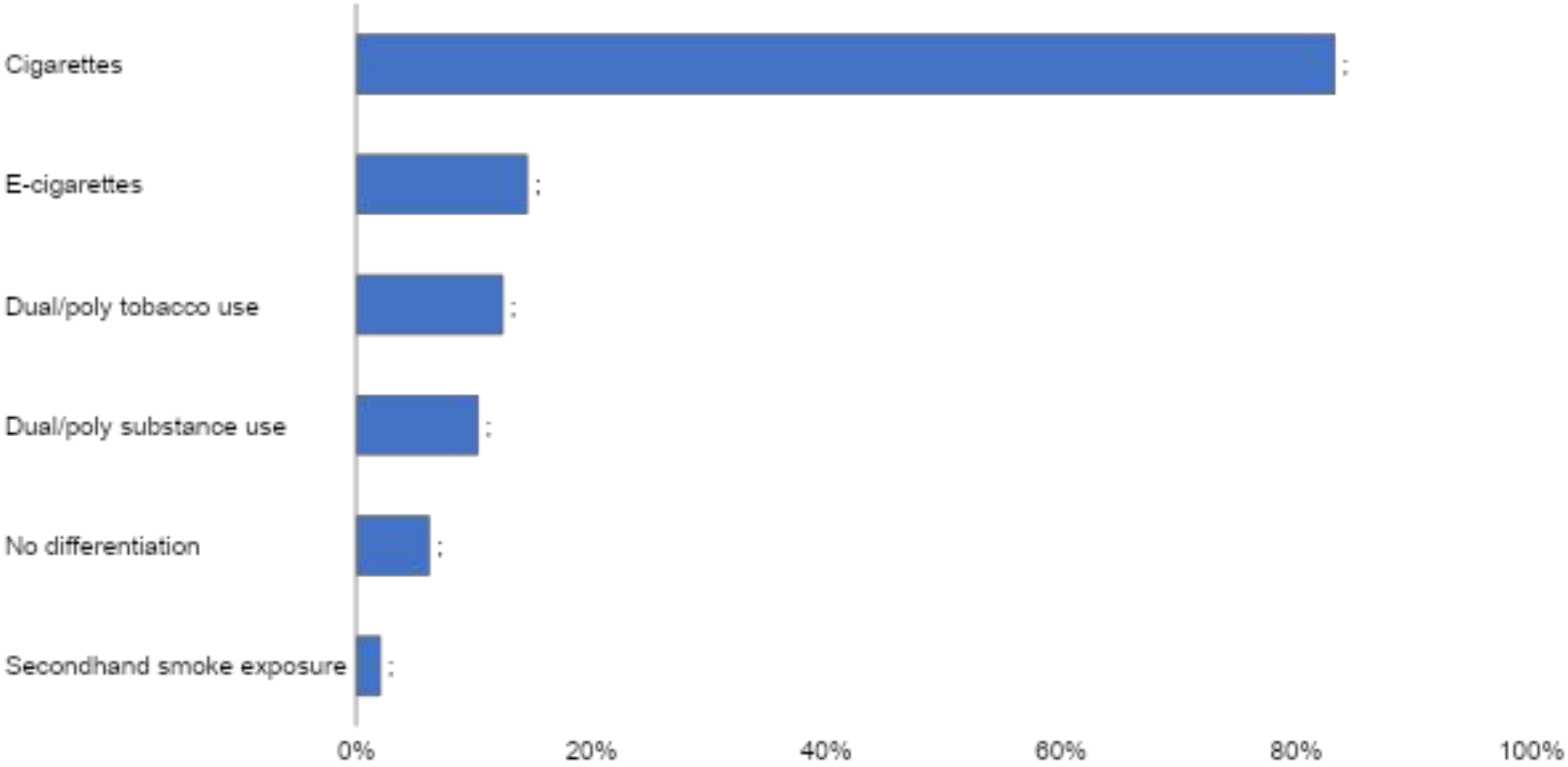
FY 25 Grants - Tobacco Type



A total of 28 grants (25.7%) focused on dual/poly tobacco use.

A total of 7 grants (6.4%) focused on dual/poly substance use (i.e., tobacco and cannabis and/or alcohol use).

FY 25 Cessation Grants - Tobacco Type



TCRB scientific priorities occur across the cancer control continuum

- All tobacco products, including nicotine analogs and replacements
- Tobacco cessation
- Determinants of tobacco use and nicotine dependence
- Poly-tobacco and poly-substance use (tobacco, alcohol, cannabis) and patterns
- Health risks of tobacco products
- Interventions to prevent tobacco use
- Interventions for populations that experience tobacco-related health disparities
- Marketing of tobacco products
- Health communication research
- Policy research
- Natural experiments including de-implementation

NIH Updates: *NIDA*

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NIH National Institute on Drug Abuse

