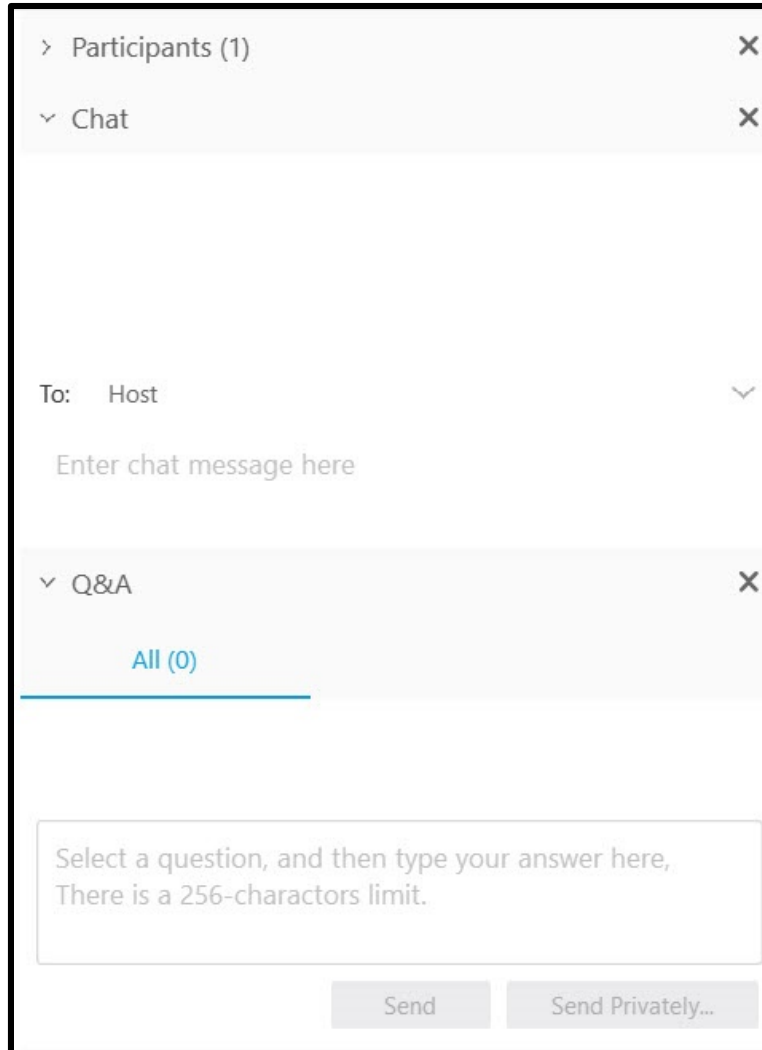


Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network RFA-CA-19-045 and RFA-CA-19-046

Introduction Webinar and Q&A

*Leah Mechanic, Elizabeth Gillanders, Wen-Ying Sylvia Chou
for the Network for Direct Patient Engagement Team*

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.

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Introduction Webinar and Q&A

*Leah Mechanic, Elizabeth Gillanders, Wen-Ying Sylvia Chou
for the Network for Direct Patient Engagement Team*

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Pre-Application Webinars for PE-CGS: Funding Opportunities (RFA-CA-19-045, RFA-CA-19-046)



- DCCPS will hold two pre-application webinars for the PE-CGS Network Funding Opportunity Announcements RFA-CA-19-045 and RFA-CA-19-046.
- These Funding Opportunity Announcements are associated with the Cancer MoonshotSM Initiative that is intended to accelerate cancer research.
- Specifically, these FOAs fall under a scientific priority designated by the Blue Ribbon Panel (BRP) as Recommendation A "Establish a Network for Direct Patient Engagement".
- The first webinar (August 7, 2019 at 1:00 p.m. - 2:00 p.m. ET) will focus on introducing both funding opportunities.
- The second webinar (September 25, 2019 at 1:00 p.m. - 2:00 p.m. ET) will focus on frequently asked questions for both funding opportunities.
- Following these webinars, NCI DCCPS will post a recording for each webinar on this website: <https://epi.grants.cancer.gov/events/pe-cgs/>

