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Overcoming Systemic Barriers to Make Patient-Partnered Research a Reality

Vinayak Venkataraman, MD[1,2]; Bailey A. Martin-Giacalone, PhD[3,4]; Bettina F. Drake, PhD, MPH[3,4]; Liz Salmi, AS[5]; Elizabeth B. Claus, MD, PhD[6,7]; Anne L.R. Schuster, PhD[8]; John F.P. Bridges, PhD[8]; Heinz-Josef Lenz, MD[9,10]; Cheryl L. Willman, MD[11,12]; Diane Diehl, PhD[13]; Katherine A. Janeway, MD, MMSi[2,14]; Jennifer W. Mack, MD, MPH[2,14]; and Suzanne George, MD[1,2]

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Direct participant engagement in research, defined as involving ongoing, bidirectional, and mutually beneficial interactions among participants and researchers where participants are included as an integral part throughout the research process,[1-3] is critical for cancer research and a central tenet of the Cancer Moonshot.[4] As described by the National Cancer Institute (NCI), engaging patients and the public in cancer research is critical to understanding the biology of cancer, how to prevent and treat it, and how to deliver care to all people with cancer.[5]

The NCI established the Participant Engagement and Cancer Genome Sequencing (PE-CGS) Network in response to the goals of the Cancer Moonshot. The PE-CGS[7] is composed of five research centers and one coordinating center, to promote effective participant engagement in cancer genomic research and to accelerate discoveries in rare, understudied cancers and in cancers that arise in diverse, underrepresented, and understudied populations.[1,7] The network's efforts to promote direct-to-participant engagement include leveraging technology, such as virtual and digital platforms, use of culturally appropriate communications and informed consents respectful of diverse cultural perspectives and beliefs, delivery of clinically certified genomic results in the clinical setting to be of direct beneficence to participants and their health care providers, and collection of data from electronic health records (EHRs) with direct delivery of genomic results to participants.[1,5-9]

PE-CGS will design systems and operations that allow any person, wherever they live, to contribute their health information, cultural and social perspectives and beliefs, biologic samples, and personal narratives of lived experiences to cancer genomic research.[1] However, after participants express their desire to participate, several structural barriers remain a challenge to full participation. Through embedded researcher-patient partnerships, the PE-CGS Network is uniquely positioned to identify, and offer solutions to, these challenges, which may have application across oncology clinical research broadly. For example, fields or research programs new to such efforts should consider building capacity for sustainable community partnerships, including those with community organizations and initiating community advisory boards. This commentary highlights a range of experiences from the research sites that have been shared and discussed through the PE-CGS Network.[7]

In this commentary, we discuss the barriers posed by processes of consent, data exchange, and EHR interoperability that hinder how researchers honor patients' desires to contribute to the advancement of cancer research. We also propose potential solutions to address these barriers.

THE CONSENT PROCESS IS BURDENSOME

Once a participant decides that they want to learn about participation in cancer genomics research, the next steps are to review and sign a consent form.

The amount of time necessary to complete the consent process, typically more than 30 minutes, can be a barrier to participation. Consent forms for cancer research are generally lengthy and verbose, with median word count over 5,000 words for clinical trials.[10]

Consent forms are not often easily readable to patients and their families, and may not be appropriately translated into less common native languages for the increasingly diverse and

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indigenous populations across the United States and the world. The median readability of consent forms for cancer clinical trials (per Flesch-Kincaid testing) is beyond the 10th grade.[11] This is problematic, given that national engagement efforts, such as PE-CGS, are focused on diverse and underrepresented populations, including those who may have less proficiency in English as a secondary language and those who may have lower levels of formal educational attainment. Additionally, consent forms are not typically tailored to pediatric and young adult populations, a population which is the focus of one of the PE-CGS centers.

Participation by young adults, men, and non-White populations in cancer genomics research is particularly limited.[12-14] Time, academic language, and technical jargon are established barriers; in addition, a lack of appreciation for diverse cultural, social, and religious practices, beliefs, and norms regarding collection, use, and storage of biospecimens, concerns over genetic privacy or discrimination or perceived harms of genetic testing, and language barriers to the consent process further worsen disparities in research engagement in underrepresented and understudied populations.[15,16] Compared with traditional biomedical studies, the PE-CGS prioritizes the optimization of equitable engagement, yet this is still time- and resource-intensive.

