

# ***The Participant Engagement and Cancer Genome Sequencing (PE-CGS) U2C Cancer Moonshot Program at Washington University in St. Louis***



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# DISCLOSURES

- No conflicts of interest
- No disclosures
- I will not discuss the off-label use of any diagnostics or therapeutics.

# 2015 – Cancer Moonshot



HOME SEARCH

The New York Times

POLITICS

## *\$1 Billion Planned for Cancer ‘Moonshot’*

By GARDINER HARRIS FEB. 1, 2016



Vice President Joseph R. Biden Jr., left, met with doctors at the Perelman School of Medicine and Abramson Cancer Center in Philadelphia last month. The vice president is leading the administration's cancer “moonshot” after his son

[Home](#) > [Research](#) > [Key Initiatives](#)


## CANCER MOONSHOT<sup>SM</sup>

Progress

Research Initiatives +

Seminar Series

Funding Opportunities +

Blue Ribbon Panel +

## Cancer Moonshot<sup>SM</sup>

The Cancer Moonshot—a bold effort to accelerate progress in cancer research—is a once-in-a-lifetime opportunity for the cancer community and our nation to come together around a single disease that touches all of us. It aims to make more therapies available to more patients, while also improving our ability to prevent cancer and detect it at an early stage.

The Cancer Moonshot has three ambitious goals: to accelerate scientific discovery in cancer, foster greater collaboration, and improve the sharing of data.

By focusing on areas of cancer research that are most likely to benefit patients as a result of new investment, the Cancer Moonshot has brought together a large community of investigators and clinicians who are dedicated to expediting research to improve the lives of people with cancer and their loved ones.

Congress passed the 21st Century Cures Act in December 2016, authorizing \$1.8 billion in funding for the Cancer Moonshot over 7 years. The funding must be appropriated each fiscal year (FY) over those 7 years. Congress appropriated \$300 million to NCI for FY 2017, \$300 million for FY 2018, \$400 million for FY 2019, and \$195 million for FY 2020.

Although it is only at the midway point in terms of funding, the Cancer Moonshot is well on its way to producing meaningful improvements for people with cancer.

[Get email updates from NCI on the Cancer Moonshot.](#)

### Cancer Moonshot Progress

Learn about the progress that has been made through the various Cancer Moonshot initiatives.

<https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative>

## CANCER MOONSHOT<sup>SM</sup>

Progress

### Research Initiatives

Direct Patient Engagement Network

Adult Immunotherapy Network

Pediatric Immunotherapy Network

Drug Resistance Network

National Cancer Data Ecosystem

Drivers of Childhood Cancers

Symptom Management

Hereditary Cancers

Prevention & Early Detection Strategies

Retrospective Analysis of Biospecimens

Human Tumor Atlas Network

New Enabling Cancer Technologies

Seminar Series

Funding Opportunities

+

Blue Ribbon Panel

+

## Cancer Moonshot<sup>SM</sup> Research Initiatives

Following receipt of the Blue Ribbon Panel (BRP) report, and the authorization of the 21st Century Cures Act, NCI established implementation teams that align with each of the BRP recommendations. The teams have identified opportunities and developed initiatives for funding that directly address each of the recommendations. These mark the beginning of a Cancer Moonshot portfolio that will continue to be expanded in future years.

The following initiatives have been established to address the goals of the recommendations:

### Establish a Network for Direct Patient Engagement

Engage patients to contribute their comprehensive tumor profile data to expand knowledge about what therapies work, in whom, and in which types of cancer.

### Create an Adult Immunotherapy Network

Establish a cancer immunotherapy research network to develop immune-based approaches for the treatment and prevention of cancer in adult patients.

### Create a Pediatric Immunotherapy Discovery and Development Network (PI-DDN)

Generate a cancer immunotherapy research network to overcome challenges in the development of immunotherapies for childhood cancers.

### Develop Ways to Overcome Cancer's Resistance to Therapy

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

### Build a National Cancer Data Ecosystem

Create a national ecosystem for sharing and analyzing cancer data so that researchers, clinicians, and patients will be able to contribute data, which will facilitate efficient data analysis.

