



# **Using Community Engagement Studios to Enhance Pharmacogenetic Study Design for Maximizing Enrollment of Diverse Children and Pregnant People**

Elizabeth Jasper, PhD, Leslie Boone, MPH, & Tiffany Israel, MSSW

# Background

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Children, pregnant individuals, and people of color are underrepresented in current pharmacogenetic (PGx) research

Testing and validation of gene-drug associations in these populations is necessary to provide appropriate recommendations and guidance to prescribers



Boyer, Alaina P. PhD et al. . A Multilevel Approach to Stakeholder Engagement in the Formulation of a Clinical Data Research Network. Medical Care 56():p S22-S26, October 2018. | DOI: 10.1097/MLR.0000000000000778

# Background:

## Community Engagement Studio

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- Built on the scaffolding of the Translational Research Studios at VUMC
  - Piloted as the Community Review Board in 2009-2010
  - Offered as service to the Vanderbilt community in 2010
  - Recognizes and amplifies the lived experiences of lay stakeholders, e.g. patients and community members
- 
- Byrne DW, Biaggioni I, Bernard GR, Helmer TT, Boone LR, Pulley JM, Edwards T, Dittus RS. Clinical and translational research studios: a multidisciplinary internal support program. *Acad Med.* **2012** Aug;87(8):1052-9. doi: 10.1097/ACM.0b013e31825d29d4. PMID: 22722360; PMCID: PMC3406254.
  - Joosten YA, Israel TL, Williams NA, Boone LR, Schlundt DG, Mouton CP, Dittus RS, Bernard GR, Wilkins CH. Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input From Stakeholders to Inform Research. *Acad Med.* **2015** Dec;90(12):1646-50. doi: 10.1097/ACM.0000000000000794. PMID: 26107879; PMCID: PMC4654264.

# What's the Difference?

## Community Engagement Studios and Focus Groups

	<b>Community Engagement Studios</b>	<b>Focus Groups</b>
<b>Purpose</b>	Obtain feedback/guidance to inform research at any stage	Qualitative research
<b>Approach</b>	A dialogue; bi-directional discussion	Uni-directional
<b>Participants</b>	Serve as consultants; experts based on “lived experience”	Research participants
<b>How participants determined</b>	In consultation with community engaged research core CE Studio team	Research team
<b>Facilitator</b>	A trained community member; balances power	Usually research team
<b>Pre-meeting activities</b>	Consultation with CE Studio team; coaching for research team; orientation for community experts	Usually none
<b>Compensation</b>	Consultant fee equivalent to local volunteer compensation rate	Incentives determined by health research team
<b>Other distinctions</b>	Written and oral comments; may request additional information; may question research approach; may peruse unanticipated topics; may contact after CE studio; paperwork as advisor	IRB approved questions/script; Informed consent obtained; qualitative analysis of transcripts; no contact after focus group; themes identified and connected with participants

# Meeting Formats:

## Community Engagement Studio Model

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### • In-Person Model

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- Community meeting space
- Meal provided
- Use of wall space to reiterate key points provided by the experts
- Compensation provided to experts
- Summary provided to researchers

