

# Office of Disease Prevention

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Council of Councils

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National Institutes of Health  
*Office of Disease Prevention*

# Mission

- The mission of the ODP is to improve the public health by increasing the scope, quality, dissemination, and impact of prevention research supported by NIH.
- ODP will fulfill this mission by providing leadership for the development, coordination, and implementation of prevention research in collaboration with the ICs and other partners.



# Prevention Research

- Prevention research at the NIH encompasses research designed both to promote health and to prevent onset of disease, disorders, or injuries and the progression of asymptomatic disease.



# Prevention Research

- Prevention research targets biology and genetics, individual behavior, factors in the social and physical environments, health services, and informs and evaluates health-related policies and regulations.
- Prevention research includes:
  - Identification and assessment of risk and protective factors,
  - Screening and identification of individuals and groups at risk,
  - Development and evaluation of interventions to reduce risk,
  - Translation and dissemination of effective preventive interventions into practice,
  - Development of research methods to support this work.

# History of ODP

- ODP was created in response to a directive in the Health Research Extension Act of 1985 to create the position of Associate Director for Prevention.
  - The Prevention Research Coordinating Committee moved to ODP in 1986.
  - The Consensus Development Program moved to ODP in 1986.



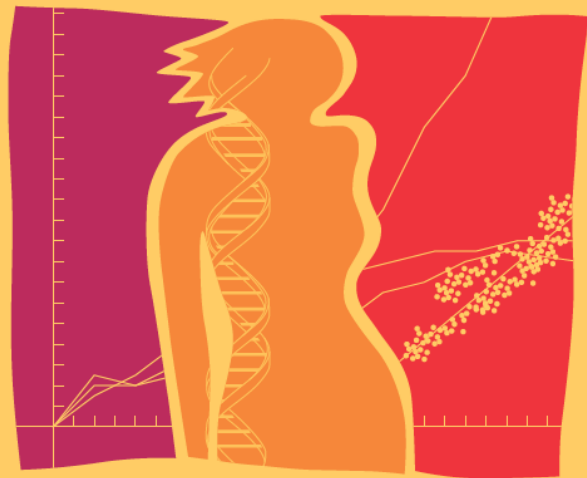
- The Office of Dietary Supplements was established in 1994.



# History of ODP

- The Robert S. Gordon Lecture was established in 1995 to recognize scientists who have contributed significantly to the field of epidemiology or clinical trials research.

An NIH Director's Wednesday Afternoon Lecture Series  
THE 2013 ROBERT S. GORDON, JR. LECTURE



Using Risk Models  
for Breast Cancer Prevention

Mitchell H. Gail, M.D., Ph.D.  
Division of Cancer Epidemiology & Genetics, National Cancer Institute

February 27, 2013  
3-4 p.m. Masur Auditorium  
Warren Grant Magnuson Clinical Center  
National Institutes of Health  
Bethesda, Maryland

# History of ODP

- Medicine in the Media was developed in 2003 to help develop journalists' and editors' abilities to evaluate and report on medical research.

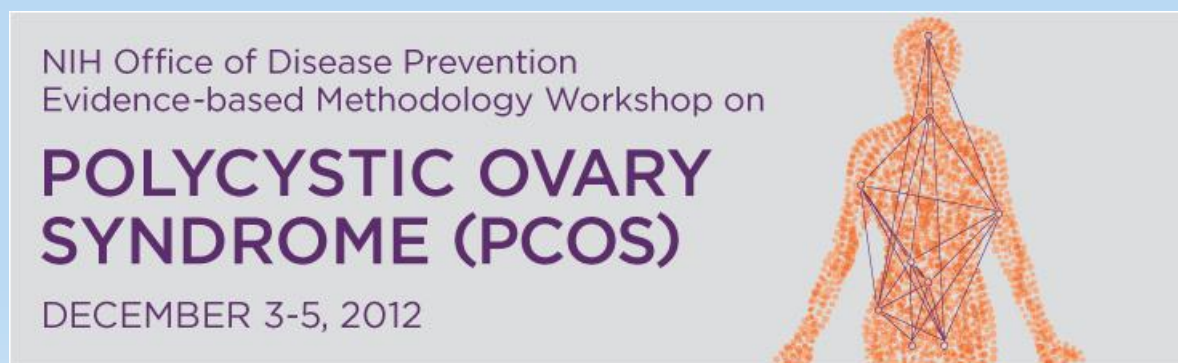


- The Medicine: Mind the Gap seminar series was established in 2007 to explore issues at the intersection of research, evidence, and clinical practice—areas in which conventional wisdom may be contradicted by recent evidence.