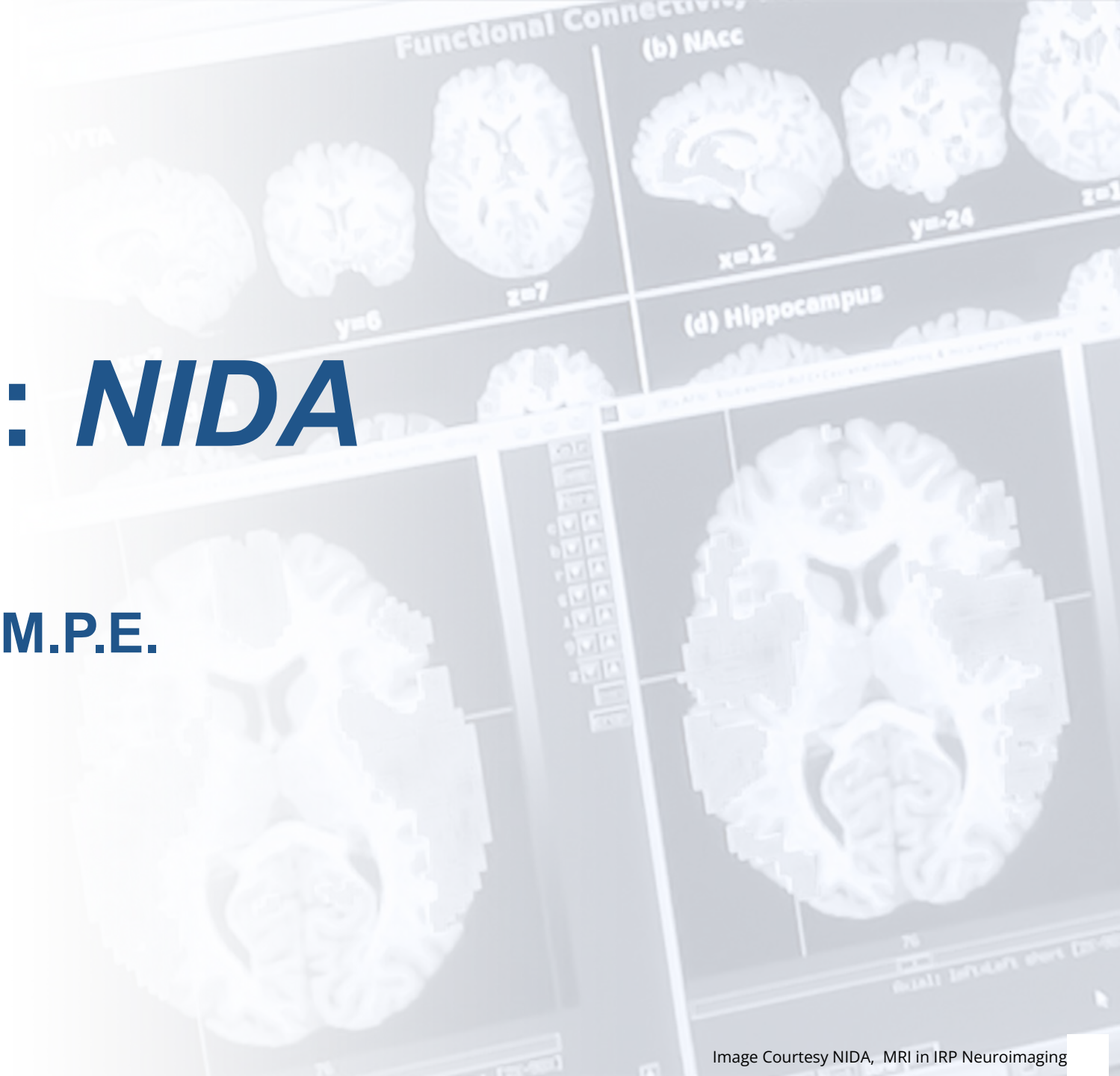

Image Courtesy NIDA, MRI in IRP Neuroimaging

Funding Disclosures

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NIDA Budget Remains Stable

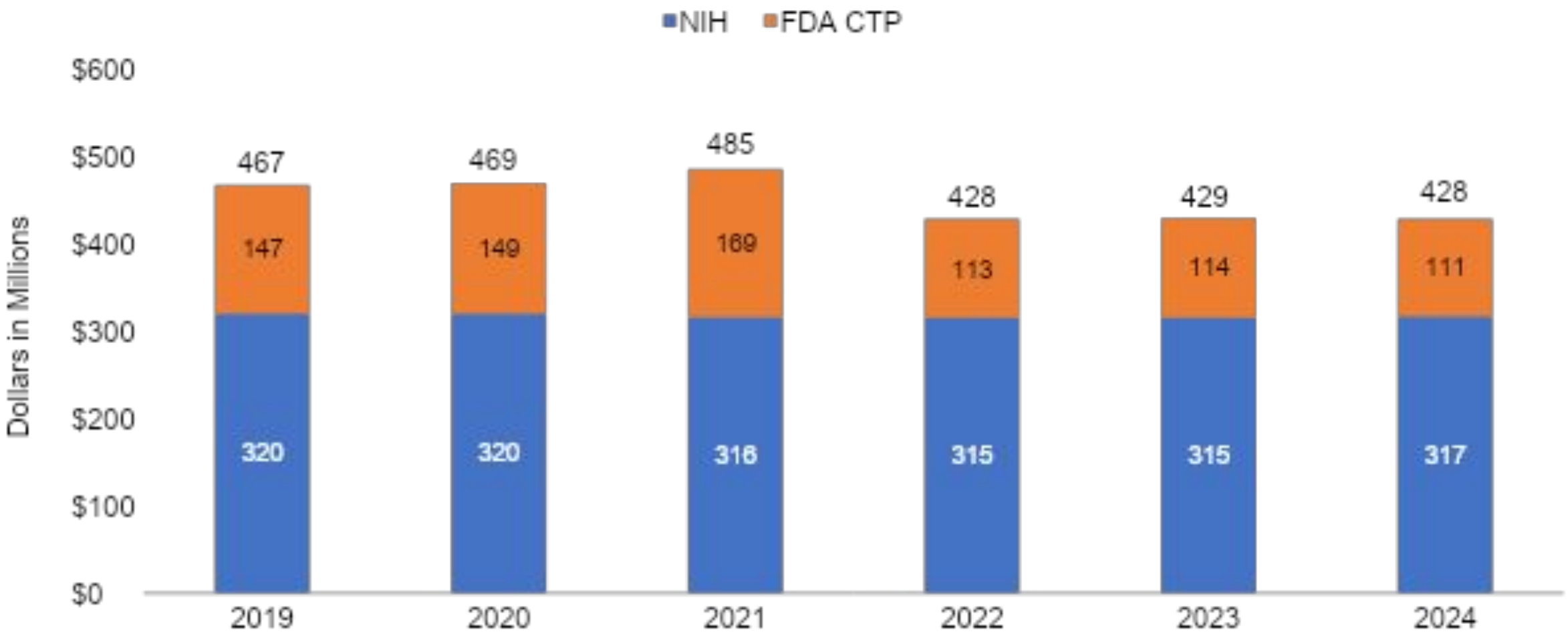
(All dollars are in thousands)

