

Pre-Application Webinar

**Center for Coordination of Analysis,
Science, Enhancement, and Logistics
(CASEL) in Tobacco Regulatory
Science (U54 Clinical Trial Not
Allowed)**

Monday, March 21, 2022

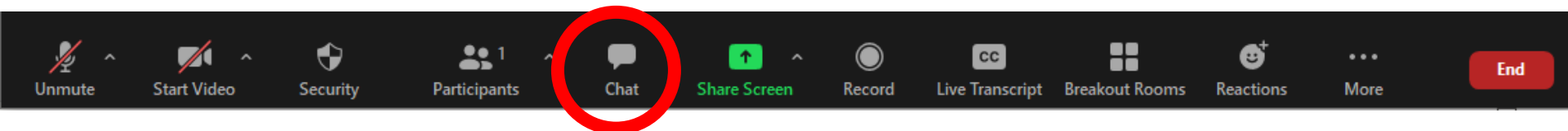
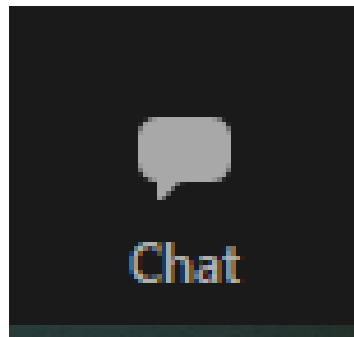


National Institutes of Health
Office of Disease Prevention

Questions or Technical difficulties?

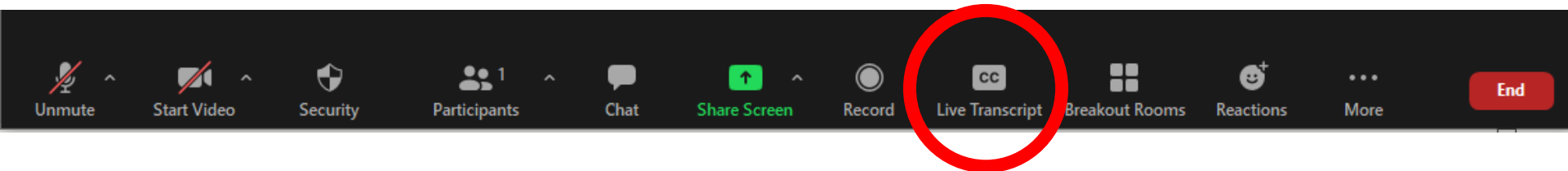
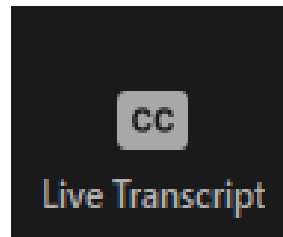


Please use **the Chat Option** to send a message to **“Technical Support”** for direct assistance



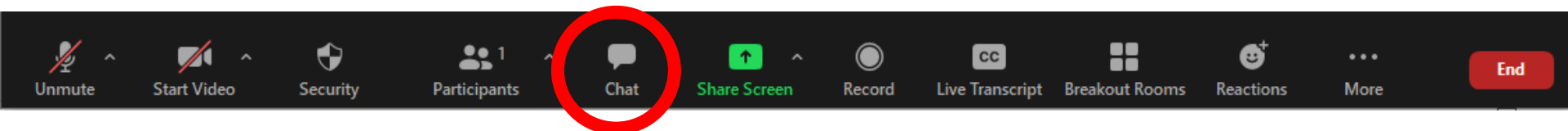
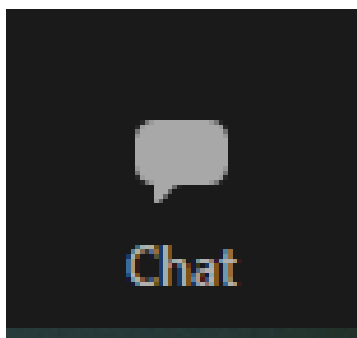
Closed Captions

- You can view live closed-captions by clicking the Closed Caption icon found at the bottom of the screen



Using the Chat for Webinar Questions

- **Questions for the panelists** should be sent directly to “**TRSP – Send Questions Here**” during the event for consideration



Post Webinar

A recording of today's webinar and presenter slides will be available on the TRSP website in approximately two weeks.

