Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network RFA-CA-19-045 and RFA-CA-19-046

Frequently Asked Questions

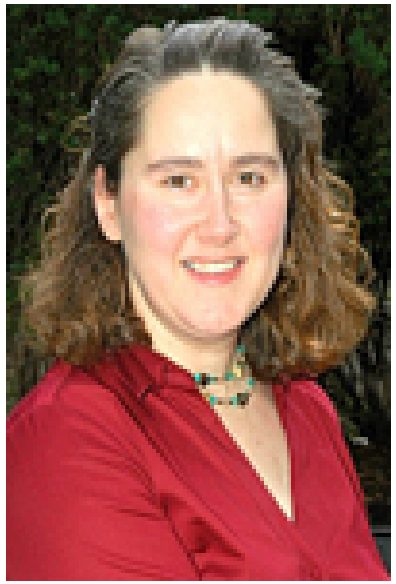
Elizabeth Gillanders, Leah Mechanic, Wen-Ying Sylvia Chou

for the Network for Direct Patient Engagement Team

NIH NATIONAL CANCER INSTITUTE

Pre-Submission Webinar
September 25, 2019

Scientific Contacts



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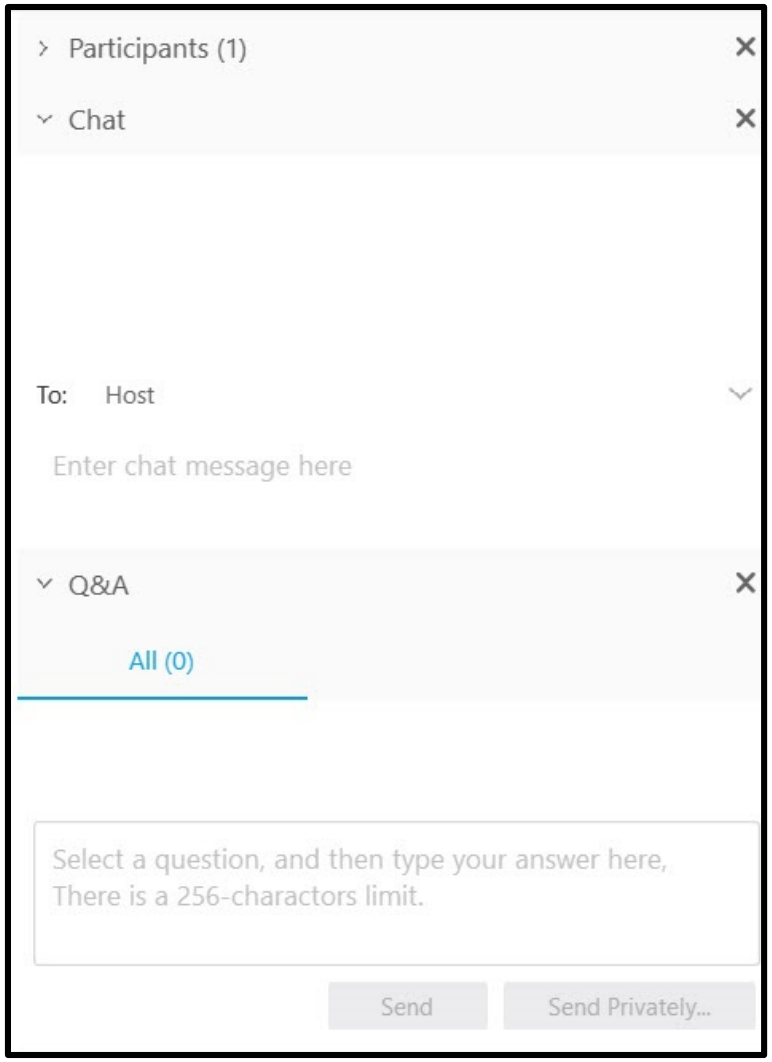
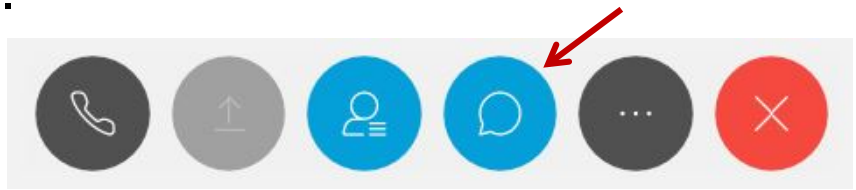
Using WebEx and Webinar Logistics

