Pre-Application Funding Opportunity Announcent (FOA) Webinar

Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes

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1:30-2:30 pm ET

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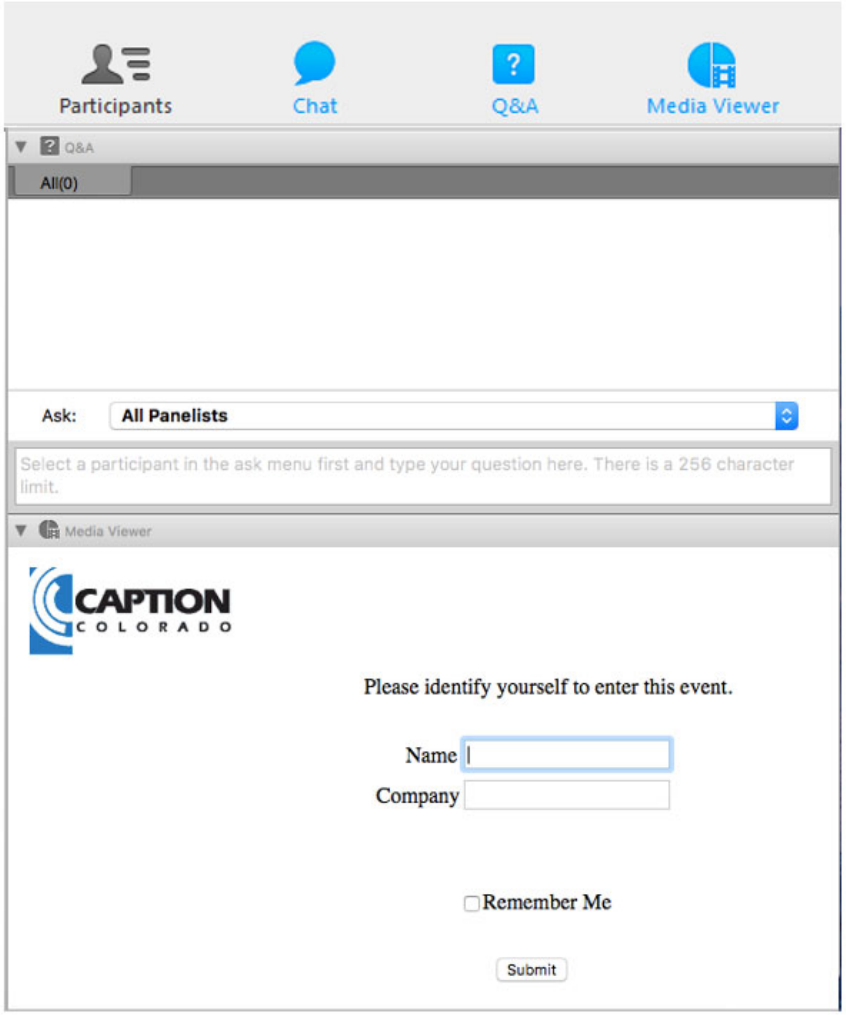
RFA-CA-17-041