### Intensify Research on the Major Drivers of Childhood Cancers

Improve our understanding of fusion oncoproteins in pediatric cancer and use new preclinical models to

<https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation>

## CANCER MOONSHOT™

Progress

Research Initiatives

### Direct Patient Engagement Network

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Blue Ribbon Panel +

## Establish a Network for Direct Patient Engagement

The Blue Ribbon Panel (BRP) recommended establishing a network for direct patient engagement that could provide cancer patients with the opportunity to receive comprehensive tumor profiling, the results of which could be entered into a linked network of databases. The information obtained would be used to help researchers better understand what interventions work, in whom, and in which types of cancer. Engaging patients and researchers to work together towards a shared vision and implementation of the network was considered to be critical to advance cancer research and care.

NCI has announced several funding opportunities that align with the Cancer Moonshot.

[See Funding Opportunities](#)

Increasing the diversity of research participants was also a critical need noted by the BRP. When and how cancer develops, and how cancer treatments work, can be different in different populations and different communities across the country. A network for direct patient engagement could help provide information and opportunities for a broad and diverse group of patients to participate in research. Representing all populations in research is extremely important in order to better understand cancer and improve therapy options for all. Such a network could also "pre-register" patients for clinical trials by enabling them or their physicians to be contacted if their tumor's profile fits the eligibility criteria for a clinical trial.

Ultimately, the hope is that a network would expand research participation, improve access to data from advanced tumor profiling to improve the identification and treatment of cancers, and improve knowledge about cancer outcomes across diverse patient populations.

NCI has funded several programs and workshops that align with this recommendation to increase direct patient engagement:

### The Cancer Moonshot Biobank

Biospecimens donated by cancer patients are an important resource for understanding and accelerating cancer research. NCI created the [Moonshot Biobank](#) to collect tumor biopsy and blood biospecimens from a

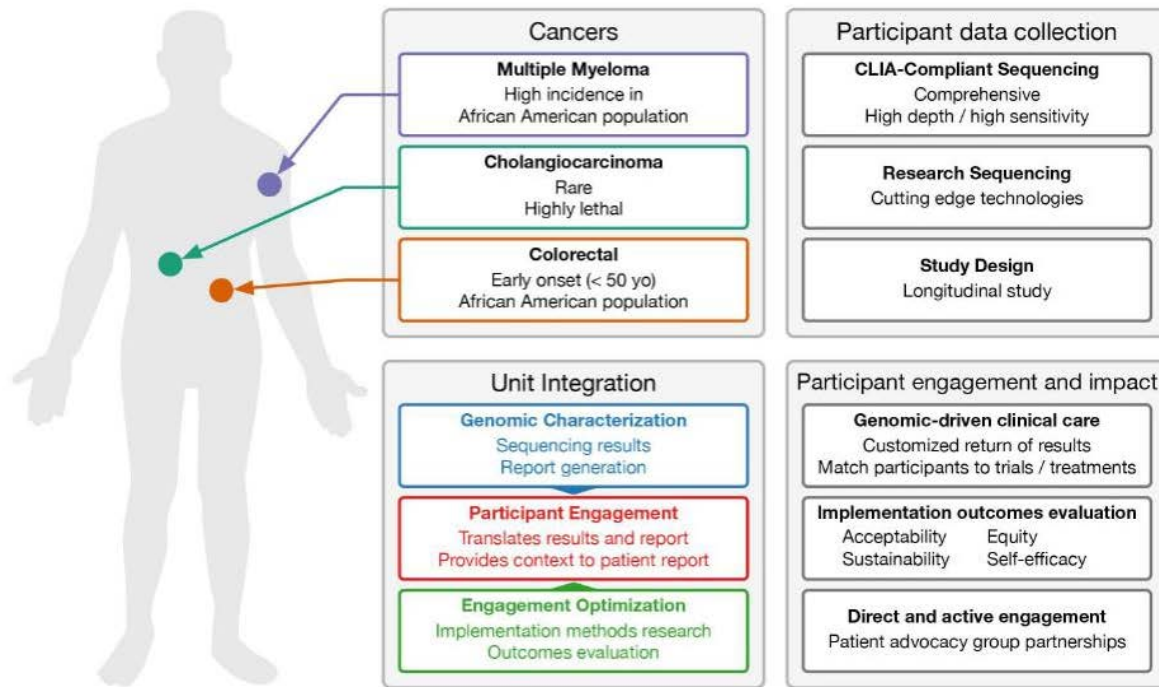
<https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/patient-engagement>