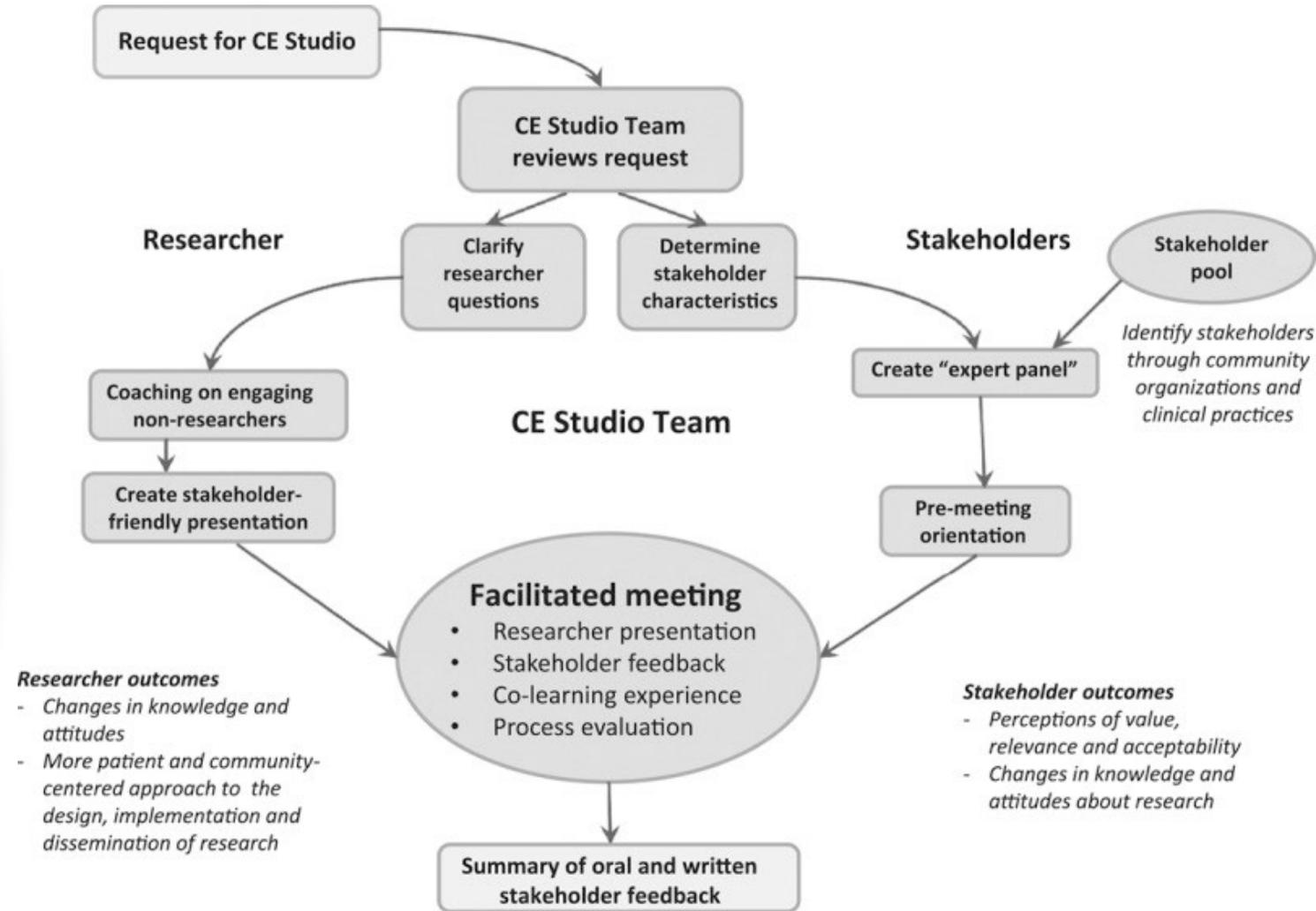
### • Virtual Model

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- Use of Zoom to connect
- Recorded session for note taking
- Experts may use chat function to capture additional thoughts
- Compensation provided to experts
- Summary provided to researchers

# Community Engagement Studio (CES)

Joosten YA, Israel TL, Williams NA, Boone LR, Schlundt DG, Mouton CP, Dittus RS, Bernard GR, Wilkins CH. Community Engagement Studios: A Structured Approach to Obtaining Meaningful Input From Stakeholders to Inform Research. *Acad Med.* 2015;90(12), 1646–1650.