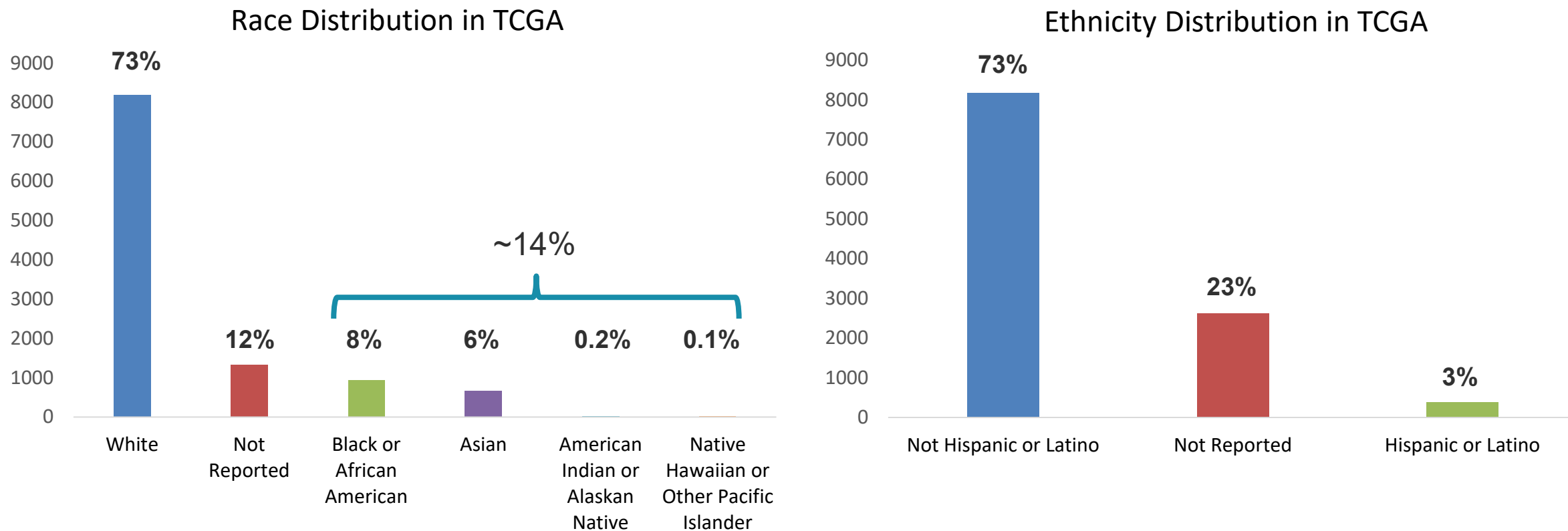
Outline for Today's Webinar

- **Background**
- **Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network**
- **RFA-CA-19-045: Participant Engagement and Cancer Genome Sequencing (PE-CGS): Research Centers (U2C Clinical Trial Optional)**
 - Overview and structure U2C
 - Application details
 - Administrative Core and units – overview and points to consider
- **RFA-CA-19-046: Participant Engagement and Cancer Genome Sequencing (PE-CGS): Coordinating Center (U24 Clinical Trial Not Allowed)**
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Background: Research Gaps in Molecular Profiling of Cancer



Results...have resulted in substantial gains in the understanding of cancer prevention and treatment, yet their generalizability to all US populations is limited due to the lack of racial and ethnic diversity. It is imperative that the Cancer Moonshot not repeat this history.

- Martinez and Paskett (2018); JAMA Oncology.

Background: Example of Direct Participant Engagement: Myeloproliferative Disorders

- An internet-based protocol collected clinical information and biological specimens for several hundred patients
- Determined that a significant number of patients had recurrent mutations which were a potential target for pharmacologic inhibition
- Highlights how the internet can expand reach beyond traditional clinic-based approaches and address a research gap

Defining Direct Participant Engagement

- **Participant engagement** is an ongoing, bi-directional and mutually beneficial interaction between participants and researchers, where participants are included as an integral part of all phases of the research process: including the identification of research priorities and the design, conduct and uptake of research (*Fergusson et al 2018*)
- By **direct participant engagement**, we mean:
 - Research teams interact directly with participants (via the web, social media, online patient communities), not through providers or the clinical care setting
 - Incorporate input throughout research process (through surveys, interviews, and regular communication from consenting to return of research results)



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

- 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 network will also include a **Steering Committee** and a **External Advisory Panel** described in the RFA.
- 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.

Addressing the Cancer Moonshot Open Access Pilot Program

- Utilizing the provision outlined in the 21st Century Cures Act, NCI has established a data sharing policy for projects that are funded as part of the Cancer MoonshotSM Initiative that requires applicants to submit a Public Access and Data Sharing Plan that:
 - (1) describes their proposed process for making resulting publications and to the extent possible, the underlying primary data immediately and broadly available to the public upon publication; and
 - (2) if applicable, provides a justification to NCI if such sharing is not possible.
- NCI will give competitive preference and funding priority to applications that comply with the strategy described.
- The data sharing plan will become a term and condition of award.
- <https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy>

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

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

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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. <i>Note: These could be selected in the first round.</i>
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.