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

- The PE-CGS Network supports the direct engagement of cancer patients and cancer survivors as participants in cancer research.
- The PE-CGS Research Centers are using direct participant engagement approaches to promote cancer genome sequencing programs that can address important knowledge gaps in the genomic characterization of tumors. The network is specifically interested in using direct participant engagement to advance the understanding of rare cancers, highly lethal cancers, cancers with an early age of onset, cancers with high disparities, and cancers that are prevalent in understudied populations.
- The PE-CGS Coordinating Center manages data sharing and collaborative network activities, performs outreach activities to the broader community, and develops best practices and procedures for the network.

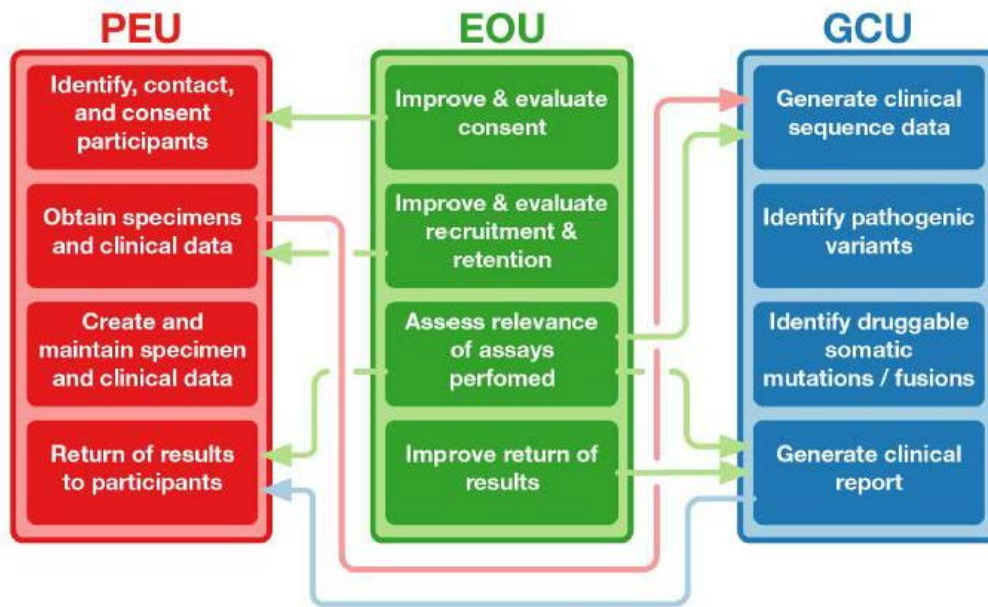
<https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/implementation/patient-engagement>

# The Participant Engagement and Cancer Genome Sequencing (PE-CGS) U2C Cancer Moonshot Program at Washington University in St. Louis