Another challenge is the large variance between different institutional review boards (IRBs) in their recommendations to investigators regarding the content detail and readability of study consent forms.[17] In addition, although many IRBs have formalized policies and practices regarding appropriate consent readability, as well as other methods to improve community engagement and participation, they are not consistently enforced.[18]

The consent process needs to be improved to make it more responsive to the needs of diverse participants. Consent forms could be improved by minimizing technical jargon and verbosity, ensuring adequate readability by validated calculators such as Flesch-Kincaid, providing consent forms in multiple languages, and proactively addressing potential concerns and misconceptions.[19] The consent process could also leverage novel technology, such as video or other interactive mobile modalities, produced in native languages for specific populations to optimize the overall process.[20,21] IRB practices should be standardized across institutions and enforce policies to ensure adequate readability and understanding of all potential participants.

A notable example of these concepts in practice is the National Institutes of Health *All of US* informed consent process, which features short animations and interactive quizzes, and was designed to assess participant understanding at enrollment. A study of the *All of US* informed consent process showed 95% of enrollees could correctly answer questions about the process upon recall.[22]

OBTAINING HEALTH INFORMATION IS FRAGMENTED, TIME-CONSUMING, AND COSTLY

As a part of the consent process, participants are generally asked for permission to review their health information. This grants researchers permission to either access health records with appropriate approval of their IRBs and/or to request transfer of patient health records from each participant's institution. These records allow researchers to examine care and outcomes and to ensure that the correct clinical data and samples are acquired. Although this task may sound straightforward, research centers face many challenges to obtaining each patient's data, despite patient consent to release their health information.

In the United States, patients have a legal right to access their health information and a right to share it with any individual or entity on the basis of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA).[23,24] This includes full access to medical and billing records held by health providers and insurance data held by health plans.[23] The 21st Century Cures Act (Cures Act), enacted in 2016, included patient protections against information blocking by health providers.[24] Starting in 2021, the Office of National Coordinator for Health IT (ONC) published a federal rule requiring all health care institutions to release health information to patients immediately once available and without charge.[24-26] As a result, HIPAA-covered entities could no longer charge patients for obtaining their health information,[23] all of which previously hindered access to and timely release of information.[24]

However, the Cures Act did not affect the fundamental tension: while *patients* own their health information, health care *institutions* own the EHRs that contain the information.[24,26] Release of health information from one institution to another is still governed by the rules of HIPAA.

Patient-partnered cancer genomic research efforts must navigate institutional rules of engagement at considerable time and financial costs (Fig 1). Although research participants sign a general consent for release of health information to research teams, individual institutions may require their own unique forms. In addition, each institution has its own staffing, resources, and priorities, taking varying amounts of time to release health information. Some require considerable payment to process requests, while others may deny initial and subsequent requests, leading to lengthy delays. In the end, research productivity suffers and, in some cases, the preferences of research participants may not be honored.

The process for release of health information must be reformed to support participant-partnered research. Potential solutions should focus on building systems and technologies that allow patients to easily view and download information from electronic systems. These systems should allow