# Optimizing tools and design through Engagement Studios

*17 priority populations identified to test*

## Community Engagement Studios:

- Website and enrollment modules
- Informed consent
- Return of Value

### Completed:

- Met w/ over 600 individuals (community experts)
- Conducted over 70 community engagement studios in 6 months

Priority Populations	
General Population	Parent/Child Dyads
Older Adults (65+)	Those living in rural areas
Sexual & Gender Minorities	Asian Americans
Native Americans	Latinos
African Americans	Individuals with limited English proficiency
Individuals with limited educational attainment/literacy	Individuals with 3 or more chronic health conditions
Individuals with no ability to access the internet	Individuals who are blind or limited vision
Individuals who are deaf or hard of hearing	Individuals with limited technical proficiency
Individuals with limited use of upper extremities	

# Model of Dissemination

## Implementation, Policy and Community Engagement Special Communication

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## Utilizing community engagement studios to inform clinical trial design at a Center of Excellence for Alzheimer's Disease

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### Abstract

Despite the disproportionate burden of Alzheimer's disease in older adults of color, the scientific community continues to grapple with underrepresentation of racial and ethnic minorities in clinical research. Our Center of Excellence for Alzheimer's Disease (CEAD) collaborated with a local community partner to conduct community engagement (CE) studios to effectively involve our community of diverse older adults in the early planning stages of a clinical trial. Given the COVID-19 pandemic, the in-person studio format was adapted to allow for virtual, real-time participation. Our objective is to describe the process and feasibility of conducting virtual CE studios in an older adult population. Ninety percent of participants were non-Hispanic Black community-dwelling woman aged 60 years and older. The overall background and proposed clinical trial design was presented to the participants who then made recommendations regarding potential recruitment strategies, the use of culturally relevant language to describe the study, and logistical recommendations to improve participation and retention among community members. Our CEAD successfully conducted virtual CE studios during the COVID-19 pandemic, by partnering with a community-based organization, to engage community stakeholders about clinical trial design. CEADs are in a unique position to implement CE studios to better support patient access to clinical trials.

### Introduction

Alzheimer's disease (AD) affects approximately 6.2 million individuals in the USA [1]. This number is projected to increase to a staggering 13.8 million individuals by 2060 [2]. It has been well established that the prevalence and incidence of AD is higher among non-Hispanic Black or African-American (NH Black) and Hispanic older adults as compared to non-Hispanic Whites (NH White) [3–5]. Despite the disproportionate burden of AD in older adults of color, the scientific community continues to grapple with the underrepresentation of racial and ethnic minorities in clinical research [6–8].

### Overview of the New York State Center of Excellence for Alzheimer's Disease (CEAD)

The Hudson Valley Center of Excellence for Alzheimer's Disease (CEAD) is one of 10 Alzheimer's Disease Centers of Excellence supported in part by a grant from the New York State Department of Health in an ambitious program that aims [montefiore.org/alzheimers-center](https://www.montefiore.org/alzheimers-center) [9] to:

- 1) Expand knowledge about AD and related dementias.
- 2) Improve access to screening, diagnosis, and clinical trial opportunities for patients.
- 3) Provide community-based support services for them and their caregivers.
- 4) Offer training programs for providers in all clinical disciplines.

The CEAD provides outpatient-based multispecialty dementia care utilizing a consultative model, in which patients undergo a comprehensive three-step evaluation by a geriatrician, neurologist, and neuropsychologist with support provided by geriatric psychiatry, physiatry, and social work. The majority of the clinical evaluations for the CEAD are conducted at the Center for the Aging Brain located in Yonkers, New York. Our patient population largely originates from Bronx County and seven counties in the Hudson Valley region: Westchester, Rockland, Putnam, Dutchess, Sullivan, Orange, and Ulster. As previously described, the patient population at the CEAD is diverse with 25% African-American, 18% Hispanic, and 5% multi-racial patients [10].