**Overview Figure.** Major goals of the WU-PE-CGS center.



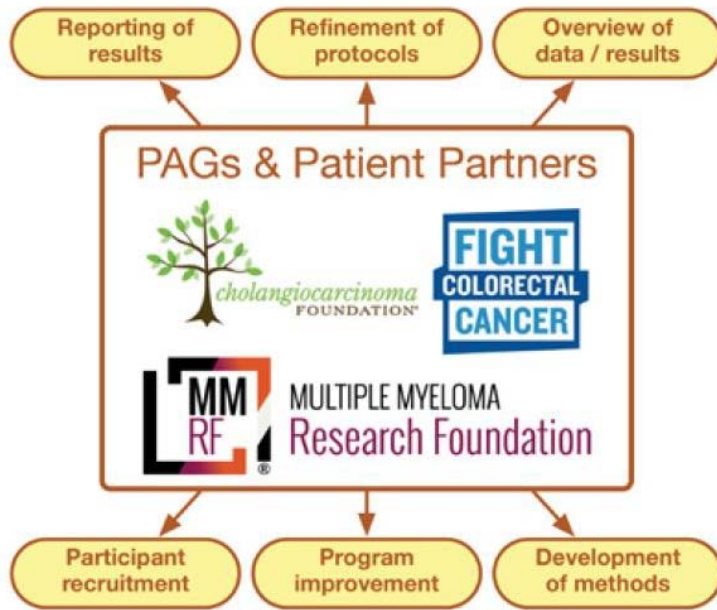


## Principal Investigators

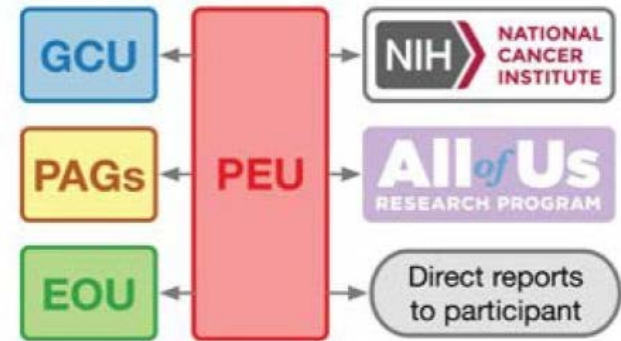
- Ryan Fields, MD – Surgical Oncology
- Graham Colditz, DrPh, MD, MPH – Public Health Sciences
- Bettina Drake, PhD, MPH – Public Health Sciences
- Li Ding, PhD – Cancer Genomics

**Figure 6. Major functions and structure of PEU, GCU, and EOU.** Interactions and cross-talks among these three units in WU-PE-CGS are indicated by arrows.





**Figure 2:** Stakeholder-centered philosophy of the PEU, incorporating patient advocacy group (PAG) and patient-partner input (center) in all aspects of the PEUs mission and aims (yellow balloons).