	FY 2024 Operating Budget	FY 2025 Operating Budget	FY 2026 Operating Budget
Base	$1,308,070	$1,308,070	$1,308,070
HEAL	$355,295	$355,295	$355,295
Total	$1,663,365	$1,663,365	$1,663,365

NIH Extramural Research Policy Changes *(selected)*

- Centralization of NIH Peer Review
- Multi-year grant funding
- New application and award structure for international collaborations NOT-OD-25-130
- SBIR and STTR lapse in legislative authority NOT-OD-26-006
- Authority to terminate award if a project no longer effectuates program goals or agency priorities NOT-OD-26-009
- Prioritizing human based research
- Supporting fairness and originality in NIH research applications NOT-OD-25-132

NIH Supported Tobacco Research



^ Funds for the PATH Study are obligated to NIDA via an IAA with the FDA's Center for Tobacco Products.
Source: RCDC Categorical Spending, QVR *FDA Awards Current FY* Standard Report, and the NIDA Financial Management Branch

PATH

Population Assessment of Tobacco and Health

A collaboration between the NIH and FDA

- A nationally representative longitudinal study of tobacco use, its determinants, and its impacts in the U.S. noninstitutionalized population, aged 12+.
- In the field continuously since 2013; collecting data in 2026 for the 14th time; over 50,000 people have participated (with multiple baselines).
- The PATH Study data can be accessed at the NIDA/CTP-funded NAHDAP.
- > 1000 publications from PATH *(so far)*

JAMA Psychiatry

Original Investigation

Cigarette Smoking During Recovery From Substance Use Disorders

Key Points

Question

Findings

JOURNAL ARTICLE CORRECTED PROOF

Correlates of the Use of Nicotine Pouches to Quit Other Nicotine and Tobacco Products among United States Adults: Results from the Population Assessment of Tobacco and Health Study Wave 7 (2022–2023)

Juhan Lee, PhD, Simay Ipek, BA, Andrea H Weinberger, PhD

Nicotine & Tobacco Research, ntaf258, https://doi.org/10.1093/ntr/ntaf258

Published: 19 December 2025 **Article history**

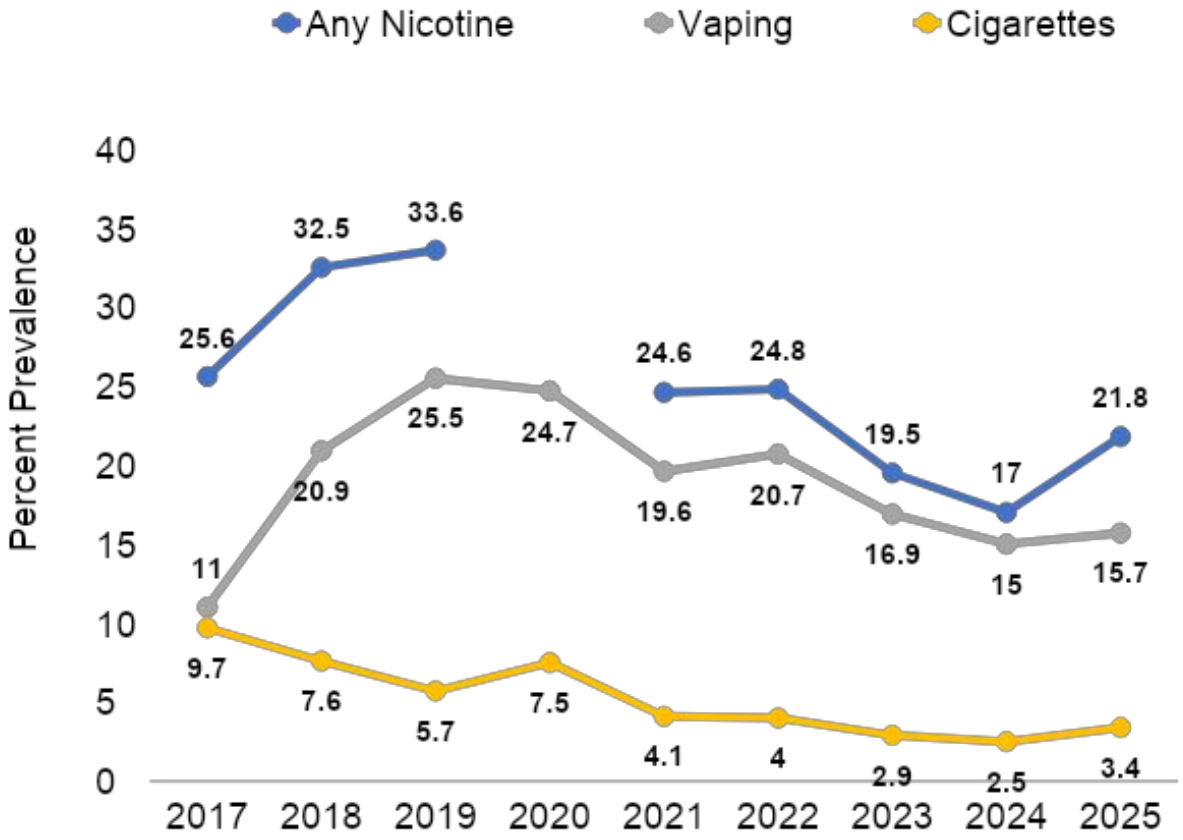
NIDA-Supported Studies Assessing Youth Tobacco Use

