NCI Webinar

Cancer MoonshotSM Funding Opportunity

Communication and Decision Making for Individuals with Inherited Cancer Syndromes (U01 Clinical Trial Optional)

RFA-CA-20-006
(reissue of RFA-CA-19-001)

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Behavioral Research Program
December 11, 2019
Using WebEx and webinar logistics

- All lines will be in listen-only mode
- Submit questions at any time during the presentation by typing into the Q&A feature on the right hand side of the WebEx interface.
  - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel on the right hand side of the screen
- This webinar is being recorded
- If you have questions or feedback following the presentation, please contact nci.brpwebinars@icf.com
  - NOTE: Questions regarding specific aims will not be addressed
 Agenda

Blue Ribbon Panel Recommendations

Background

RFA-CA-20-006

NIH Clinical Trial Requirements

Questions
Recommendations

A. Establish a network for direct patient involvement

Identify therapeutic targets to overcome drug resistance through studies that determine the mechanisms that lead cancer cells to become resistant to previously effective treatments.

D. Build a national cancer data ecosystem

Accelerate the development of guidelines for routine monitoring and management of patient-reported symptoms to minimize debilitating side effects of cancer and its treatment.

G. Expand use of proven cancer prevention and early detection strategies

Reduce cancer risk and cancer health disparities through approaches in development, testing and broad adoption of proven prevention strategies.

J. Develop new cancer technologies

Evolve from a precancerous lesion to advanced cancer.

Develop new enabling cancer technologies to characterize tumors and test therapies.

www.cancer.gov/brp
Recommendation

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

Strategies

Improve communication of genetic risk to individuals with an inherited susceptibility to cancer and their families so at-risk individuals can make informed clinical risk management decisions

Improve communication of uncertain genetic test results

Improve the delivery and uptake of evidence-based services

  Genetic counseling and testing

  Preventive and early detection services

  Ongoing surveillance
Background

Inherited susceptibility to cancer accounts for ~ 10% of all cancers

Genetic counseling and testing is underutilized

Cancers are associated with multiple genetic syndromes

Genetic testing has become increasingly complex (single gene to multi-gene panel tests and tumor sequencing)

Knowledge gaps in effective messaging of complex and uncertain genomic information
Background

Communication is essential to understanding risk and managing uncertainty.

Understanding risk is influenced by many factors (e.g., cognitive biases, cultural beliefs, personal illness experiences, family history of cancer).

Communication strategies are needed to:

- Promote guideline-concordant genetic testing and follow-up healthcare
- Facilitate disclosure of genetic test results to family members
- Improve the counseling process for the return of an uncertain test result (e.g., variant of uncertain significance)
- Address the unique needs of underserved populations
Purpose: Support projects to develop, test, and evaluate interventions and implementation approaches, or adapt existing approaches to improve cancer risk communication between patients with an inherited susceptibility to cancer (and their families) and providers so that affected individuals can make informed clinical risk management decisions.
Advance scientific efforts focused on:

1. Culturally competent genetic counseling strategies that address the unique needs of underserved populations (e.g., low income, the uninsured, minority, rural, low literate, low numerate, non-English speaking)

2. Approaches to communicate uncertain genetic test results to individuals with an inherited susceptibility to cancer and their families; examine the behavioral, psychological, and clinical outcomes of receiving an uncertain test result

3. Technological, verbal, and written communication approaches to genetic counseling and testing that promote understanding of genetic risk and help guide clinical management decisions

4. Communication approaches for cancer risk disclosure to family members who may be at risk for cancer due to an inherited cancer syndrome

5. Decision-making tools and techniques that promote understanding of risk and informed risk management decisions
RFA-CA-20-006: Examples of Research Projects

Develop culturally competent strategies to communicate genetic risk for underserved individuals who have cancer or are at risk due to a known or suspected inherited cancer syndrome (e.g., low literate, low income, racial/ethnic minorities)

Develop strategies to communicate an uncertain genetic test result; examine behavioral, psychological, and clinical outcomes of receiving an uncertain test result

Develop communication strategies to help manage uncertainty surrounding a genetic risk estimate or uncertain genetic test result

Implement technology that can enhance genetic counseling and understanding of genetic risk

Develop strategies to facilitate disclosure of genetic information to family members
RFA-CA-20-006: Communication and Decision Making for Individuals with Inherited Cancer Syndromes

**U01: Cooperative Agreement**

Assistance mechanism with substantial NCI programmatic involvement
Include travel funds for an annual investigator meeting in application budget
- Budget funds for 2 senior investigators
- Share knowledge, challenges, progress, and findings
- Bring together investigators on NIH-funded parallel projects

**Funding**

NCI intends to commit $5.0 million (total costs) in FY2020
Fund up to 5 awards
Applications limited to no more than 5 years
Budgets limited to $600,000 DC/year; must reflect the proposed science
No Awaiting Receipt of Application (ARA) necessary

Application Due Date: January 21, 2020
RFA-CA-20-006: Communication and Decision Making for Individuals with Inherited Cancer Syndromes

Clinical trial optional

Multi-PD/PI (investigator) optional

Does the PI(s) have the expertise to represent the scientific components of the proposal?

Do the investigators have complementary and integrated expertise?

Is the leadership approach, governance and organizational structure appropriate for the project?