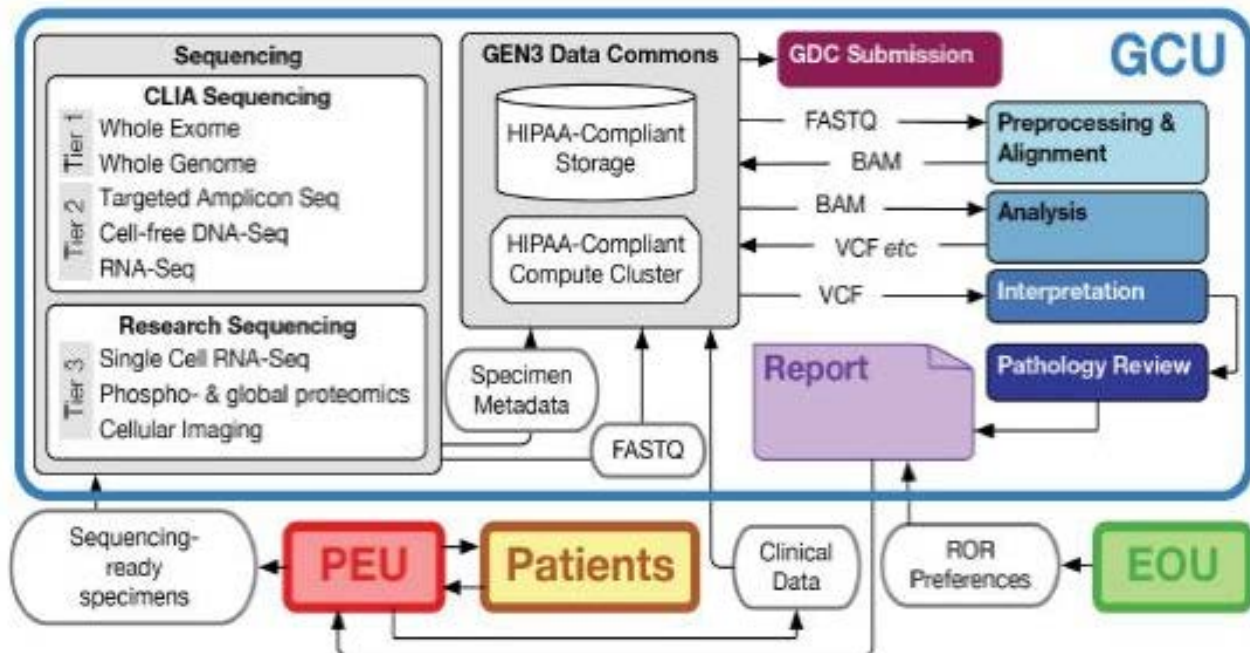


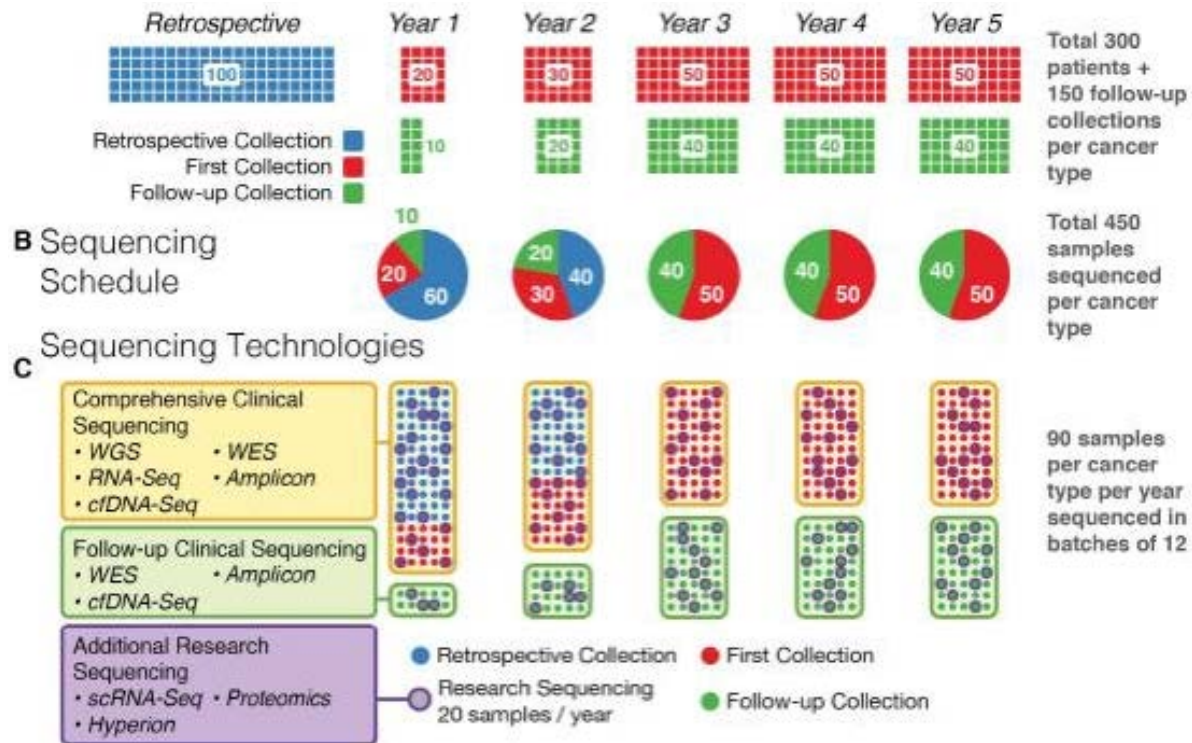
**Figure 3:** PEU outputs to all stakeholders vested in the overall mission of the PE-CGS program.