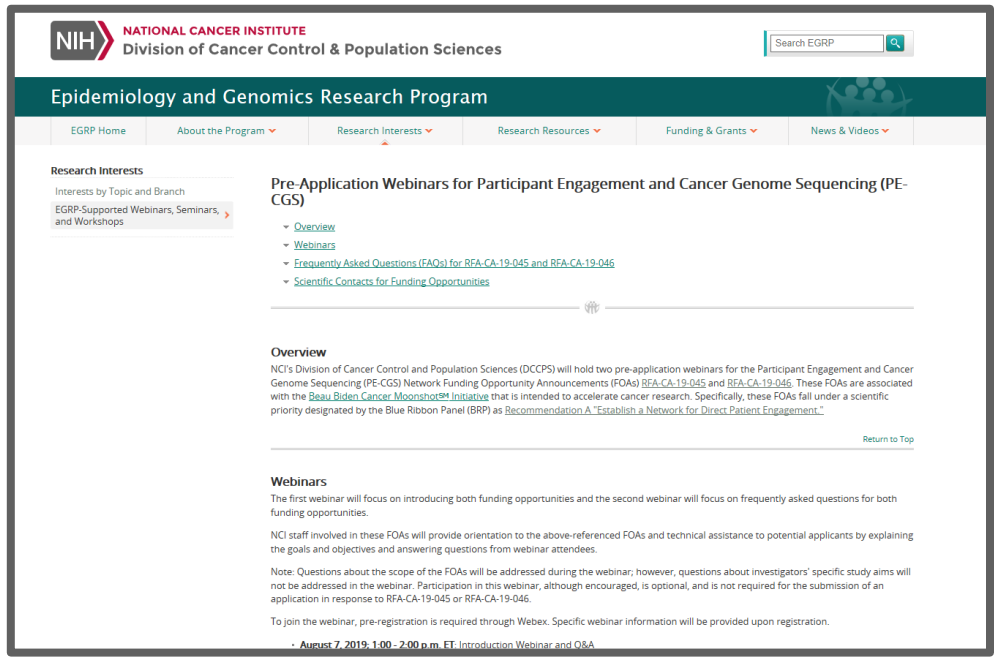


- All lines will be in listen-only mode
- Submit questions at any time using the Q&A or Chat Panel and select *All Panelists*
- You may need to activate the appropriate box using the floating navigation panel. Found on the center of your screen.



- Closed captioning is available by clicking the link in the chat box.
- This webinar is being recorded.

Pre-Application Webinar recordings for PE-CGS



- DCCPS held a pre-application webinar on August 7, for the PE-CGS Network Funding Opportunity Announcements (RFA-CA-19-045 and RFA-CA-19-046). Slides from that webinar, a list of Frequently Asked Questions (FAQs), and other program details are posted to this website: https://epi.grants.cancer.gov/events/pe-cgs/

- To directly access the recording for the first pre-application webinar, please use the following link: https://www.youtube.com/watch?v=2PTTLtxV7co&feature=youtu.be

- Today's webinar will focus on frequently asked questions for both funding opportunities.

Outline for Today's Webinar

- **Overview of Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network**
  - RFA-CA-19-045: Participant Engagement and Cancer Genome Sequencing (PE-CGS): Research Centers
  - RFA-CA-19-046: Participant Engagement and Cancer Genome Sequencing (PE-CGS): Coordinating Center
- **Frequently Asked Questions**
  - Application Details
  - Study Design
  - CLIA Certification
  - Molecular Characterization Platforms
- **Questions**

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Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network

- The Participant Engagement and Cancer Genome Sequencing (PE-CGS) RFAs are associated with the Cancer Moonshot℠ Initiative and fall under a scientific priority designated by the Blue Ribbon Panel as Recommendation A “Establish a Network for Direct Patient Engagement”.

- The National Cancer Institute (NCI) intends to support the PE-CGS Network, which will include:
  - Several U2C Research Centers (to be supported under RFA-CA-19-045); and
  - One U24 Coordinating Center (to be supported under RFA-CA-19-046).

- The PE-CGS Network will **function as a collaborative network** allowing PE-CGS U2C Research Centers to **address common issues, share best practices and lessons learned, and utilize common methods** where appropriate.

Goals of RFA-CA-19-045 and RFA-CA-19-046

There are two goals:

- To promote and support direct participant engagement of cancer patients and post-treatment cancer survivors as participants in cancer research; and

- **To use direct participant engagement approaches for rigorous cancer genome sequencing programs addressing important knowledge gaps in the genomic characterizations of tumors** in areas such as, but not limited to:
  - Rare cancers or rare cancer subsets;
  - Highly lethal cancers;
  - Cancers with an early age of onset;
  - Cancers with high disparities in incidence and/or mortality; or
  - Cancers in understudied populations.