Scientific Focus of the PE-CGS U2C Research Centers

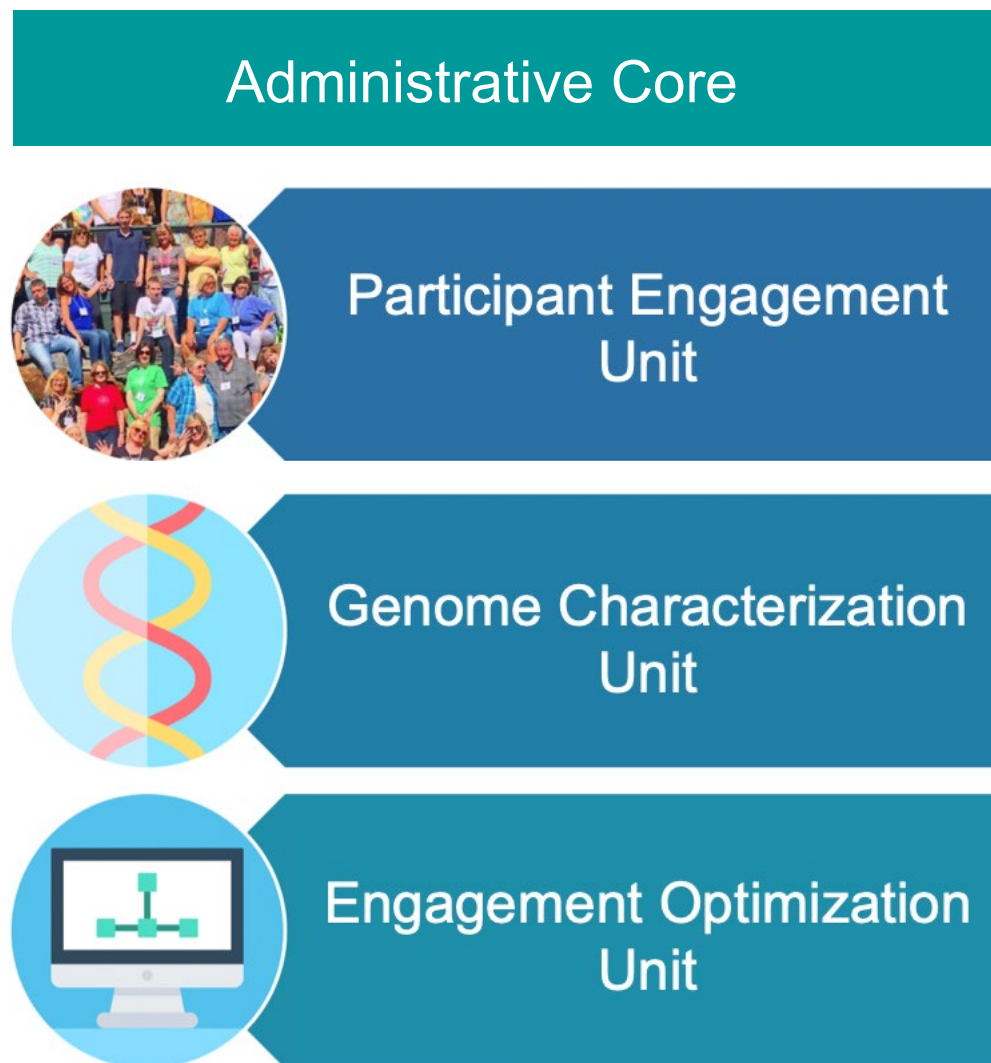
- Each proposed PE-CGS U2C Research Center should be centered on addressing a unique research knowledge gap in the genomic characterizations of tumors.
- Knowledge gaps proposed for characterization are expected to be mainly identified in several specific areas of interests (Interest Areas 1-5 below).
 - 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.

PE-CGS U2C Research Centers: Points to Consider

- The multidisciplinary team should include an appropriate combination of such specialties as:
 - Social and behavioral scientists (with expertise in direct engagement, health communication, and health literacy);
 - Oncologists and pathologists (with expertise in biospecimen science);
 - Molecular biologists, geneticists, and bioinformaticians (with expertise in genomic characterizations as well as integration and evaluation of "omics" data); and
 - Genetic counselors
- Each PE-CGS U2C Research Center will be expected to collaborate across the PE-CGS Network with other U2C Research Centers.
 - These collaborations will be facilitated by special set-aside “collaborative funds”.
 - Collaborative projects are intended to facilitate sharing best practices, optimizing approaches, and addressing common issues.

