

NIH-FDA Tobacco Control Regulatory Science

Administrative and Budgetary Requirements

Pre-Application Webinar

March 21, 2022; 3:30-5:00pm

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

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Award Information

- ◆ The NIH, via support from the FDA Center for Tobacco Products (CTP), intends to fund approximately **one** application, with total costs up to \$3.8 million for FY 23.
 - ◆ Future year total costs will ultimately depend upon the availability of funds.
 - ◆ Applicants may request a project period of up to **5** years
- ◆ **NOTE:**
 - Non-domestic entities and non-domestic components **are not** eligible to apply.
 - Foreign components **are** allowed.
 - NIH GPS - definition of foreign involvement

Award Information

- ◆ The following dates are based on this RFA's cited Scientific Merit and Advisory Council Review dates:
 - ◆ Letters of Intent are due: **May 15, 2022 (60 days ahead of the application due date)**
 - ◆ Application due date: **July 14, 2022**
 - ◆ Earliest possible start date: **September 2023**
- ◆ Awards will include a special term, requiring a **separate mid-period progress** report at the six-month portion of each budget year.

Award Information

- ◆ The NIH funding mechanism planned for these applications is the Cooperative Agreement.
 - ◆ Cooperative Agreements do not allow automatic carryover authority.
 - ◆ A prior approval request must be submitted for situations where there is a bona fide need for using unobligated funds.
 - ◆ Cooperative Agreements are designated as 'Non-SNAP.'
 - ◆ If an application is selected for funding, please note that future progress reports (RPPRs) will be due 60 days prior to the cycle start date listed on the Notice of Award (NoA).

Award Information

- ◆ CASEL will include several unique components, detailed in [RFA-OD-22-003](#) One of these components is “Analysis and Rapid Response Core”
 - ◆ This Core will include an Opportunity Fund (OF) to support time-sensitive ‘Rapid Response Projects’ designed to address FDA’s high-priority research quickly.
 - ◆ The CASEL recipient is expected to set aside \$1,500,000 of its direct costs annually, to award subawards for this purpose.
 - ◆ The CASEL recipient will be entrusted, per NIH policy to handle all post-award management of said subawards, unless a change in scope and/or aims would result.

QUESTIONS and/or CONCERNS?

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