## Virtual Community Engagement Studio (V-CES): Engaging Mothers With Mental Health and Substance Use Conditions in Research

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### OPEN ACCESS

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## Use of Community Engagement Studios to Adapt a Hybrid Effectiveness-Implementation Study of Social Incentives and Physical Activity for the STEP Together Study

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Physical activity is known to contribute to good health, but most adults in the United States do not meet recommended physical activity guidelines. Social incentive interventions that leverage insights from behavioral economics have increased physical activity in short-term trials, but there is limited evidence of their effectiveness in community settings or their long-term effectiveness. The STEP Together study is a Hybrid Type 1 effectiveness-implementation study to address these evidence and implementation gaps. This paper describes the process of adapting study procedures prior to the effectiveness trial using Community Engagement (CE) Studios, facilitated meetings during which community members provide feedback on research projects. Six CE Studios were held with community members from the priority population. They were conducted remotely because of the COVID-19 pandemic. Fifteen liaisons representing 13 community organizations and 21 community members from different neighborhoods in Philadelphia participated. Three elements of the study design were modified based on feedback from the CE Studios: lowering the age requirement for an 'older adult', clarifying the definition of family members to include second-degree relatives, and adding a 6-month survey. These adaptations will improve the fit of the effectiveness trial to the local context and improve

participant engagement and retention. CE Studios can be used to adapt intervention strategies and other aspects of study design during hybrid implementation-effectiveness trials. This approach was successfully used with remote online participation due to the COVID-19 pandemic and serves as a model for future community-engaged implementation research.

**Keywords:** physical activity; older adults; gamification; social incentives; charity; family; community-based research; community engagement; health behavior

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# Project 1 Aim 1

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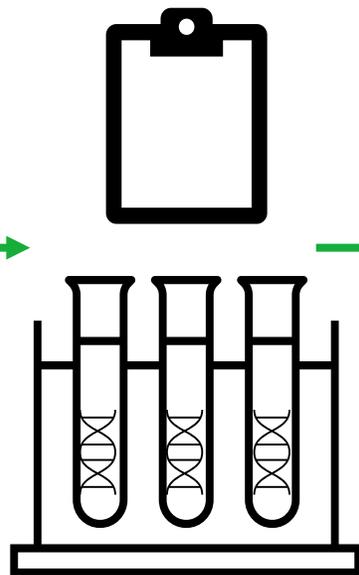
- Knowledge and Attitudes Regarding Pharmacogenomics Testing Among Children with Chronic Disease and Pregnant Persons



Vanderbilt Integrated  
Center of Excellence in  
Maternal & Pediatric  
Precision Therapeutics  
(VICE-MPRINT)



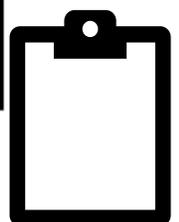
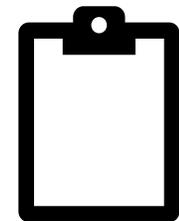
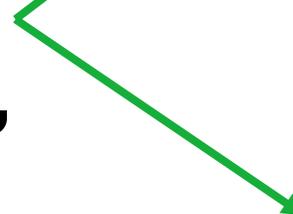
Recruit  
250 pregnant people 250  
children