Structure of the PE-CGS U2C Research Centers

Each proposed PE-CGS U2C Research Center must include the following components:



PE-CGS U2C Research Centers Application Structure

- Sections: Overall, Administrative Core, Participant Engagement Unit, Genome Characterization Unit, Engagement Optimization Unit

Component Types (or Sections)	Research Strategy/Program Page Limits
Overall	12
Administrative Core	6
Participant Engagement Unit	12
Genome Characterization Unit	12
Engagement Optimization Unit	12

PE-CGS U2C Research Centers Application Structure

- Each section has its own required PHS 398 Research Plan Structure (Research Strategy sub-sections). *See RFA for details
- For example for the “Overall” section these sub-sections include:
 - Sub-section A: Research Focus and Significance
 - Sub-section B: Research Center Organization and Team Integration
 - Sub-section C: Overall Approach and Structure of Research Units
 - Sub-section D: Milestones and Timelines
 - Sub-section E: Network-wide Collaboration
 - Sub-section F: Health Disparities
- NOTE: Be sure to also speak to significance and innovation of your approach.
- NOTE: Be sure to review RFAs for further details regarding structure and review criteria

PE-CGS U2C Research Centers Attachments (Overall Section)

- Other Attachments: Applicants must provide the following additional materials in support of their application. Each attachment should be uploaded as a separate PDF using the indicated filenames (which will serve as application bookmarks).
 - Attachment 1: A table listing of Available Partnerships and Infrastructures along with their main characteristics [use file name “Partnerships and Infrastructure”].
 - Attachment 2: PE-CGS U2C Research Center Engagement Process [use file name “Engagement Process”].
 - Attachment 3: Example draft consent form(s) [use file name “Consent”]

Administrative Core

Administrative Core

- The Administrative Core will provide the administrative support to the PE-CGS U2C Research Center leadership.
- The main roles of the Administrative Core will include:
 - Oversight and support of all research activities;
 - Facilitating interaction among the three functional units of the Center;
 - Support coordination among PE-CGS U2C Research Centers and implementation of agreed upon PE-CGS Network practices and principles

Participant Engagement Unit



Participant Engagement Unit

- This Unit will be responsible for a direct participant engagement for the purpose of performing genomic characterization
- Direct participant engagement, recruitment, tissue acquisition (normal and tumor), data collection, return of information to participants
- Number of participants justified by cancer frequency and characteristics of cancer
- Critical role for oncologists, pathologists and genetic counselors

Participant Engagement Unit: Points to Consider

- The participant engagement strategies proposed are expected to use current state-of-the-art, culturally sensitive approaches.
- This unit should be designed to ensure continuous improvements to the engagement process by interactions with and adapting research findings from the Engagement Optimization Unit
- See RFA for more details regarding activities including:
 - Reporting research findings to participants as well as returning individual-level genetic information to those participants who are interested in receiving such data;
 - Maintaining an ability to re-contact participants, e.g., to obtain follow-up clinical and/or epidemiology data.
- Blood specimens should be proposed as a source for normal DNA, however, in situations where it is not possible to collect blood specimens, an alternative source may be proposed if appropriate.

Return of Information to Participants

- The return of individual research results is a critical way to engage and respect research participants;
- Participants need to be able to **opt-in** to receive, depending on their preferences:
 - Summary of individual health information used in the study
 - Ongoing study updates
 - Aggregated results
 - Lay summary of scientific findings/ research results
 - Individual germline and somatic genetic results
 - Other information preferred by participants



PE-CGS Policy for Returning Genetic Information

- Clinical Laboratory Improvement Amendments (CLIA) sequencing allows for broader return of genetic information
- **NCI PE-CGS Recommended Germline Return policy** – Report back to participants and their oncologist pathogenic variants within the ACMG59 cancer genes
- **NCI PE-CGS Recommended Somatic Return policy** – Report back to participants and their oncologist potentially actionable variants
- Additional plan details (relevant to specific cancer type or population of study) can be suggested by U2C investigators
- It is anticipated that this area will evolve and this policy will be periodically evaluated and revised



Genome Characterization Unit



- This Unit should be capable of completing all the steps required for the tumor and normal characterizations (i.e., DNA and RNA sequencing, bioinformatic analyses and interpretations, etc.).
- Sequencing to be performed in a laboratory certified and fully compliant with Clinical Laboratory Improvement Amendment (CLIA) (to allow for return of genetic information)
- Required Characterization: Whole Exome Sequencing, RNA Sequencing, low pass Whole Genome Sequencing
- Applicants may propose additional types of genome characterization if appropriate
- Data to be submitted to the NCI Cancer Genomics Data Commons (GDC)

Genome Characterization Unit: Points to Consider

- NOTE: Sequencing should be performed in batches to maximize the efficiency of sequencing.
- Investigators must be prepared to discuss the possible need for a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) with their IRBs and document the outcome of those discussions, and to subsequently engage in pre-submission discussions with the FDA if the IRB determines they are needed.
- Each PE-CGS U2C Research Center is expected to share information about algorithms used for interpretation and will be encouraged to share informatics tools.