The Adolescent Brain Cognitive Development Study® (ABCD)

- **Participants were 9–10-years-old at the time of recruitment with 17-18 year-old follow up in 2025-2026.**
- **1 in 10 pre-teen children say they're curious about using alcohol or tobacco** (Martz, et al. 2022)—Greater curiosity to use tobacco associated with being male, perceived peer cigarette use, easy availability of cigarettes, and no parental rules about cigarette use.
- **Tobacco use in children is associated with poorer cognitive function and smaller brain structures** through a 2-year f/u (Dai, et al. 2022)**.**
- **Parental, environmental, and psychosocial factors are associated with childhood tobacco** (Dai et al., 2023). Parental monitoring and a positive school environment were associated with reduced susceptibility to tobacco use. Susceptibility to e-cigarette use and dual cigarette use was associated with age, female sex, and substance use history Zhang, et al., 2026).
- **Phone ownership and social media at ages 11-12 years old associated with greater odds of nicotine/tobacco use** (Doran, et al., 2025).

Monitoring the Future

Past Month Use among 12th Graders



Insufficient data for 2020 Any Nicotine Use data point.

Basic Research: GWAS Along the Smoking Trajectory

Initiation
(ever *vs.* never)

→

Regular smoking
(Cigarettes per day)

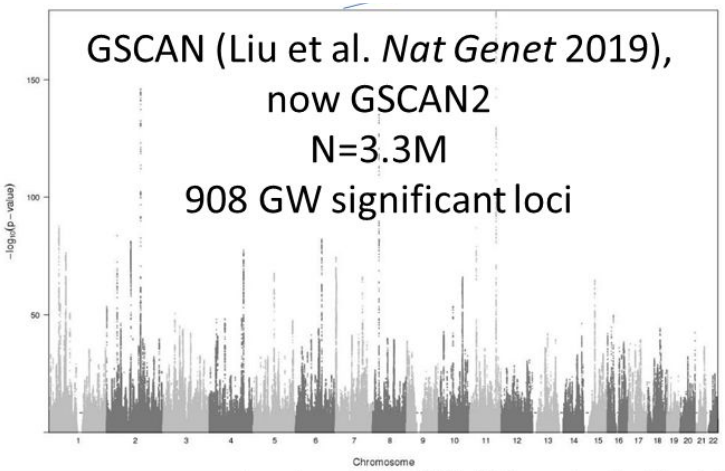
→

Dependence

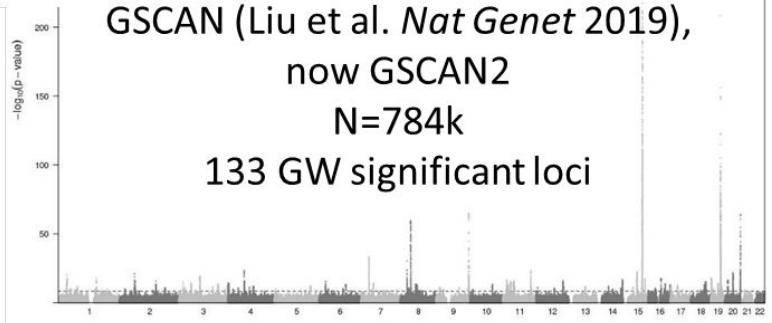
→

Cessation
(current *vs.* former)