# History of ODP

- Evidence-Based Methodology Workshops began in 2012 to identify methodological and scientific weaknesses in an area and move the field forward through an unbiased and evidence-based assessment of a complex clinical issue.





# History of ODP

- The Tobacco Regulatory Science Program was transferred to ODP in 2012.
  - TRSP is a trans-NIH collaborative effort with the FDA's Center for Tobacco Products to conduct research to support FDA's regulatory authority for tobacco products.



# ODP Today

## Research Coordination

- ODP co-funds NIH research projects, meetings, and workshops.
  - ODP seeks to co-fund activities that support prevention research, including conferences, grants, and other activities.
  - ODP manages the Tobacco Regulatory Science Program.
- ODP maintains collaborations with other Federal Partners.
  - Healthy People 2020
  - Task Force on Community Preventive Services
  - National Prevention Strategy
  - U.S. Preventive Services Task Force

# Family Smoking Prevention and Tobacco Control Act



June 22, 2009

# FDA Designated Primary Federal Regulatory Authority

- FDA granted authority to regulate
  - tobacco products intended for human consumption
  - cigarettes, roll-your own, and smokeless tobacco products
- FDA intends to assert jurisdiction over other tobacco products
  - cigars, pipe tobacco, e-cigarettes, etc.





## FDA CENTER FOR TOBACCO PRODUCTS



Center for  
Tobacco Products

- CTP is funded by user fees from the tobacco industry ~\$500M for FY13
  - Approximately 1/3 to be used for research to support regulatory science

# Tobacco Regulatory Science Program

- The Tobacco Regulatory Science Program created to allow NIH to fund research to support FDA's regulatory authority.
  - FDA has expertise in tobacco regulatory science and authority and resources to support research
  - NIH has expertise in tobacco research and the infrastructure for receipt, review, and administration
  - TRSP allows NIH to support FDA's mandate for research in regulatory science
  - TRSP provides new funding opportunities that complement existing NIH tobacco research

# Current And Planned Funding Opportunities For FY13

- Intramural research projects
- R01s, R03s, R21s
- P50 Tobacco Centers of Regulatory Science
- P30 competitive revisions
- K announcements forthcoming



# TRSP Expenditures

	Expenditures by FY (\$Millions)		
	FY10	FY11	FY12
<b>Grants, supplements, competitive revisions</b>	1.0	3.4	35.4
<b>Research contracts</b>	0.0	8.5	31.0
<b>TOTAL</b>	1.0	11.9	66.4



■ [Home](#)

■ [Tobacco Regulatory Research](#)

- ▶ [About the FSPTCA](#)
- ▶ [Research Priorities](#)
- ▶ [Funding Opportunities](#)
- ▶ [Research Portfolio](#)
- ▶ [Resources](#)

■ [Prevention Research at NIH](#)

■ [Events and Programs](#)

■ [Consensus Development Program](#)

■ [In the News](#)

■ [About Us](#)

■ [Contact Us](#)

[ODP Home](#) > Tobacco Regulatory Research

## 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.

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 an interagency partnership to foster tobacco regulatory research. The NIH has the infrastructure for the solicitation, review, and management of research, and several NIH Institutes and Centers have long supported tobacco-related research as part of their missions. The FDA has expertise in tobacco regulatory science and the authority and resources to support research responsive to FDA's regulatory authority. NIH biomedical, behavioral and social sciences research supported via funding from FDA will provide the scientific evidence needed to better inform FDA's regulatory authorities.