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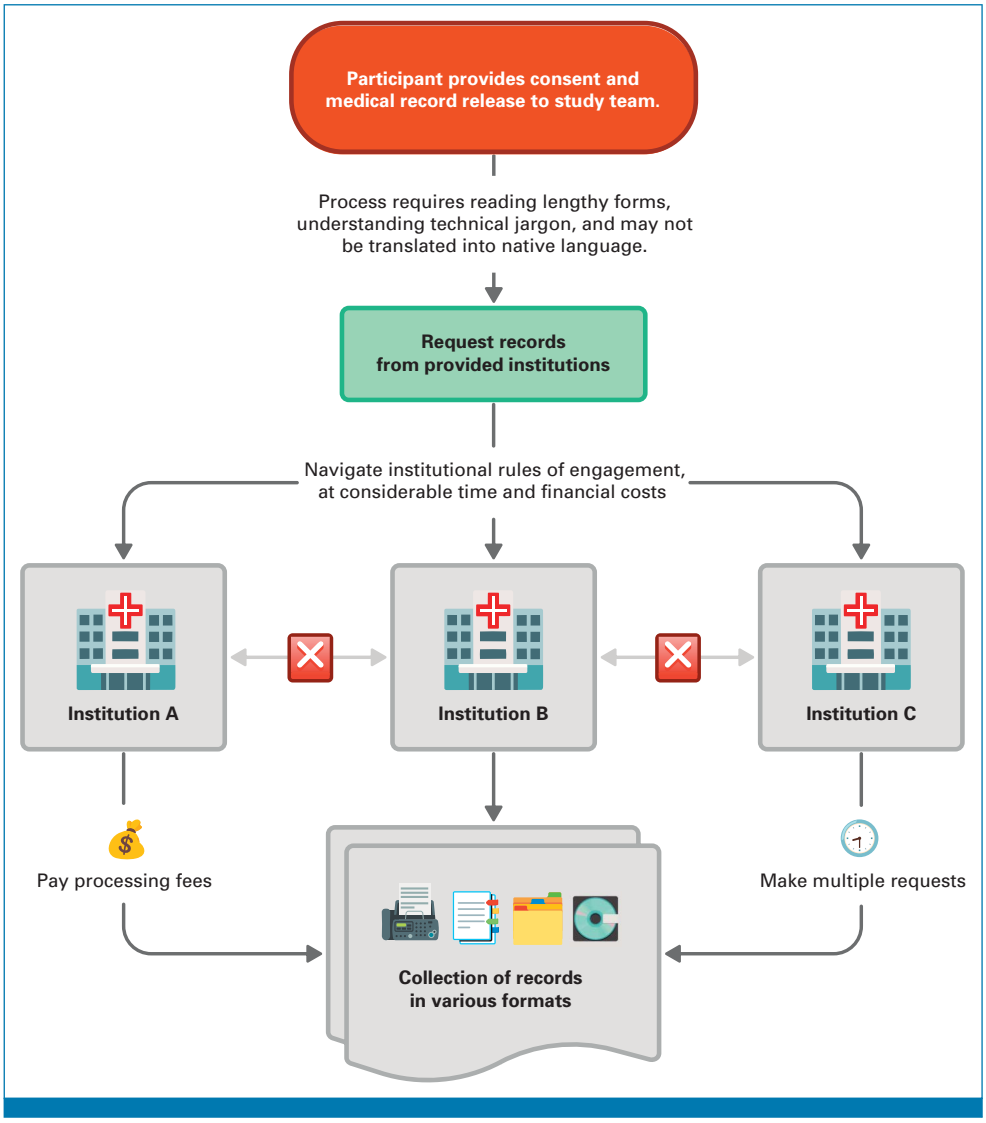

FIG 1. Barriers related to consent process, data exchange, and EHR interoperability hinder researchers' ability to honor patients' desires to contribute to cancer research. EHR, electronic health record.

participants to directly share their health information with whomever they choose in a readable, usable, high-fidelity, secure, and transparent format.

A requirement of the Health Information Technology for Clinical and Economic Health (HITECH) Act is for health care providers to ensure people have digital access to their own health records. This typically leads to multiple portals for an individual to access to their full health data, each for a unique site/health system of care. And although there are emerging commercial entities that aim to aggregate these data for an individual, the cost may be significant depending on the specific use case, and scalable, affordable, accessible processes for research are still in development.[27-29]

In addition, mobile technologies that aggregate records assume that participants have access to their portals that meet their needs for digital engagement (which may be housed across multiple hospital systems, pharmacies, etc). Although patients are accessing their online patient portals more often than they used to, the number remains only 60% in 2022.[30] Of these patients who accessed their portal, only 33% downloaded their health information for their own use, and only 20% shared this information with a third party. In addition, only 2% of patients combined electronic health information from different patient portals, and even for this very small number of patients, it is unclear if they were able to successfully aggregate and transmit this full medical journey to a third party for clinical care or research.[30] Even when the process may be successful for some people, it remains nonstatic and limited to those who engage with these platforms, that is, if a patient changes their password or the health care facility updates its software (Epic Systems, Verona, WI, etc), the mobile technology must also be updated to continue access. This process also assumes patients have interest in, access to, and the ability to manage this information electronically.

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ELECTRONIC HEALTH RECORD SYSTEMS CONTINUE TO LACK INTEROPERABILITY

Once health care institutions agree to release health information, transferring and accepting information from one institution to another remains a significant barrier. The HITECH Act—enacted as part of the American Recovery and Reinvestment Act of 2009—provided $35 billion US dollars to expand adoption of EHR systems across the country.[31] At the time, HITECH was successful in incentivizing health care institutions to adopt individual EHRs systems.