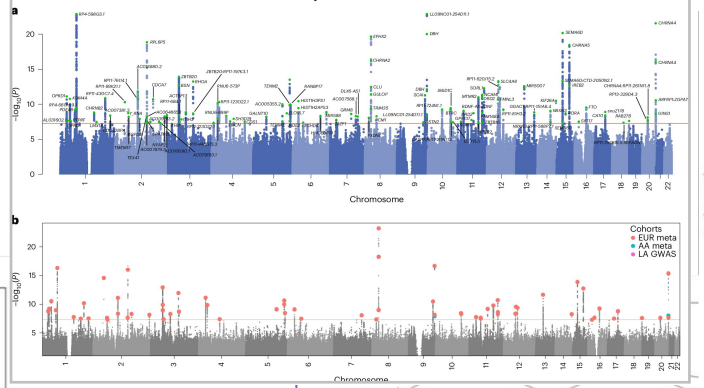
GSCAN (Liu et al. *Nat Genet* 2019),
now GSCAN2
N=3.3M
908 GW significant loci



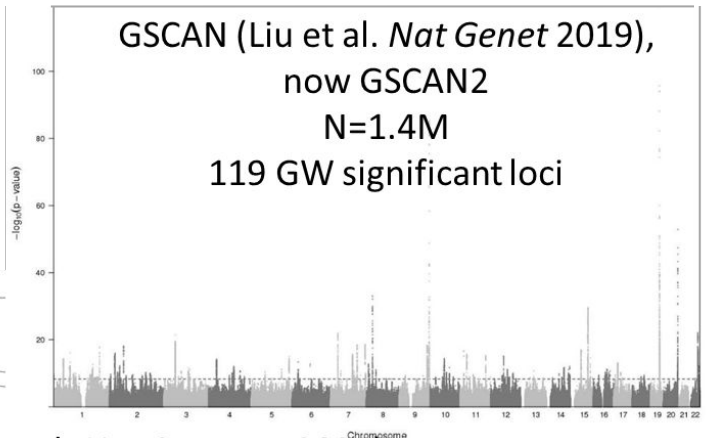
GSCAN (Liu et al. *Nat Genet* 2019),
now GSCAN2
N=784k
133 GW significant loci



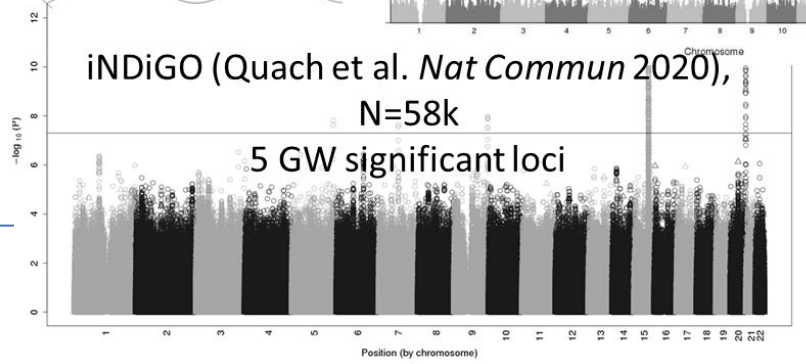
Toikumo et al., Nat Hum Beh 2024),
Multi-ancestry of TUD
N=898K, 461 Risk loci



GSCAN (Liu et al. *Nat Genet* 2019),
now GSCAN2
N=1.4M
119 GW significant loci



iNDiGO (Quach et al. *Nat Commun* 2020),
N=58k
5 GW significant loci



New Targets/Approaches in Tobacco Cessation Intervention Development *(Highlights)*

- **Novel compounds developed from drug discovery forward for tobacco cessation:**
  - Alpha3Beta4 partial agonist
  - mrGlu2 PAM
- **Precision non-invasive neurostimulation targeting reward, executive control, etc., circuits with high specificity:** rTMS for smoking cessation in adults with co-morbid schizophrenia and closed loop rTMS.
- **Repurposing of existing medications FDA-approved for non-smoking related indications**, as monotherapy or as adjuvants to existing gold-standard cessation medications: GLP1s (exenatide) + NRT
- **Existing drugs with no FDA-approved use**: Psilocybin and THCV.
- **Digital therapeutics and behavioral therapies**, including treatments targeting adolescent vaping.

NIDA Small Business Innovation Research Program Supports Development and Commercialization of Novel Therapies

- **Current research**
  - Assessment of a Digitally Controlled Aerosolized NRT (R42DA060773).
  - Innovative E-Vape Administration of Cytisine to Enhance Patient Adherence and Treatment Completion (R43DA061725).
  - Preventing SU Risk in Upper Elementary School Students (R44DA061665).
- **Products moving towards or already commercialized**
  - A Brief Behavioral Activation Mobile Application for Nicotine Vaping Cessation Among Adolescent Primary Care Patients (R41DA053856) is available as the VapeX app.
  - QuitBet: A Digital Social Game that Pays You to Stop Smoking (5R44DA048668) based on contingency management is moving towards commercialization.
  - Benefit and Safety of Cytisinicline (cytisine) for Cessation of Nicotine E-cigarette Use (4R44DA054784). RCT findings demonstrated efficacy of cytisinicline for 12 weeks, with behavioral support, in adults (Rigotti, et. al., 2024). The company was awarded the FDA Commissioner's National Priority Voucher.