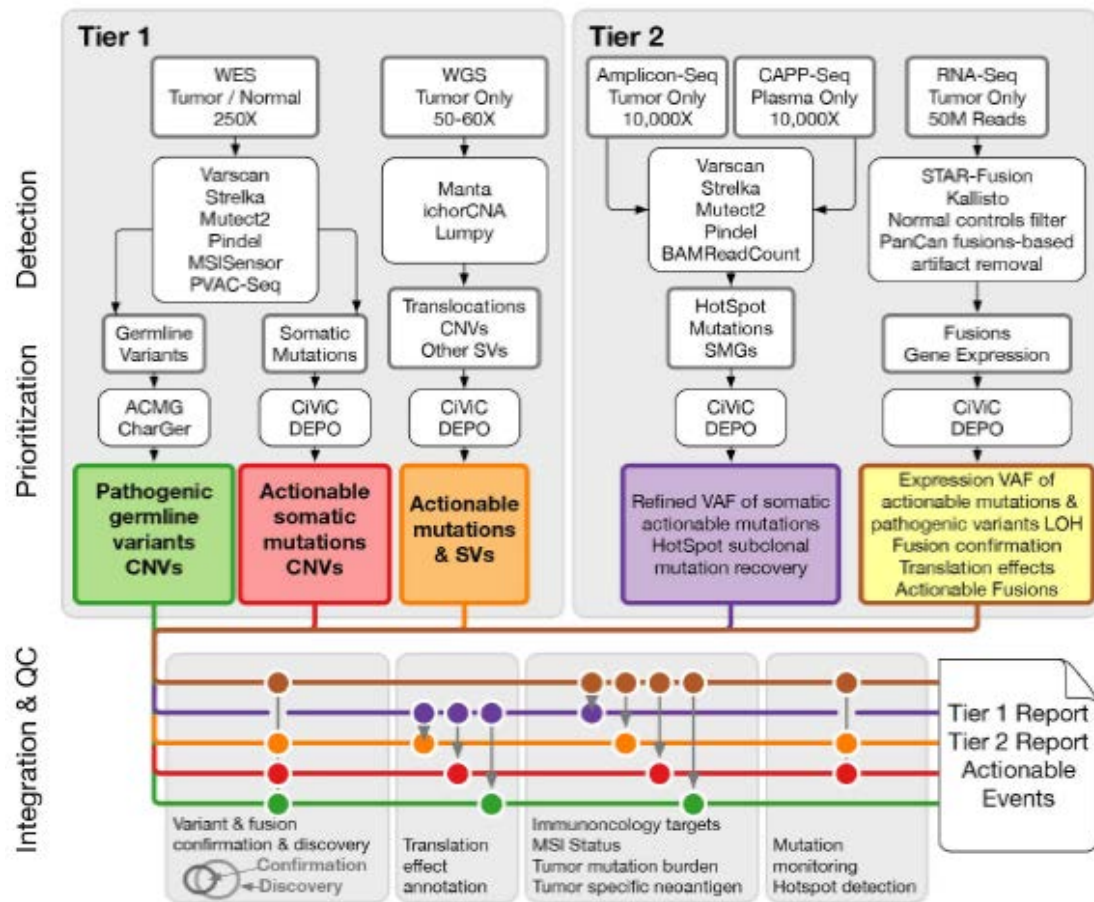
	Objective	Year 1				Year 2				Year 3				Year 4				Year 5			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
General PEU Components	PRMC and IRB approval	█																			
	Creation of PEU REDcap database	█																			
	Creation of PEU informatics portal & dashboard		█																		
	Identification of retrospective participants		200‡																		
	Consenting of retrospective participants		100‡																		
	Identification of prospective participants *				50			100				150			200					250	
Consenting of prospective participants *				40			80			120			160						200		
Participant Data	Obtain participant tumor/normal specimens *		100‡		40			80			120			160					200		
	Obtain participant clinical data/metadata *		100‡		40			80			120			160					200		
	Entry of participants into PEU databases *		100‡		40			80			120			160					200		
	Follow-up with all participants (at least quarterly)	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█
PEU Output	Handoff of specimens to GCU *			100‡	20			80			120			160					200		
	Return of results to participants *						100‡	80			120			160					200		
	Follow-up with all participants (at least quarterly)	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	
	WU PE-CGS quarterly newsletter publication	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	█	

\* Cumulative prospective benchmarks for each cancer type at each timepoint, unless otherwise specified.

‡ Retrospective samples for each cancer type.