However, the Act did not provide adequate incentives for EHR health systems to adopt sustainable interoperability practices. Each patient's health information is stored in myriad institutional EHRs and these EHRs hold siloed data. Vendors are also financially incentivized to design products that limit data interoperability or make interoperability financially inaccessible.[31] Progress is being made in development and implementation of Fast Healthcare Interoperability Resources (FHIR) as a technical standard for exchange of health information.[32] However, the field lacks a single accepted standard for the data elements themselves, thereby limiting the usability of data without significant data processing when exchanged by FHIR standard. In addition, health systems and researchers are piloting these processes at varying rates and in a variety of applications with significant cost and unique technical expertise, which is not universally available across US health systems.[33-35] As a result, most EHR systems continue to lack interoperability today.[31,36]

Lack of data interoperability significantly limits participant-partnered research initiatives, which must navigate a fragmented network of different EHR systems with different coding, specifications, capabilities, and transfer fidelity. It is not uncommon for health information to come in the form of fax or PDF, even within the same EHR vendor (eg, Epic to Epic, Oracle/Cerner to Oracle/Cerner), which significantly limits the promise of cost-effectively integrating data from EHRs into research studies and drawing meaningful insights from the data. This subpar usability and fidelity for researchers means that EHRs are often unable to deliver the right information, in the right format, through the right channels, at the right time.[31,36,37] Third-party commercial entities, such as Datavant (San Francisco, CA), have attempted to fill this void, serving as an example of the inadequacy of the current system to facilitate research.[38,39]

Emerging policies might change this situation. Similarly, ONC's ongoing interoperability initiatives (Trusted Exchange Framework and Common Agreement, US Core Data for Interoperability),[40] enhancing interoperability of research data is a national priority for researchers and patient participants.

In conclusion, enhancing participant engagement and promoting patient-partnered research are national priorities in cancer care and research. People with rare and understudied cancers or those diverse populations who have not traditionally participated or had the opportunity to participate in cancer research are often highly motivated to participate in genomics research that is appropriately respectful of their cultural mores and to contribute their health information to advance cancer research. However, the informed consent process must be streamlined and culturally and language appropriate, the flow of the health data exchange must be improved, and EHR interoperability must be promoted. To grow a thriving research ecosystem, we should minimize participants' burden and develop systems that demonstrate our commitment and respect for their wishes to contribute to cancer research. The PE-CGS will continue to work with patient partners to improve the consent process within each research center and consider how to address the systems-level issues related to EHR interoperability on a larger scale.

AFFILIATIONS

[1]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA
[2]Harvard Medical School, Boston, MA
[3]Washington University School of Medicine, St Louis, MO
[4]Alvin J. Siteman Cancer Center, St Louis, MO
[5]Beth Israel Deaconess Medical Center, Boston, MA
[6]Department of Biostatistics, Yale School of Public Health, New Haven, CT
[7]Department of Neurosurgery, Brigham and Women's Hospital, Boston, MA
[8]The Ohio State University College of Medicine, Columbus, OH
[9]Keck School of Medicine of USC, Los Angeles, CA
[10]Norris Comprehensive Cancer Center, Los Angeles, CA
[11]Mayo Clinic Comprehensive Cancer Center, Mayo Clinic, Rochester, MN
[12]The University of New Mexico School of Medicine, Albuquerque, NM
[13]Count Me In, The Broad Institute of MIT and Harvard, Boston, MA
[14]Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Boston, MA

CORRESPONDING AUTHOR

Suzanne George, MD; e-mail: Suzanne_George@dfci.harvard.edu.

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AUTHOR CONTRIBUTIONS

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Liz Salmi
Honoraria: Medscape
Travel, Accommodations, Expenses: Medscape

Elizabeth B. Claus
Consulting or Advisory Role: Servier
Travel, Accommodations, Expenses: Servier

Anne L.R. Schuster
Research Funding: Pfizer (Inst)

John F.P. Bridges
Consulting or Advisory Role: Boehringer Ingelheim
Travel, Accommodations, Expenses: Boehringer Ingelheim

Heinz-Josef Lenz
Honoraria: Merck Serono, Roche, Bayer, Boehringer Ingelheim, Isofol Medical, G1 Therapeutics, Jazz Pharmaceuticals, OncoCyte, Fulgent Genetics
Consulting or Advisory Role: Merck Serono, Roche, Bayer, BMS, GlaxoSmithKline, 3T BioSciences, Fulgent Genetics
Travel, Accommodations, Expenses: Merck Serono, Bayer, BMS

Cheryl L. Willman
Patents, Royalties, Other Intellectual Property: Patents related to genomic diagnostics for cancer

Katherine A. Janeway
Honoraria: Foundation Medicine, Takeda
Consulting or Advisory Role: Bayer, Ipsen, Illumina
Travel, Accommodations, Expenses: Bayer

Suzanne George
Stock and Other Ownership Interests: Abbott Laboratories, Pfizer
Honoraria: CStone Pharmaceuticals
Consulting or Advisory Role: Blueprint Medicines, Deciphera, Bayer, Lilly, UpToDate, Research to Practice, MORE Health, Daiichi, Kayothera, Immunicum, BioAtla
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