### About the FSPTCA

[Provisions of the Law and Center for Tobacco Products Information](#)

### Research Priorities

[Research topic areas and projects](#)

### Research Portfolio

[NIH-FDA Grants and contracts](#)

### Funding Opportunities

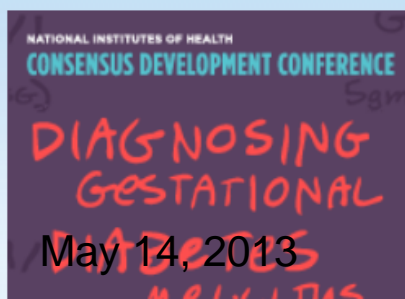
[Current funding announcements and application instructions](#)

### What's New

- [NIH Revision Applications](#)  
[RFA-OD-12-007 \(P30\)](#)  
[Pre-Application Webinar](#)  
[Frequently Asked Questions](#)
- [Tobacco Control Regulatory Research](#)  
[PAR-12-267 \(R01\)](#)  
[PAR-12-268 \(R03\)](#)  
[PAR-12-266 \(R21\)](#)  
[Frequently Asked Questions](#)
- [FDA CTP 56 Research Questions](#)

[Questions?](#)  
[Contact the TRSP](#)

[E-mail Updates from the](#)  
[FDA Center for Tobacco Products](#)



# 10 Research Interest Areas

- Nicotine dependence threshold among youth and adults and impact of nicotine reduction on tobacco product use behavior
- Cigar initiation, use, perceptions, dependence and toxicity
- Smokeless tobacco initiation, use, perceptions, dependence and toxicity
- E-cigarettes initiation, use, perceptions, dependence, toxicity
- Other tobacco product initiation, use, perceptions, dependence, toxicity
  - For example...pipes, dissolvables.

# 10 Research Interest Areas

- The impact of tobacco product characteristics on initiation, especially among youth and other vulnerable populations
- Toxicity thresholds for each of the 20 harmful and potentially harmful constituents identified in March 2012 by the FDA
- Statistical modeling of the public health impact of FDA/CTP regulation of potential modified risk tobacco products
- Consumer perceptions of tobacco products including the impact of labeling and marketing
- Effective communication strategies regarding harmful and potentially harmful constituents and risks of tobacco products

# ODP Today

## Evidence Assessment

- Consensus Development Program
  - Gestational Diabetes Mellitus
  - Inhaled Nitric Oxide Therapy for Premature Infants
  - Vaginal Birth After Cesarean
  - Lactose Intolerance and Health
  - Management of Hepatitis B
  - Hydroxyurea Treatment for Sickle Cell Disease
- Evidence-based Methodology Workshops
  - Polycystic Ovary Syndrome
  - Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
  - Opioids in the Treatment of Chronic Pain

# ODP Today

## Training and Education

- Medicine in the Media Course
- Medicine: Mind the Gap Seminar Series
  - Example: Raising the Bar: Engineering Optimized Behavioral Interventions for Increased Public Health Impact, Linda M. Collins, PhD., March 26, 2013
- Robert S. Gordon, Jr. Lecture Series
  - Example: Using Risk Models for Breast Cancer Prevention, Mitchell Gail MD, PhD, February 27, 2013

# The Future of ODP

- ODP is seeking broad input to develop its first strategic plan (FY 2013-18).
  - A Working Group of NIH, other federal, extramural, and public partners is guiding the process.
  - Interviews with NIH Institute and Center Directors and other key leaders informed the mission, vision, and proposed strategic priorities.
  - Program and review staff participated in focus groups.
  - Public comment was sought on strategic priorities, measurable objectives, timelines, and benchmarks.
  - ODP has actively engaged professional societies and extramural investigators.

# Strategic Priorities

- Systematically monitor NIH investments in prevention research and the progress and results of that research.
- Identify and promote prevention research areas that deserve expanded effort and investment by the NIH.
- Promote the use of the best available methods in prevention research and support the development of new and innovative approaches.
- Encourage development of collaborative prevention research projects and facilitate coordination of such projects across the NIH and with other public and private entities.
- Identify and promote the use of effective evidence-based interventions.
- Increase the visibility of prevention research at NIH and across the country.

# Vision

- By 2018, the ODP will be a valuable resource to NIH and the broader prevention research community,
  - Providing guidance in prevention research methodology,
  - Identifying gaps in existing evidence and facilitating the coordination of new activities to address those gaps,
  - Promoting quality improvements in the review and administration of prevention research,
  - And increasing the impact and visibility of prevention research.



**prevention.nih.gov**



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