Engagement Optimization Unit



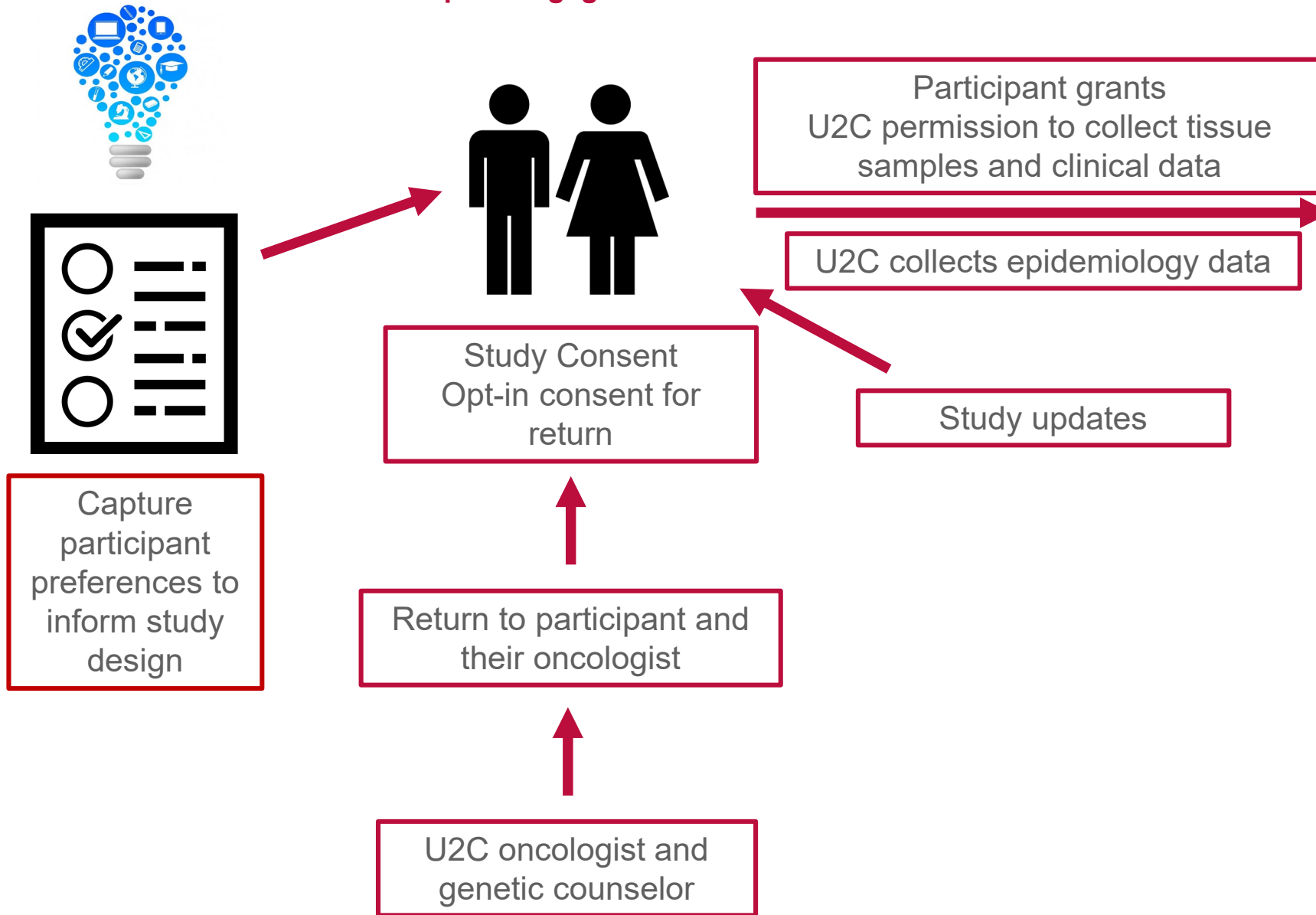
Engagement Optimization Unit

- This Unit should be able to incorporate rigorous behavioral research on optimal approaches to participant engagement in various aspects ranging from recruitment, communication, to education about genomic characterization goals and discoveries.
- Interventions to be developed and tested should be designed to identify optimal approaches. For example:
 - Directly reaching and communicating with potential participants about goals and values of genomic characterization
 - Engaging with understudied and/or underrepresented populations
 - Using Web-based and social media platforms
 - Leveraging established partnerships with patient communities

