NCI Webinar

Cancer Moonshot℠ 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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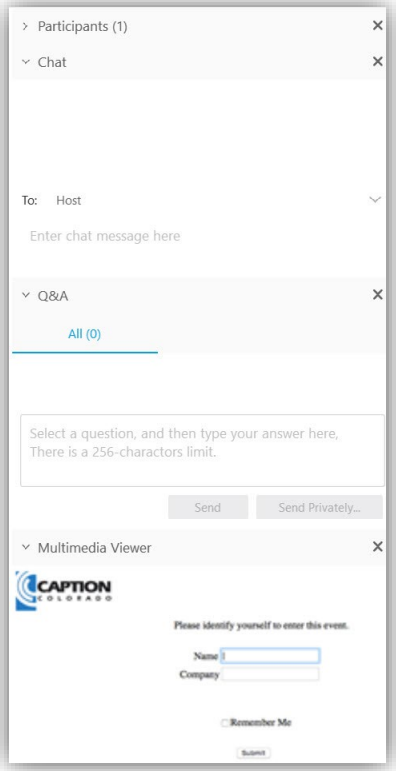
NIH NATIONAL CANCER INSTITUTE

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

for sharing and researchers, able to

eatment's cts

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.

evolves from a precancerous lesion to advanced cancer.

J. Develop new cancer technologies

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

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.

www.cancer.gov/brp

Precision Prevention and Early Detection WG

Cancer Prevention and Early Detection in Individuals at High Risk

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

Precision Prevention and Early Detection WG

Cancer Prevention and Early Detection in Individuals at High Risk

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

Precision Prevention and Early Detection WG

Cancer Prevention and Early Detection in Individuals at High Risk

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

▪RFA-CA-20-006

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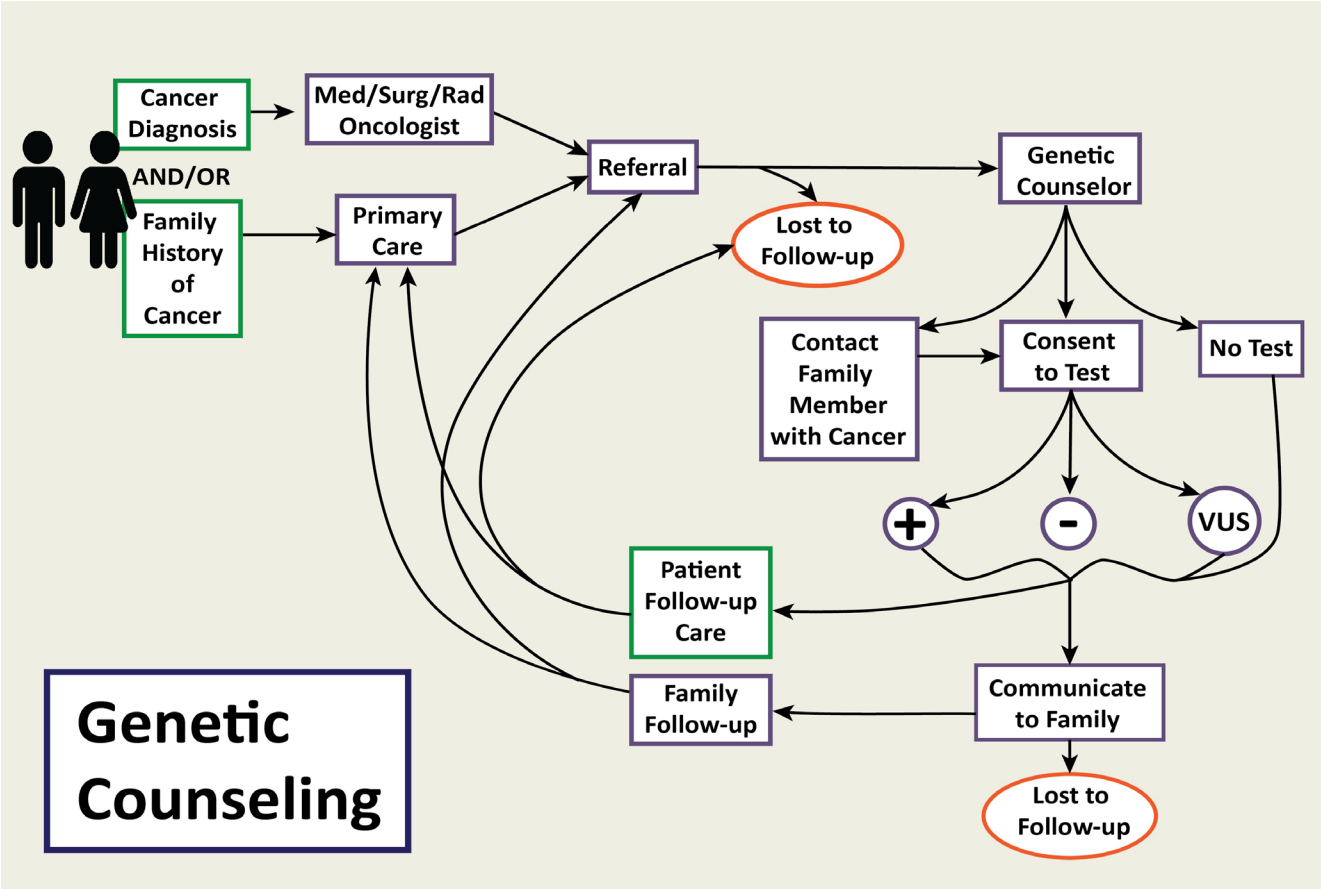
Communication and Decision Making for Individuals with Inherited Cancer Syndromes