Research Areas of Opportunity

- **Mitigating harms**: switching rather than total abstinence
- **Understanding impact of other product use on smoking cessation or switching** (e.g., e-cigarettes, nicotine pouches, heat not burn, synthetic nicotine)
- **Nicotine reduction** as a strategy for decreased abuse liability
- **Eliminating menthol** from tobacco products
- **Marijuana co-use** via combustibles and vaping
- **New products/ingredients**
- **Big Tobacco "targeted" populations** and health disparities
- **Definitions** and self-classification as a "Smoker"

NIH Updates:
Tobacco Regulatory Science Program (TRSP)

Office of Disease Prevention
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, NIH

Kay Wanke, Ph.D., M.P.H.
Acting Director
Tobacco Regulatory Science Program

Kay.Wanke@NIH.gov

National Institutes of Health
Office of Disease Prevention

March 5, 2026

Funding Disclosures

This presentation was supported by the NIH Office of Disease Prevention and the FDA Center for Tobacco Products

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Tobacco Regulatory Science Program (TRSP)

FDA & NIH

NIH National Institutes
Office of Disease Preventic

Tobacco Regulatory Science Program

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS

NIH National Institute on Drug Abuse

NIH National Heart, Lung, and Blood Institute

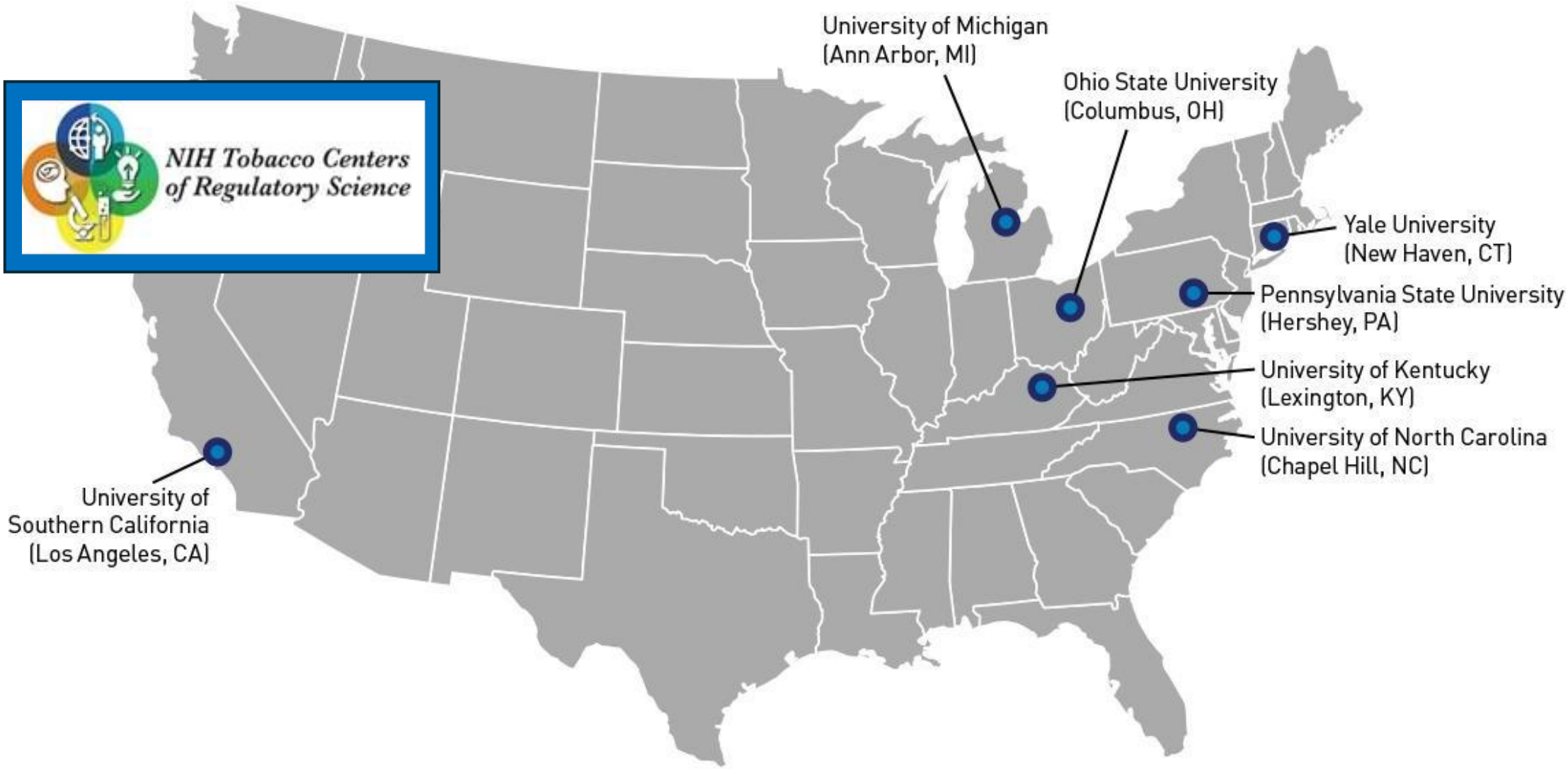
NIH NATIONAL CANCER INSTITUTE

NIH National Institute of Environmental Health Sciences

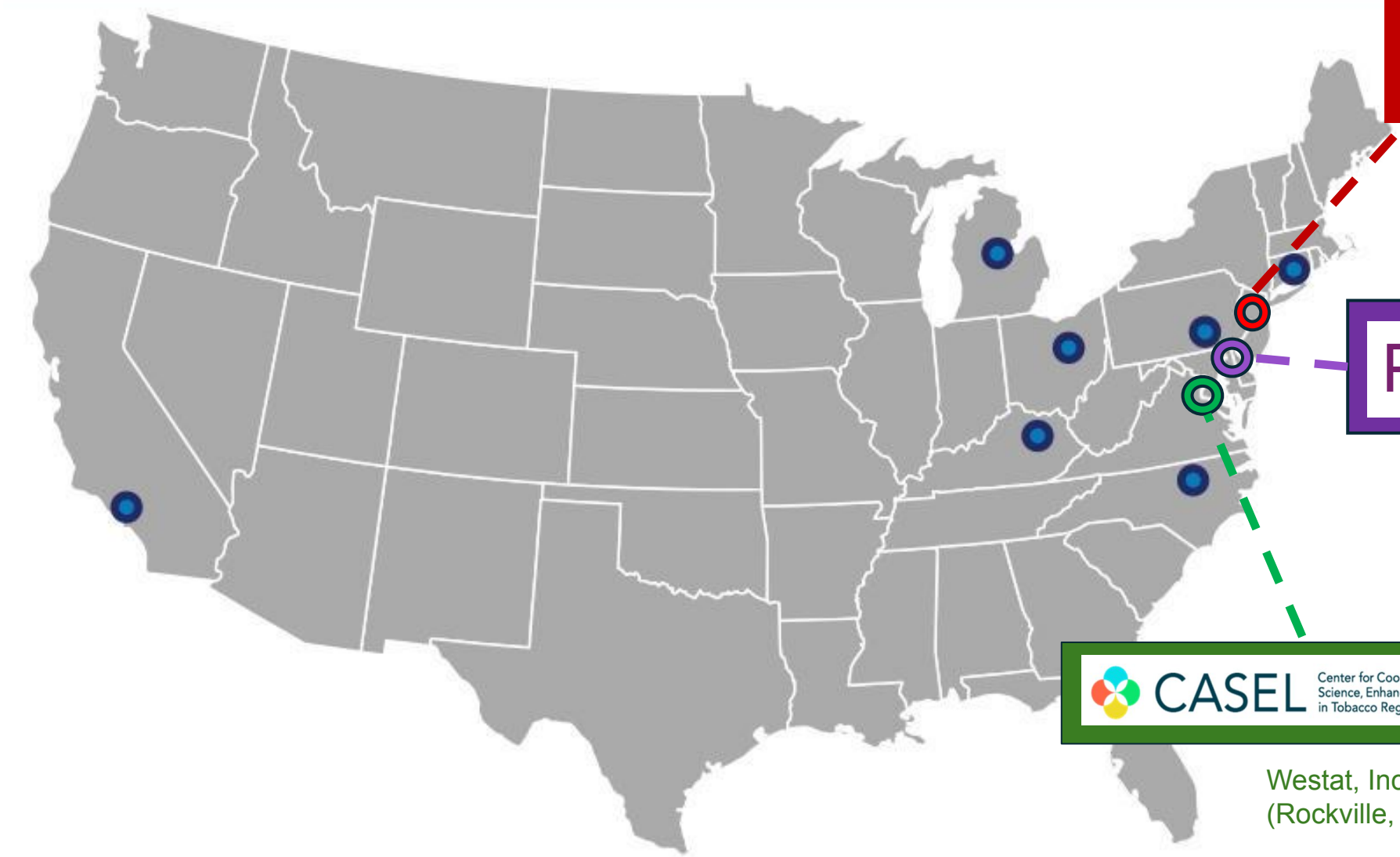
TRSP Portfolio

- **Objective:** Conduct programs of multidisciplinary research to inform FDA Center for Tobacco Products (CTP) regulatory activities
- **Cooperative Agreement Grants** (U54, U01):