PE-CGS Research Centers (U2C Clinical Trial Optional) RFA-CA-19-045 by the numbers

Open Date (Earliest Submission Date)	September 30, 2019
Letter of Intent Due Date(s)	30 days prior to due date (September 30, 2019) Send to: **NCI_PE-CGS@mail.nih.gov**
Application Due Date(s)	October 30, 2019; July 30, 2020
Funds Available and Anticipated Number of Awards	NCI intends to commit $12 million (total costs) in FY2020 to fund up to three awards. *Note: These could be selected in the first round.*
Award Budget	Application budgets are limited to no more than $2.5 million per year (direct costs) and need to reflect the actual needs of the proposed program.
Award Project Period	The maximum project period is 5 years.

PE-CGS Coordinating Center (U24 Clinical Trial Not Allowed) RFA-CA-19-046 by the numbers

Open Date (Earliest Submission Date)	September 30, 2019
Letter of Intent Due Date(s)	30 days prior to due date (September 30, 2019) Send to: **NCI_PE-CGS@mail.nih.gov**
Application Due Date(s)	October 30, 2019; July 30, 2020 *Note: If an awardee is selected in the first round, the FOA will be expired.*
Funds Available and Anticipated Number of Awards	NCI intends to commit $500,000 (total costs) in FY 2020 to fund one award.
Award Budget	Application budgets are limited to no more than $350,000 direct costs and need to reflect the actual needs of the proposed project.
Award Project Period	The maximum project period is 5 years.

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- **Frequently Asked Questions**
  - Application Details
  - Study Design
  - CLIA Certification
  - Molecular Characterization Platforms

- **Questions**

Frequently Asked Questions: Application Details

Q. What is required for a Letter of Intent (LOI)?

A. The letter of intent should include the following information: Descriptive title of proposed activity; Name(s), address(es), and telephone number(s) of the PD(s)/PI(s); Names of other key personnel; Participating institution(s); and Number and title of this funding opportunity. This should be emailed to NCI_PE-CGS@mail.nih.gov.

Q. For RFA-CA-19-045, what if we do not complete our application in time for the October 30, 2019 submission deadline?

A. There are currently two receipt dates for the FOAs: October 30, 2019 and July 30, 2020. This is to allow for resubmissions or for new applications that missed the initial submission deadline. The second date will depend on the availability of funds.

Frequently Asked Questions: Application Details

Q. Is it possible to apply for both the U2C (RFA-CA-19-045) and U24 (RFA-CA-19-046) FOAs?

A. Yes, the same institution/investigators to apply for both FOAs.

Q. What is the distinction between the Participant Engagement Unit (Unit 1) and the Engagement Optimization Unit (Unit 3)?

A. The Participant Engagement Unit (Unit 1) is to be responsible for the implementation and operations of the Participant Engagement, while the Engagement Optimization Unit (Unit 3) provides supporting (behavioral/communication) research to develop and test the optimal approaches to participant engagement. Participant Engagement Unit (1) should develop initial protocols based on the state of the science for participant engagement, but with flexibility in the protocol to adapt to research findings from the Engagement Optimization Unit (3). In other words, the research performed in the Engagement Optimization Unit (3) will iteratively guide the implementation and operations of the Participant Engagement Unit (Unit 1).

Frequently Asked Questions: Application Details

Q. Is there an extension of the submission deadline for investigators participating on study section?

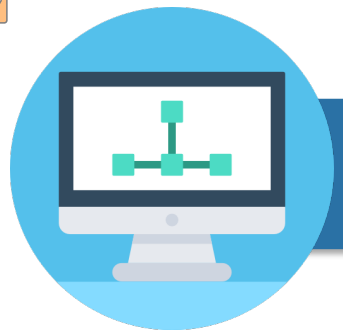
A. No, since RFA-CA-19-045 and RFA-CA-19-046 do not use the standard receipt dates, the continuous submission policy does not apply. In addition, these FOAs will not accept any late applications. Therefore, there is no extension of the submission deadline for members of study section.

Frequently Asked Questions: Study Design

Q. What cancer type is appropriate for this FOA?

A. The U2C research centers should be centered on addressing a unique research knowledge gap in the genomic characterizations of tumors. Knowledge gaps proposed for characterization are expected to be mainly identified in Interest Areas 1-5 (see below). However, knowledge gaps outside of the first five interest areas may also be proposed with strong scientific justification.