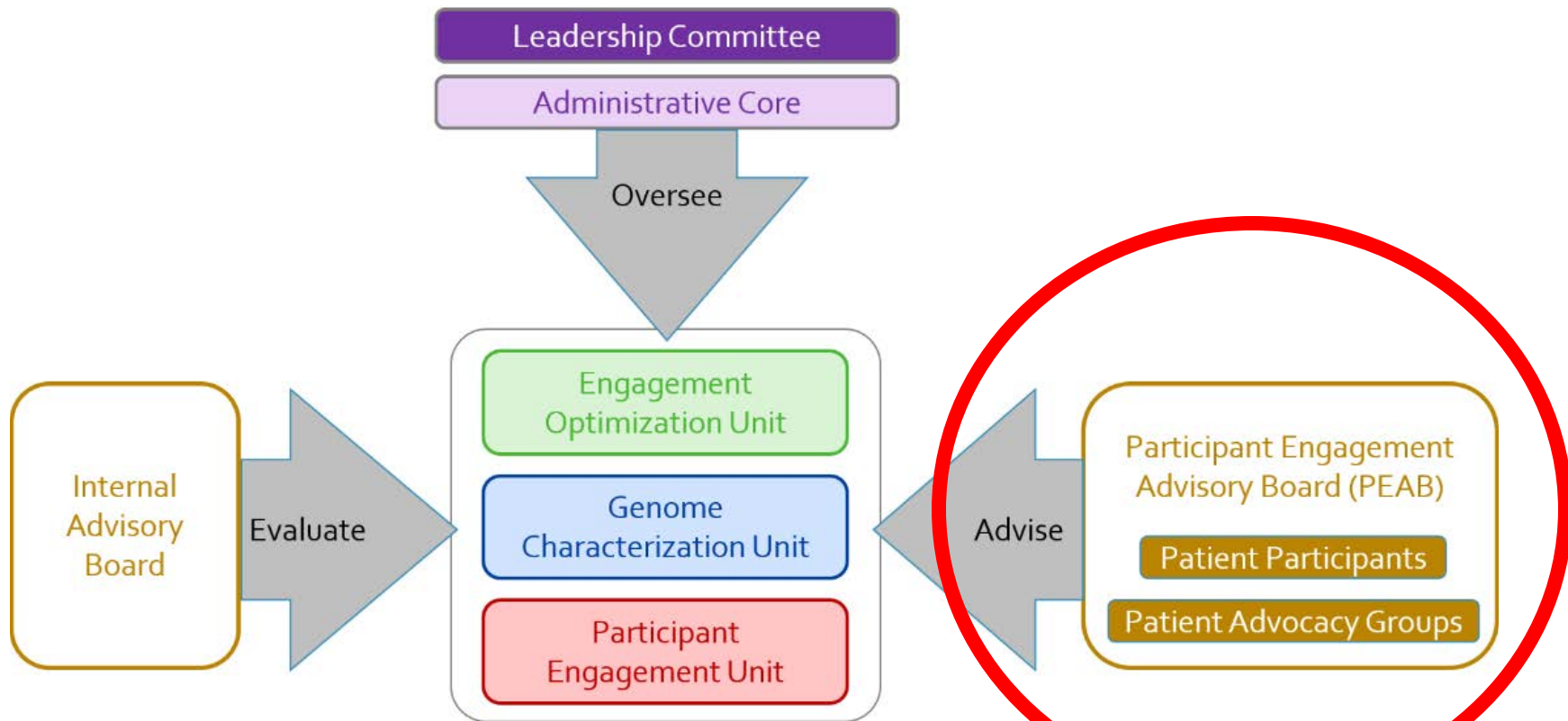






# Engagement Optimization Unit (EOU)

- Evaluate participant engagement related to genomic testing among underserved populations with rare cancers
  - Improve and evaluate recruitment and retention
  - Improve and evaluate consent
  - Improve and evaluate return of results
- Conduct a randomized trial comparing an expanded web-based education and decision aid with the standard practice to improve the return of results process
- Qualitative Interviews with patients, families, and people who decline
- Use an embedded ethics approach to better understand and address ethical, legal, and social implications (ELSI) of this research