[Research Priorities](#)[Tobacco Regulatory Science Program](#)[Funding](#)[Education & Training](#)[News & Events](#)[About the ODP](#)

Tobacco Regulatory Science Program



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About TRSP

Funded Research: Tobacco Regulatory Science Program

Tobacco Centers of Regulatory Science

TRSP Funding Opportunities

TRSP Application Review Criteria

Pre-Application Webinar for Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL)

Pre-Application Webinar for Tobacco Centers of Regulatory Science (TCORS)

Pre-Application Webinar for the Center for Rapid Surveillance of Tobacco (CRST)

Webinar for Career Development

Pre-Application Webinar for Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54 Clinical Trial Not Allowed)

March 21, 2022, 3:30 - 5:00 p.m. ET

[Register for the webinar](#)

About the Webinar

A pre-application webinar will be held on March 21, 2022, for all prospective applicants interested in the following Funding Opportunity Announcement (FOA):

- RFA-OD-22-003: Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54 Clinical Trial Not Allowed)

Pre-Application Webinar Coordination of Analysis, Science, Enhancement, and Logistics (CASEL)

March 21, 2022

RFA-OD-22-003 (U54)

Helen I. Meissner, Ph.D.

Director, Tobacco Regulatory Science Program

Office of Disease Prevention



National Institutes of Health
Office of Disease Prevention

Tobacco Regulatory Science Program (TRSP) Background

- TRSP coordinates the partnership between FDA's Center for Tobacco Products (CTP) and the NIH
- TRSP has NIH oversight responsibility for the trans-NIH grant activities with CTP (FOAs, grantee mtgs., etc.)
- All TRSP-supported research must be responsive to CTP regulatory authorities
- 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.
- More information available at: <http://prevention.nih.gov/tobacco>

TRSP Website

Tobacco Regulatory Science Program



COVID-19

Get the latest public health information from CDC
Get the latest research information from NIH | Español

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TRSP Research Priorities

Tobacco Regulatory Research Tools & Resources

The Tobacco Regulatory Science Program (TRSP) is an interagency partnership between the NIH and the **FDA Center for Tobacco Products** to foster tobacco regulatory research.

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 establish a comprehensive research agenda in tobacco regulatory science.

Funding

New Funding Opportunities

- **RFA-OD-22-002:** Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (U01 Clinical Trial Not Allowed) — **Pre-application webinar**

Research Priorities

FAQs: Responsiveness to FDA's Center for Tobacco Products Regulatory Authority (PDF)

These FAQs clarify research that is and is not within scope of the FDA's Center for Tobacco Products (CTP) regulatory authority. Only research that is within the regulatory authority of the FDA CTP will be

News

FDA Makes Progress in Application Review

The FDA has taken action on over 90% of more than 6.5 million 'deemed' new tobacco product applications that were submitted by September 9, 2020, including issuing Marketing Denial Orders for more than 946,000 flavored ENDS products because their applications

Companion Funding Opportunities

RFA-OD-22-004 - Tobacco Centers of Regulatory Science (TCORS) (U54)

- **NOT-OD-OD-22-094** - Notice of Change to RFA-OD-22-004, Tobacco Centers of Regulatory Science (TCORS) for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (U54 Clinical Trial Optional)

RFA-OD-22-001 - Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (U01)

Note the following regarding personnel for center grants:

- A CASEL PD/PI or other members of the CASEL awardee team cannot serve as PI/PD or other key personnel on TCORS or CRST

More information available at: <http://prevention.nih.gov/tobacco>

CASEL WEBINAR AGENDA

- FDA Center for Tobacco Products and the Tobacco Control Act – Dana van Bemmelen (CTP, FDA)
- Application – Heather Kimmel (NIDA)
- Review – Lauren Fordyce (CSR)
- Grants Management – Amy Buchheimer (NIDA)
- Questions and Answers

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