Baseline survey  
PGx testing



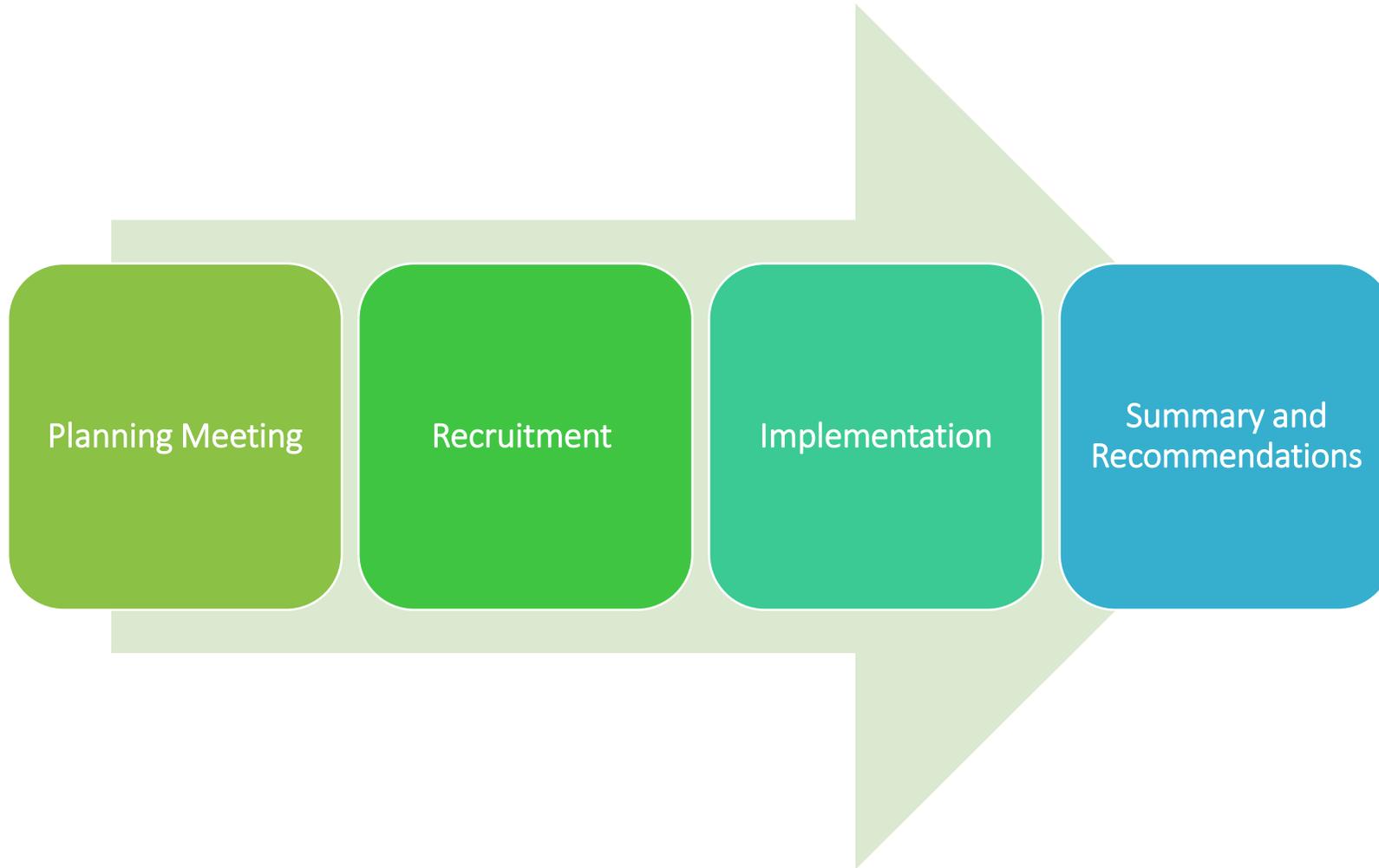
PGx results via  
MHAV portal



Educational video  
Follow-up survey

# CES Process

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# Planning Meeting

- 1- hour meeting with research team
  - Narrow to 2-3 key topics
  - Define community expert characteristics
  - Discuss ground rules
  - Presentation Review

# Recruitment

## Two Community Engagement Studios

- Pregnant/Parents Studio
- Parents of Children with Chronic Diseases Studio

## Recruitment Strategies

- Past CES Experts
- Social Media
- Internal clinical space

Are you pregnant or a parent of a child under the age of 3?

Do you care for a child of any age with a chronic condition?

Do you see a Vanderbilt pediatrician?

**\$75  
Gift Card**

**WE WANT YOUR FEEDBACK!**

**What** | 1-time online meeting to give input on a project aiming to understand parents' opinions on genetic testing.

You will not be recruited for research.

**Who** | Pregnant women and parents of children (0-3 years)  
Parents of children of any age with chronic health conditions.