Using WebEx



- All lines will be in listen-only mode
- Make sure icons are selected for them to appear as a drop down option
- Submit questions at any time during the presentation. Type into the Q&A panel on the right hand side of the interface and press “send”
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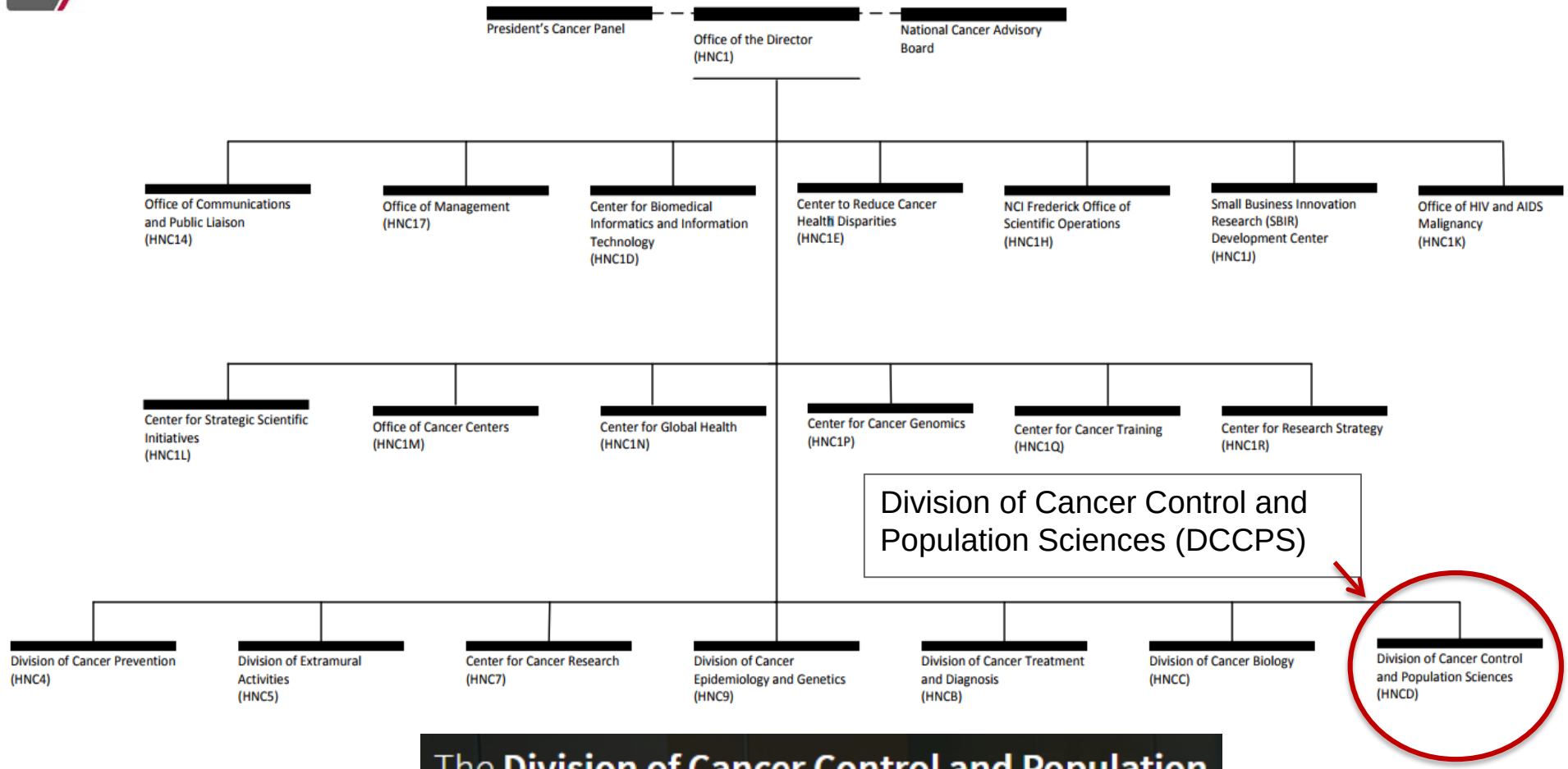

The **Division of Cancer Control and Population Sciences (DCCPS)** aims to reduce cancer risk, incidence, and death and enhance quality of life for cancer survivors by supporting innovative research and recommending ways to apply that research in quality health care delivery.

Blue Ribbon Panel Recommendation:
Cancer Prevention and Early Detection in Individuals at High Risk for Cancer

Recommendation:

- Sponsor initiatives to improve the current state of genetic counseling and testing, prevention, early detection, and knowledge landscape for those with an inherited predisposition.

Goals:

- Increase case ascertainment for probands and at-risk relatives
- Improve the delivery of evidence-based services
  - Genetic counseling
  - Preventive & early detection services
  - On-going surveillance

Blue Ribbon Panel Recommendation:
Cancer Prevention and Early Detection in Individuals at High Risk for Cancer

Background:

- Inherited susceptibility to cancer ~ 10% of all cancers
- Under-utilization of cancer genetic counseling & testing
- Cancers associated with multiple genetic syndromes
- Increasing complexity of genetic testing over the past 2 decades
  - From single gene to multi-gene panel tests and tumor sequencing

Genetic Counseling/Testing Process

Cancer Diagnosis

AND/OR

Family History of Cancer

Med/Surg/Rad Oncologist

Primary Care

Referral

Lost to Follow-up

Genetic Counselor

Contact Family Member with Cancer

Consent to Test

No Test

+

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VUS

Patient Follow-up Care

Family Follow-up

Communicate to Family

Lost to Follow-up

Missed: "No family history"
-Unknown
-Small family

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AIMS:

1. Develop and test strategies to increase case ascertainment of hereditary cancers through different approaches
2. Develop, test and adopt evidence-based health care delivery models for hereditary cancer prevention and detection
3. Test sustainable implementation strategies across health care settings and populations
4. Study the behavioral and psychosocial outcomes of counseling and testing on at-risk individuals and the impact on their follow-up care
5. Identify how the healthcare delivery approaches can be sustained

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- **U01: Cooperative Agreement**
  - Assistance mechanism with substantial NCI programmatic involvement
  - Each funded application will be assigned 2 NCI Program Directors
  - Steering Committee:
    - Non-voting body
    - Share challenges/successes and findings
    - Include meeting travel funds into application budget

Application Due Date: January 9, 2018

- **Funding**
  - NCI intends to commit $4.0 million (total costs) in FY2018
  - Fund up to 4 awards
  - Applications limited to no more than 5 years
  - Length and budget are project specific; must reflect proposed science

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- **Multi-PI U01 application**
  - PI expertise needs to represent the scientific components of the proposal
  - Example: An application could include experts in epidemiology, implementation science, or clinical scientists (genetics, oncology, healthcare delivery) along with experience in implementing programs/quality improvement

- **Foreign Applicants**
  - Foreign institutions/components are not eligible for moonshot funding
  - RFA goal is to test U.S. models of care delivery

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- **Required data/resource sharing with existing NIH resources**
  - Submit a Pubic Access and Data Sharing Plan
    - Genomic Data Commons (GDC)
    - Cancer Epidemiology Data Repository (CDER)

- **Review criteria specific to Moonshot Initiatives**
  - Significance: near-term translational potential
  - Approach:
    - Cancer Moonshot Public Access Strategy
    - Included adequate outcome measures
    - Human subjects protection

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- Strategy targets
  - Patient, provider, family, healthcare system
- Complementary approaches
  - Tumor-based testing and/or family history-based ascertainment
- Healthcare settings
  - Solo or small group practices, large group or integrated healthcare practices, or tertiary care settings
- Diverse populations
  - Urban, rural, age, socioeconomic, minority or cultural groups
- Best practice for counseling, informed consent, and follow-up
- Behavioral and psychosocial impact of genetic testing
- Workforce needs to support the approach

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All applications MUST:

- Develop, test and adopt strategies to ↑ case ascertainment
- Improve evidence-based healthcare delivery for those with an inherited susceptibility to cancer
- Focus on multiple hereditary cancer syndromes
- Include at least 2 different healthcare settings OR population groups
- Compare more than one strategy (may include usual care)
- Focus on implementation and sustainability of interventions

Subjects Selection:
"Those with an inherited susceptibility to cancer"

- Responsive applications must address ascertainment, genetic testing and follow-up care of either/both:
  - Patients with active cancer or a history of cancer
  - At-risk individuals

- Applications must address the totality of care
  - Includes methods to ascertain individuals with an inherited cancer susceptibility <u>through</u> delivery of follow-up care
  - Both those with cancer and at-risk individuals

Subject Section: "Include at least 2 different healthcare settings or population groups"

- RFA Goal: to demonstrate what method(s) work(s) across various groups and health care settings.
- A one-size fits all approach across all populations and settings may not obtain the desired case ascertainment and follow-up.
- Responsive examples:
  - Utilizing an integrated healthcare setting that services multiple populations (race, SES, age, etc.) in multiple care settings (academic center with affiliated community sites)
  - Utilizing a primary care network that includes several counties or states
  - Comparing strategies across pediatric and adult populations
  - Comparing strategies across socioeconomic groups

Approach: Implementation and Sustainability

Implementation:

- Study findings should lead to sustainable implementation of care delivery models at study completion.
- Risk prediction tool development – not supported

Sustainability:

- Goal is to identify sustainable models of case ascertainment, testing and follow-up care
  - Consider testing methods obtainable via insurance or nation, state, local or private programs
  - Develop care models that are/will be sustained by the workforce
- If genetic testing or workforce costs are included in the grant budget:
  - Justify why the services cannot be covered otherwise
  - Describe how service will be sustained after grant funding has ended

near-term translational potential

Questions?

- To submit questions, type into the Q&A feature on the right of the interface and press “submit.”
- After the webinar, a list of Frequently Asked Questions will be posted online at https://healthcaredelivery.cancer.gov/media/inherited.html.

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