Foreign Applicants

Foreign institutions are not eligible to apply

Foreign components are allowed
RFA-CA-20-006: Communication and Decision Making for Individuals with Inherited Cancer Syndromes

Address the Cancer Moonshot Public Access Pilot Program

Submit a Public Access and Data Sharing Plan:

- Describe the process for making publications and de-identified underlying primary data immediately and broadly available to the public
- Justify if such sharing is not possible

RFA requires data coordination and sharing with existing resources at and supported by NIH

cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy
RFA-CA-20-006: Considerations

Studies should focus on individuals who have cancer or who are at risk of cancer due to a known or suspected inherited cancer syndrome

Applicants are encouraged to focus broadly on hereditary cancer syndromes

Studies of all inherited cancer syndromes are encouraged

Applicants are encouraged to include diverse and underserved populations

Applicants are encouraged to focus on a variety of clinical settings and counseling methods

Clinical trials and/or observational/qualitative studies are allowed
RFA-CA-20-006: Evaluation Criteria

Projects should:

Facilitate understanding of genetic risk and/or delivery of genetic counseling

Include racially/ethnically, socioeconomically, and geographically diverse populations, including medically underserved groups (e.g., minority, rural, low-income, low literate, non-English speaking)

Address disparities in communication related to genetic counseling and testing, and risk management decision making

Focus on a variety of clinical settings and counseling methods

Demonstrate interdisciplinary collaborations
NIH Clinical Trials
New Clinical Trial Requirements (Jan 2018)

RFA-CA-20-006: Clinical Trial Optional

Policy determines whether you need to:

Respond to a clinical trial-specific FOA

Address additional review criteria specific for clinical trials

Register and report your clinical trial in ClinicalTrials.gov

grants.nih.gov/policy/clinical-trials/reporting/index.htm
NIH Clinical Trial Definition

Does your study…

Involve one or more **human subjects**?

**Prospectively assign** human subject(s) to intervention(s)?

Evaluate the **effect of intervention(s)** on the human subject(s)?

Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial.
Specific Review Criteria

**Significance**

Is the scientific rationale and need for your study well supported by preliminary data, clinical studies, or the literature?

**Investigator(s)**

Is the leadership expertise and experience sufficient to organize, manage and implement the project?

**Innovation**

Does the research plan includes innovative elements that have the potential to advance scientific knowledge or clinical practice?
Specific Review Criteria

Approach
Is the study design appropriate to address outcome measures?
Are human subjects protections adequate?
Is the process for consent and assent appropriate?

Environment

Study Timeline and Milestones
Is the timeline feasible and well justified?
Have you accounted for start-up time, enrollment, and follow-up assessments?
New Application Packages (FORMS-E)

Due Dates after January 25, 2018

FORMS-E Application Package is REQUIRED (including new Human Subjects and Clinical Trials form)

PHS Human Subjects and Clinical Trials Information Form

Consolidates information from multiple forms (human subjects, inclusion enrollment, clinical trial)

Incorporates structured data fields

Collects information at the study level

Presents key information to reviewers and agency staff in a consistent format

Registering and Reporting NIH-Funded Clinical Trials
https://www.clinicaltrials.gov/

**Who:** All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017

**What:** Register and report the results of trials in ClinicalTrials.gov

**When:** Register the trial no later than 21 days after enrolling the first subject

Update the clinical trial record at least every 12 months

Submit summary results to the Protocol Registry System no later than a year after clinical trial completion
Single Institutional Review Board (sIRB) Policy for Multi-Site Research

As of January 25, 2018, domestic, multi-site, non-exempt human subjects research studies require a single IRB of record

Policy to streamline IRB review process for multi-site research

Applications must include a plan for using a single IRB

sIRB policy, guidelines, and resources available at link below

Grant Appendix Materials

Allowed
Blank data collection forms, blank survey forms and blank questionnaire forms -- or screenshots thereof
Simple lists of interview questions
Blank informed consent/assent forms
Other items only if they are specified in the FOA as allowable Appendix materials

Not Allowed
Protocols
Relocating disallowed materials to other parts of the application

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<tr>
<th>Mechanism</th>
<th>U01 cooperative agreement</th>
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<tr>
<td>Clinical trial requirement</td>
<td>- Clinical trial optional</td>
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<td></td>
<td>- Observational/qualitative studies allowed</td>
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<td>Leadership</td>
<td>Single or multiple PIs allowed</td>
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<td>Aims</td>
<td>Intervention and implementation approaches and/or observational/qualitative studies to improve communication of genetic risk so that individuals can make informed clinical management decisions</td>
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<td>Populations of interest</td>
<td>- Patients with cancer</td>
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<td>- At-risk family members</td>
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<td>Study requirements</td>
<td>- Projects should involve at least 1 health care setting</td>
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<tr>
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<td>- All inherited cancer syndromes are of interest</td>
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<td>- Represent underserved and diverse populations</td>
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<td>High priority research areas</td>
<td>- Culturally competent genetic counseling that addresses the needs of underserved populations</td>
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<td>- Communication of uncertain genetic test results; outcomes of receiving an uncertain genetic test result</td>
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<td>Letter of intent (encouraged)</td>
<td>RFA; descriptive title; PI(s) contact information; names of key personnel and their institutions; study abstract and aims also accepted but not required</td>
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<td>Address letter of intent to: <a href="mailto:nelsonw@mail.nih.gov">nelsonw@mail.nih.gov</a></td>
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## Important Dates

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<th>Important Date</th>
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<tbody>
<tr>
<td>Earliest submission date</td>
<td>December 20, 2019</td>
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<tr>
<td>Application due date</td>
<td>January 21, 2020</td>
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<tr>
<td>Letter of intent due date</td>
<td>30 days prior to January 21, 2020</td>
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<tr>
<td>Scientific merit review</td>
<td>April 2020</td>
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<td>Earliest start date</td>
<td>September 2020</td>
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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.