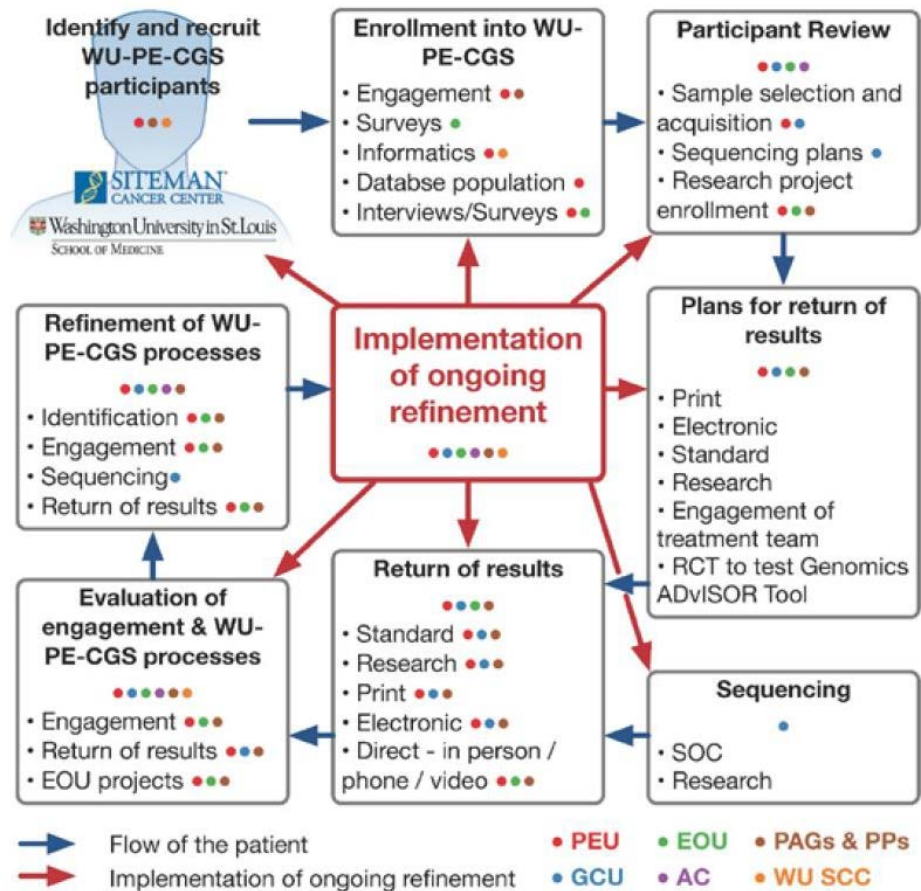


# Participant Engagement Advisory Board

- Provide patient and engaged stakeholder (advocates, caregivers, etc) input on multiple center processes, including recruitment, consenting, and return of results.
- Review surveys and research findings
- Advise researchers on how to best use study findings to improve our approach
  - improving consent process
  - making genomic testing results clear to participants
- Share research results and study information with your community partners
- Identify challenges and advise in addressing barriers







# Help Us To Learn More About Colorectal Cancer!

Colorectal Cancer in young (under 50) Black patients is a priority area of research as part of the National Cancer Institute's "Cancer Moonshot" program. We are inviting patients and survivors within this population from around the country to be a part of this study to learn more about this cancer, especially its genetics.

This research study involves surveys and interviews with participants, a review of previous medical records, and a genetic study of previous biopsy tissue. **No extra patient visits or procedures are needed.**

If you are interested in being part of this study or just want to learn more, **please contact us at:**

email : [pecqs@wustl.edu](mailto:pecqs@wustl.edu)

phone: 314-273-2434

web: [sites.wustl.edu/pecqs](http://sites.wustl.edu/pecqs)

**FIGHT**<sup>™</sup>  
★  
**COLORECTAL CANCER**

 **SITEMAN**  
CANCER CENTER

 Washington  
University in St. Louis  
SCHOOL OF MEDICINE

 **BJC** HealthCare

**NCI** CANCER MOONSHOT  
A program of the National Cancer Institute  
of the National Institutes of Health

*ent and Cancer Genome Sequencing (WU-PE-CGS)  
al Cancer" patient advocacy group.*