

Pre-Application Webinar

Tobacco Centers of Regulatory Science for Research (TCORS) Relevant to the Family Smoking Prevention and Tobacco Control Act (U54)

Monday, March 21, 2022

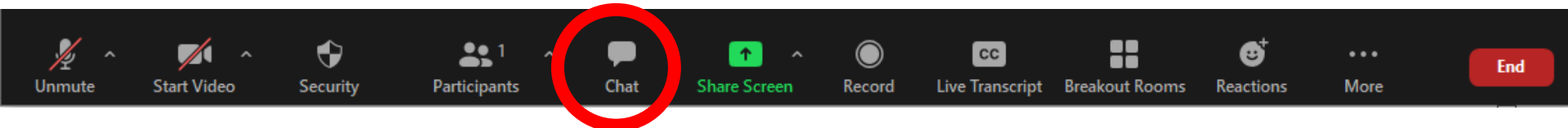
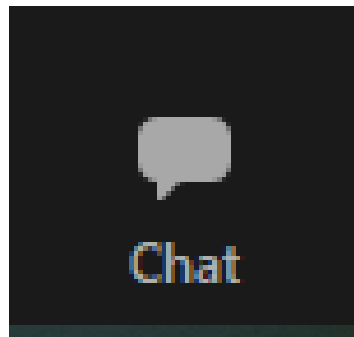


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Questions or Technical difficulties?

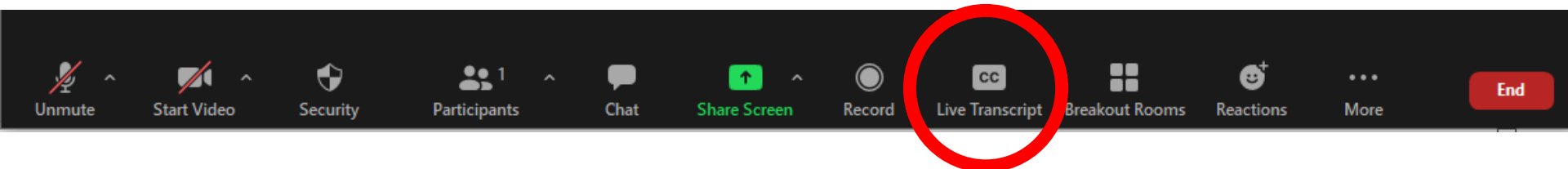
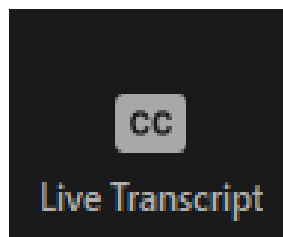


Please use **the Chat Option** to send a message to **“Technical Support”** for direct assistance



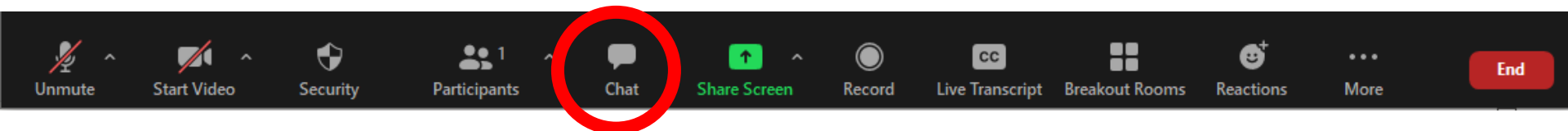
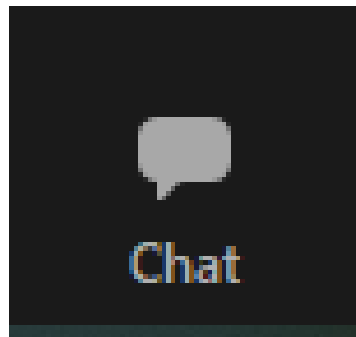
Closed Captions

- 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.

Tobacco Regulatory Science Program



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Pre-Application Webinar for Tobacco Centers of Regulatory Science (TCORS) for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (U54)

March 21, 2022, 1:00 - 2:30 p.m. ET

[Register for the webinar](#)

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

March 21, 2022

RFA-OD-22-004 (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



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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

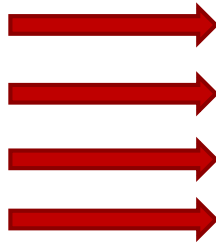
FAQs: Responsiveness to FDA's Center for Tobacco Products Regulatory Authority (PDF)

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



<http://prevention.nih.gov/tobacco>

Companion Funding Opportunities

RFA-OD-22-003 - Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54)

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

NOT-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)

Note the following regarding personnel for center grants:

- A TCORS PD/PI **cannot** serve as PD/PI of CRST grant
- A TCORS PD/PI or other key personnel **cannot** serve as a member of a CASEL awardee team

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

TCORS WEBINAR AGENDA

- FDA Center for Tobacco Products and the Tobacco Control Act – Dana van Bemmelen (CTP, FDA)
- Application – Mary Garcia-Cazarin (TRSP)
- Review – Lauren Fordyce (CSR)
- Grants Management – Amy Bucheimer (NIDA)
- Questions and Answers

Webinar and FAQs will be posted to website

<http://prevention.nih.gov/tobacco>