Engagement Optimization Unit: Points to Consider

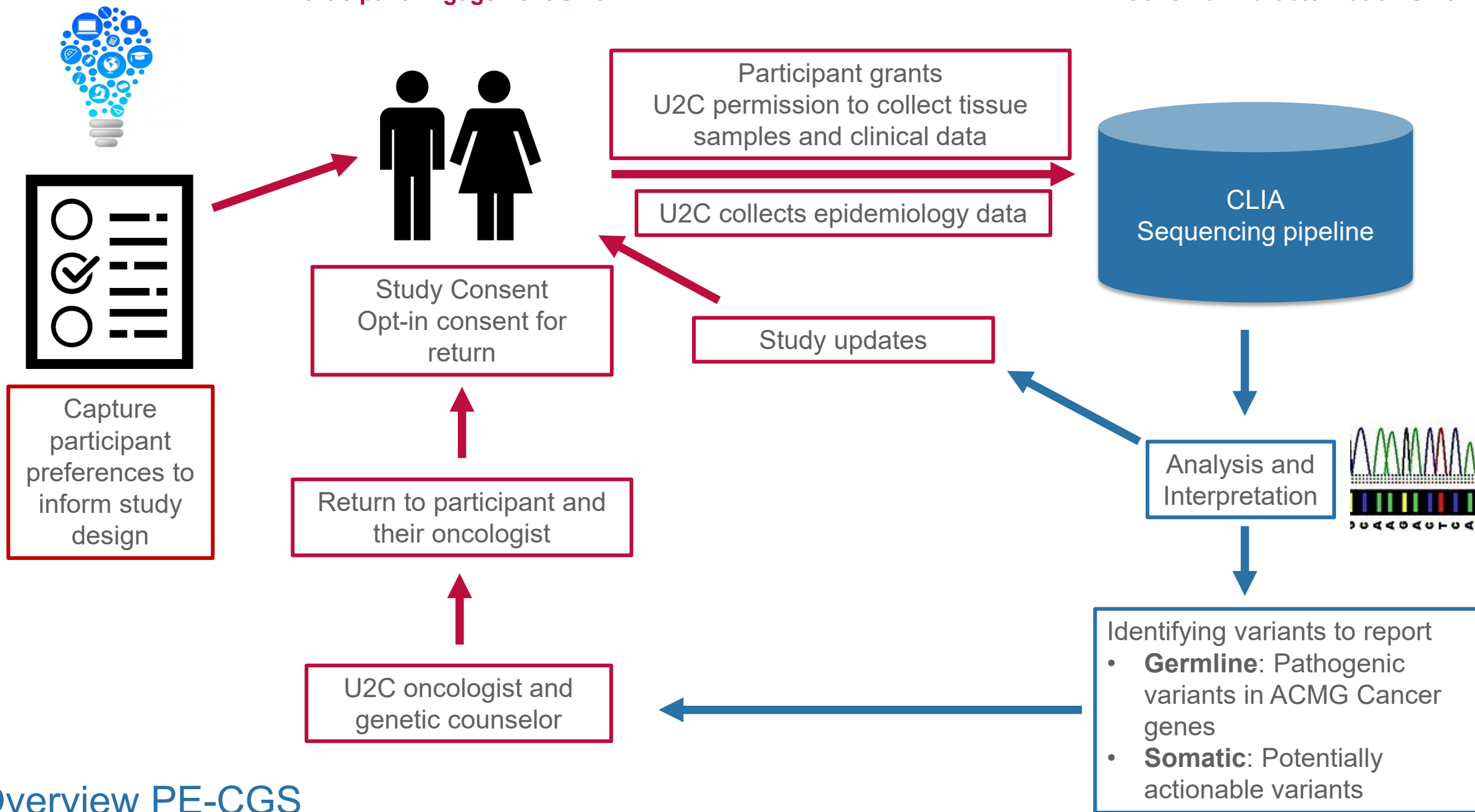
- Research activities/interventions to be developed by the Engagement Optimization Unit should be fully integrated and serve overall goals of the U2C Research Center
- Applicants must identify initial empirical research questions and provide plans to address these questions.
- Applicants must describe how results from the Engagement Optimization Unit will inform protocols developed by the Participant Engagement and Genome Characterization Units.