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


Cancer Diagnosis
Med/Surg/Rad Oncologist
AND/OR
Family History of Cancer
Primary Care
Referral
Lost to Follow-up
Genetic Counselor
Contact Family Member with Cancer
Consent to Test
No Test
+
-
VUS
Patient Follow-up Care
Family Follow-up
Communicate to Family
Lost to Follow-up
Genetic Counseling

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

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

Application Due Date:
January 21, 2020

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

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)

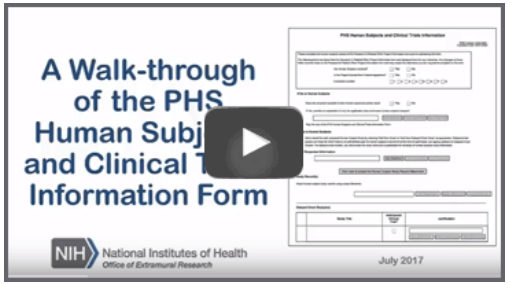
PHS Human Subjects and Clinical Trials Information Form

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



https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

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

https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

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

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html

RFA-CA-20-006	
Mechanism	U01 cooperative agreement
Clinical trial requirement	- Clinical trial optional - Observational/qualitative studies allowed
Leadership	Single or multiple PIs allowed
Aims	Intervention and implementation approaches and/or observational/qualitative studies to improve communication of genetic risk so that individuals can make informed clinical management decisions
Populations of interest	- Patients with cancer - At-risk family members
Study requirements	- Projects should involve at least 1 health care setting - All inherited cancer syndromes are of interest - Represent underserved and diverse populations
High priority research areas	- Culturally competent genetic counseling that addresses the needs of underserved populations - Communication of uncertain genetic test results; outcomes of receiving an uncertain genetic test result
Letter of intent (encouraged)	RFA; descriptive title; PI(s) contact information; names of key personnel and their institutions; study abstract and aims also accepted but not required Address letter of intent to: nelsonw@mail.nih.gov

Important Dates

Earliest submission date	December 20, 2019
Application due date	January 21, 2020
Letter of intent due date	30 days prior to January 21, 2020
Scientific merit review	April 2020
Earliest start date	September 2020

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.

www.cancer.gov

www.cancer.gov/espanol