  - **TCORS:** Tobacco Centers of Regulatory Science
  - **CRST:** Center for Rapid Surveillance of Tobacco
  - **P2B:** Perceptions to Behavior (Tobacco Products Continuum of Risk Messaging)
  - **CASEL:** Center for Coordination of Analysis, Science, Enhancement, and Logistics
- **Funding Opportunities** (Clinical Trial Optional):
  - **RFA-OD-25-008 (R03):** TRS Small Grant Program for New Investigators
  - **RFA-OD-26-006 (R01):** Forecast – High-Priority Research in TRS
  - **NCATS with ODP – PAR-25-296 (UG3/UH3):** Limited Competition: Clinical and Translational Science Award (CTSA) Program: Collaborative and Innovative Acceleration Award

TRSP Cooperative Agreements



TRSP Cooperative Agreements



CRST
CENTER for RAPID SURVEILLANCE of TOBACCO

Rutgers
(New Brunswick, NJ)

P2B From Perceptions To Behavior

Johns Hopkins University
(Baltimore, MD)

CASEL Center for Coordination of Analytics, Science, Enhancement, and Logistics in Tobacco Regulatory Science

Westat, Inc.
(Rockville, MD)

RFA-OD-25-008: Tobacco Regulatory Science Small Grant Program for New Investigators (R03)

- **Eligibility:**
  - New and Early-Stage Investigators
  - Not a previous recipient of TRSP funding
- **High-Priority Research Topics**:
  - Addiction, Behavior, Health Effects, Product Composition and Design, and/or Toxicity
- **Award information:** $75,000 in direct costs per year and 2-year project period
- **Application due date**: July 14, 2026
- **New! Preapplication consultation:** NOT-OD-26-045
  - Nonresponsive applications withdrawn prior to review
  - Consult with Agency Contacts (Section VII of RFA)
  - FAQ document: Contact TRSP@nih.gov
  - Send proposed Specific Aims for responsiveness feedback **by May 14 to** TRSP@nih.gov