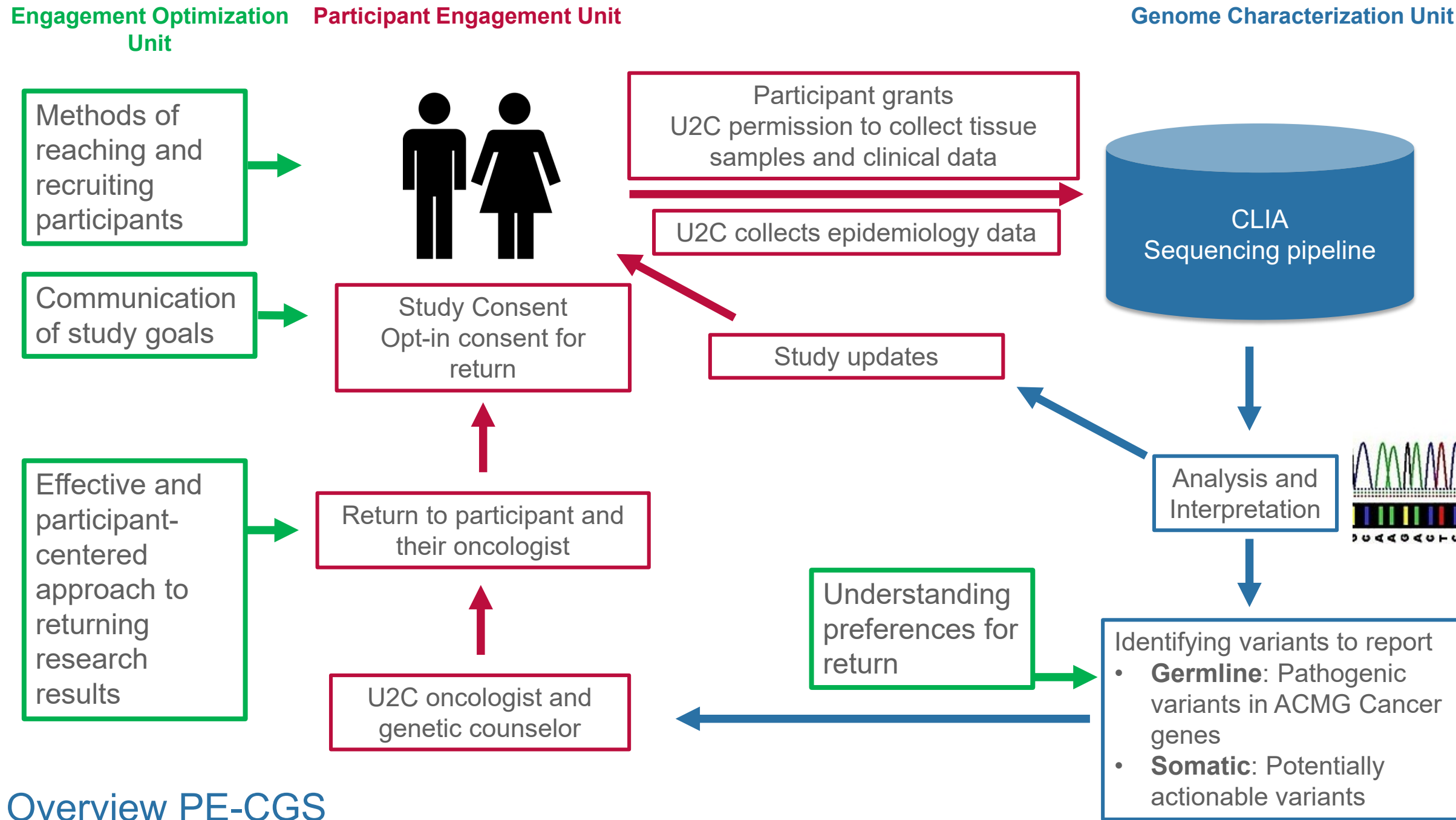
Participant Engagement Unit



Participant Engagement Unit

Genome Characterization Unit





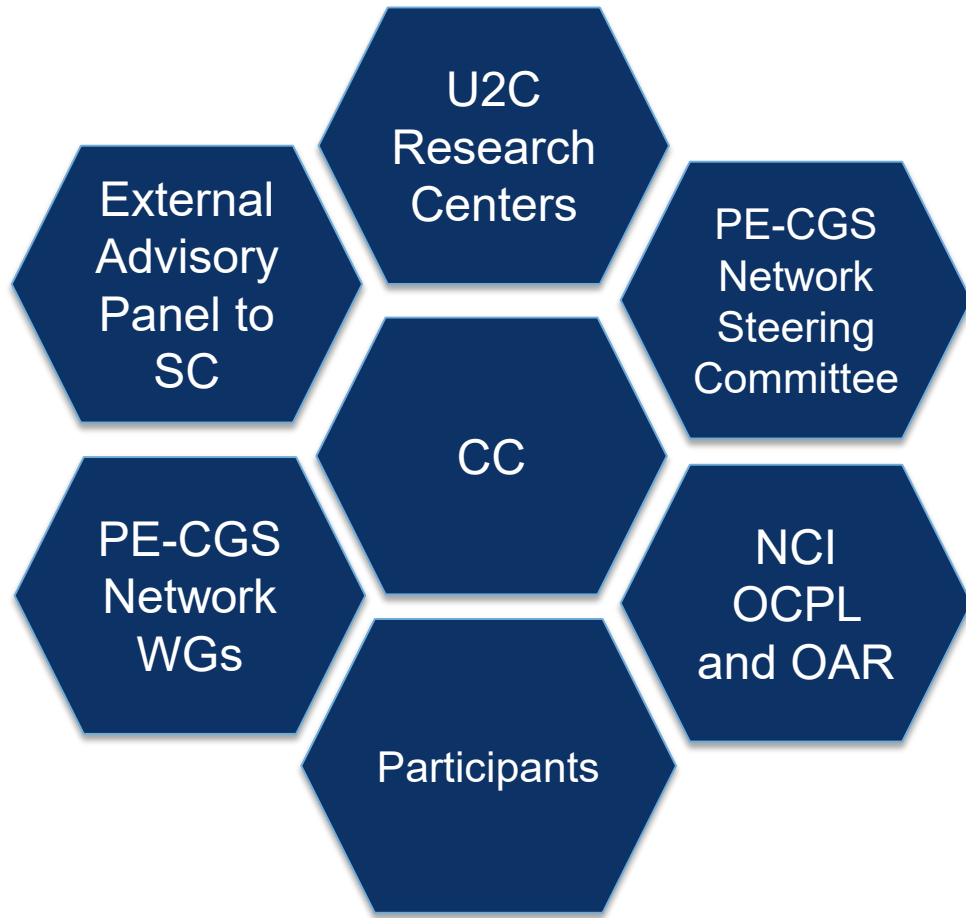
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PE-CGS: Coordinating Center (U24 Clinical Trial Not Allowed) RFA-CA-19-046 by the numbers

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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* <i>Note: If an awardee is selected in the first round, the FOA will be expired.</i>
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.

PE-CGS: Coordinating Center (U24)



- The PE-CGS U24 Coordinating Center will operate as supporting infrastructure for the PE-CGS Network.
- Collaborate with PE-CGS U2C Research Center investigators and interact with involved NCI staff members and with other stakeholders, as needed.
- Major responsibilities of the Coordinating Center will include:
 - Administrative and scientific coordination of Network activities (**Network Coordination**);
 - Development and coordination of outreach and promotion materials and communication channels (**Outreach and Promotion**); and
 - Development and implementation of standardized approaches to data collection and processing as well as other "best practices" for the Network (**Network Best Practices**).
- NOTE: see RFA-CA-19-046 for Specific functions

U24 Coordinating Center: Points to Consider

- The composition of the research team must ensure the requisite expertise in participant engagement and cancer genome characterization.