Interest Area 1: Rare cancers or rare cancer subsets;
Interest Area 2: Highly lethal cancers;
Interest Area 3: Cancers with an early age of onset;
Interest Area 4: Cancers with high disparities in incidence and/or mortality;
Interest Area 5: Cancers in understudied populations; and
Interest Area 6: Other cancer and/or population subsets justified to be highly relevant to the goals of this FOA.



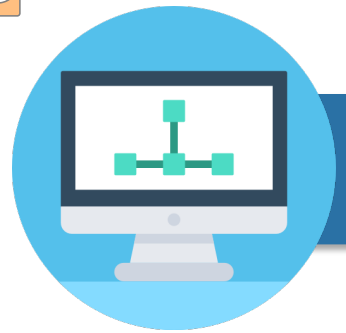
Frequently Asked Questions: Study Design

Q. Does Interest Area 3: “Cancers with an early age of onset”, refer to pediatric cancers or cancers that traditionally occur in older individuals impacting people of younger ages?

A. For Interest Area 3 we were referring to cancers that typically affect older individuals occurring in participants of younger ages. As far as many pediatric cancers are rare or understudied, these could also fit under the other areas of interest.

Q. How many participants/tumors are required?

A. The proposed minimal number of unique tumors to characterize (i.e., the proposed number of participants to engage) should be sufficiently high to ensure rigorous and interpretable results for the specific research proposed. This number may differ depending on the cancer type selected.



Frequently Asked Questions: Study Design

Q. We have already identified the population we want to engage for participation, but how important is it that we address research gap in the genomic characterizations of tumors?

A. For applications to be considered responsive to the RFAs, it is critically important that the team identifies and articulates the particular knowledge gap(s) in the molecular characterization of a particular cancer and/or population subset. Importance of providing adequate justification for chosen knowledge gap and selection of participants.

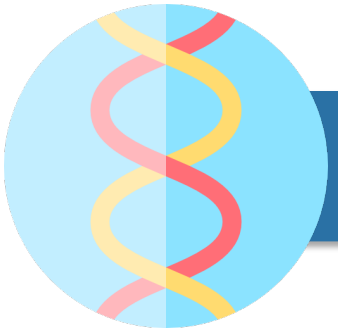
Q. Can we use existing infrastructure or resource for enrolling cancer patients or study participants?

A. Investigators are encouraged for the U2C to build on existing infrastructures. However, it must also be possible for any participant meeting the inclusion criteria to have the ability to enroll in the project.

Frequently Asked Questions: Study Design

Q. How much preliminary data is required for the Engagement Optimization Unit (Unit 3)?

A. You will want to provide some details on anticipated initial major research questions and include any specific (pilot) project ideas (e.g. testing different modes of obtaining consent or gauging participant preference in return of results). There should be enough detail for reviewers to feel confident that the research will be feasible and successful and will inform the larger protocol in Unit 1. However, by design the Engagement Optimization Unit's work will be iterative in nature, therefore providing comprehensive details of all the work that could be completed would not be expected.



Frequently Asked Questions: CLIA Certification

Q. Should each of the required genomic characterizations (whole exome sequencing, RNA-sequencing and low pass whole genome sequencing) be performed in a CLIA certified laboratory?

A. The whole exome sequencing (WES) should be performed in a CLIA-certified laboratory allowing for the return of individual-level genetic information to those participants who are interested in receiving such data. However, the low-pass whole genome sequencing and the RNA Sequencing need not be done using a CLIA pipeline.

Q. Is it possible to perform the whole exome sequencing (WES) is a research laboratory and follow up with clinical validation in a CLIA certified laboratory?

A. Hybrid approaches (like sequencing in a research lab and validating of actionable targets in CLIA), would not be appropriate. We are expecting the return policy to evolve. Whole exome sequencing must be performed in CLIA environment to allow for broader return of results in anticipation of these potential changes.

Frequently Asked Questions: Molecular Characterizations Platforms

Q. Is there flexibility in the selection of platforms for the genomic characterization?

A. For each cancer or population subset, the characterizations must include, at a minimum: Whole exome sequencing (WES); Low-pass whole genome sequencing (coverage of 15X); and RNA sequencing. However, applicants may propose additional types of genomic characterizations, if appropriate for the study focus. Note, all activities must be within the allowable budget (no more than $2.5M direct costs per year).

Questions?

Contact: NCI_PE-CGS@mail.nih.gov