Letters of Intent No Longer Accepted (NOT-OD-26-019)

Updated Application Policies: NIH Administrative Burden Reduction Effort – Removal of Requirements for Letters of Intent and Unsolicited Applications Requesting $500,000 or More in Direct Costs

Notice Number:

NOT-OD-26-019

Release Date:

December 03, 2025

Letters of Intent

Effective immediately NIH will no longer request or accept Letters of Intent (LOIs) as part of the application process. NIH has occasionally requested LOIs within Section IV of the Notice of Funding Opportunity (NOFO) to help Institute, Center, and Office (ICO) staff estimate the potential peer review workload and recruit reviewers. An LOI was never required, binding, nor considered during the peer review process.

Given NIH's centralization of peer review processes to improve efficiency and strengthen integrity through the Center for Scientific Review (CSR), the LOI is no longer serving the same purpose to estimate ICO workload. To further increase efficiency and minimize applicant burden, NIH is removing the LOI from the application process.

LOIs that have been submitted will not be acknowledged nor reviewed by the respective ICO or CSR. Potential applicants are encouraged to review NOFO instructions carefully as they are subject to change.

Preapplication Consultation is Strongly Encouraged (NOT-OD-26-045)

Notice of Information Encouraging Submission of Pre-Application Consultation Information for RFA-OD-25-008, "Tobacco Regulatory Science Small Grant Program for New Investigators (R03 Clinical Trial Optional)"

Notice Number:

NOT-OD-26-045

Release Date:

February 27, 2026

NEW!

Purpose

This Notice of Information **strongly encourages** applicants to request a Pre-Application Consultation to discuss the responsiveness of their proposed research to RFA-OD-25-008, "Tobacco Regulatory Science Small Grant Program for New Investigators (R03 Clinical Trial Optional)," Notice of Funding Opportunity (NOFO), and the FDA Center for Tobacco Products' (CTP) regulatory authorities.

To be considered responsive to this NOFO, applications must propose research aims that fall within (1) FDA CTP's regulatory authority and (2) one or more of the High-Priority Research Topics identified in RFA-OD-25-008. Applications that do not meet these criteria will be withdrawn prior to peer review. Applicants are **strongly encouraged** to participate in a Pre-Application Consultation to determine responsiveness before submitting an application.

To ensure timely consultation, applicants are asked to submit a draft Specific Aims page to TRSP (TRSP@nih.gov) no later than May 14, 2026.

FORECAST - RFA-OD-26-006: High-Priority Research in Tobacco Regulatory Science (R01)

- **High-Priority Research Topics**: Addiction, Behavior, Communications, Health Effects, Product Composition and Design, and/or Toxicity
- **Award information**: $500,000 in direct costs per year and 5-year project period
- **Application due dates**: *Final dates forthcoming*
- **Contact:** Erik Rodriquez TRSP@nih.gov

PAR-25-296: NCATS Collaborative and Innovative Acceleration Award (UG3/UH3, Clinical Trial Optional)

- **Goal:** accelerate translational research by supporting the collaborative development, dissemination, and sustainable implementation of innovative solutions across the CTSA Program Consortium and beyond
- **Funding Mechanism:** Biphasic exploratory/developmental cooperative agreement
  - UG3 Phase: development, adaptation, and/or demonstration
  - UH3 Phase: dissemination, implementation, and evaluation
- **Limited Competition:** Requires collaboration with at least 3 eligible organizations
- **Award information:** $650,000 in direct costs per year and 5-year project period
- **Application due dates:** Feb, Jun, Oct (expiration date: Oct 20, 2027)

Funded through NCATS (with ICO co-funding): Does **not** require FDA responsiveness

PAR-25-296: NCATS Collaborative and Innovative Acceleration Award (UG3/UH3, Clinical Trial Optional)

- **Eligibility:** Limited to partnerships with 2 or more CTSA Hubs
  - **Clinical and Translational Science Award (CTSA) Program:**
    - NCATS' national network of more than 60 medical research hubs
    - DIRECTORY: https://ccos-cc.ctsa.io/resources/hub-directory
  - **May include RFA-listed NIH Centers: Includes TCORS, CASEL, and CRST**

- **Project examples:** diagnostics and clinical trial design, patient-reported outcomes, video repositories, clinical decision support, analytic tools, community engagement

TRSP-Relevant Resources

- **NIH NOFOs, policies, etc.**
  - NOFOs and Forecasts now found in Grants.gov instead of the NIH Guide
  - NIH Guide still publishes Notices of NIH policies, requirements, and procedural changes
  - NIH Central Resource for Research Grants and Funding Information Grants.nih.gov
- **TRS community resources**
  - CASEL's Tobacco Regulatory Science Knowledge Center https://trskcdemo.wesdemo.com/
  - CRST's fact sheets, briefings, and weekly Tobacco Industry Marking (TIM) Alerts, https://tobaccocrst.org/
  - Contact us - TRSP@nih.gov -or- Kay.Wanke@nih.gov

Thank you!

Questions?