- The team should be capable of effective communications and productive collaborations with various stakeholder groups
- The team is expected to include senior members with considerable leadership skills and experience in coordination of multi-center networks with large research teams and/or multi-stakeholder groups in diverse settings
- Experience in the development of accessible, user-friendly communications materials and ability to leverage various communication channels to share information to target end-users

PE-CGS U24 Coordinating Center Application Structure

- Research Strategy: In lieu of the standard sub-sections listed in the SF424 (R&R) Application Guide, the Research Strategy must consist of the following modified sub-sections:
 - Sub-Section A: Vision and Organization
 - Sub-Section B: Network Coordination
 - Sub-Section C: Network Outreach and Promotion
 - Sub-Section D: Network Best Practices
 - Sub-Section E: Health Disparities
- NOTE: Be sure to also speak to significance and innovation of your approach.
- NOTE: FOA specific review criteria and Cooperative Agreement Terms and Conditions of Award

What will this PE-CGS Network Accomplish?

- Address research gaps in molecular profiles of cancer
- Determine effectiveness of direct participant engagement approach
- Provide insights into development and sustainability of a larger network for direct participant engagement
 - Learn and respond to participant preferences
 - Identify optimal methods of engagement and communication
- Data will be shared as a resource

Questions?

Contact: NCI_PE-CGS@mail.nih.gov



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