**When** | Early to mid-November 2021

**FOR MORE INFORMATION:**

Please fill out our interest survey here:

**<https://redcap.link/vumcparents>**



**Questions?**

**Email:** [cestudios@vumc.org](mailto:cestudios@vumc.org)



# Implementation

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- Individual screenings and orientations
- Scheduling confirmations
- Reminders
- Studio Facilitation

## **VICE-MPRINT: Maternal and Pediatric Pharmacogenetics Survey**

Sara Van Driest, MD, PhD,

Digna Velez Edwards, PhD, MS

Elizabeth Jasper, PhD

Departments of Pediatrics and Obstetrics and Gynecology

October 29, 2021

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Community Engagement Studio

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# Summary & Recommendations

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Project Name:	VICE-MPRINT: Maternal and Pediatric Pharmacogenetics Survey		
Facilitator: Notes Prepared By:	Tiffany Israel, MSSW CES Team	Location:	Virtual
Researcher/PI:	Sara Van Driest, MD, PhD Digna Velez Edwards, PhD, MS Elizabeth Jasper, PhD		
1. Research			
Inform project focused on pharmacogenetic testing for those who are pregnant or children with certain chronic conditions.			
3. Recommendations			
<b>Recruitment:</b> <ol style="list-style-type: none"><li>Utilize established trust between patients and their providers by collaborating with OB/GYN/Peds to recruit women and their children for genetics studies.</li><li>Conduct study outreach by posting study info in a variety of locations i.e., provider offices, wait rooms, pharmacy.</li><li>Develop study info inserts that can be attached to prescriptions for the specific types of medications involved in the testing.</li><li>Highlight study on MyHealth accounts of</li></ol>		<b>Survey:</b> <ol style="list-style-type: none"><li>Include options for parents to add additional information for context (i.e., if the child is biological).</li><li>Add a description to the personal questions section in the REDCap survey to help participants understand the relevance of questions.</li><li>Add context setting sentences to the REDCap survey, to highlight that answers provided should be based on individual experience and insight.</li><li>Utilize hover-over definitions to define complex terms used in the survey such as</li></ol>	

# CES Results

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- **Pregnant/Parents Studio**

- 4 females
- All identified as African American/Black
- One under 30 years old and 3 between 30 and 55 years old
- Education: H.S. to post-graduate

- **Parents of Children with Chronic Diseases Studio**

- 6 female parents
- 2 identified as African American/Black and 4 as White
- 5 between 30 and 55 years old
- Education: some college to post-graduate

# Pharmacogenetic Testing

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- Interested but apprehensive
- Particularly helpful in certain situations
- Helpful to know choices and potential problems with medications
- Would alleviate stress and worry, especially for parents of children with chronic conditions
- Fears of being experimented on

# Concerns, Challenge, and Barriers

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- Lack of information communicated by physicians and researchers contributes to skepticism
- Parents of children with chronic conditions were knowledgeable about testing and their questions tended to be more technical
- Communication and education: convey information to the patient in understandable terms and being able to relate to the patient

# Recruitment

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- Participants with less of a rapport with their physicians said common and communal areas would be best
  - *Flyers– every peds clinic and OBGYN clinic...*
  - *Using the pharmacy or like a flyer. And it could say something like “frustrated with the trial and error of medications?”*
  - *In one of the social media groups...*
  - *Through My Health portal...*
- Those with a better patient-physician relationship preferred recruitment by their physician

# Study Materials

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- Both groups expressed concern over several baseline questions
- Several participants were not comfortable with all providers having access to [PGx] information
- Terminology: they preferred the use of “DNA” over “genetic” when referring to testing and “medication” over “medicine”
- Educational video
  - Preferred the use of a woman’s voice
  - Definitions for ultra-rapid and slow metabolizer status

# Recommendations

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## Recruitment

- Utilize established trust between patients and their providers
- Conduct study outreach by posting in variety of locations
- MyHealthatVanderbilt

## Materials

- Add description to personal questions to help participants understand relevance
- Provide info on medications that are part of the test and address possible need for future testing

## Other

- Clarify how results will be provided and who will have access to them

# Tutorial: Using Community Engagement Studios to Enhance Pharmacogenetic Study Design for Maximizing Enrollment of Diverse Children and Pregnant People

Elizabeth A. Jasper<sup>1</sup> , Sabrina E. Holley<sup>2</sup>, Sarah H. Jones<sup>3</sup>, Michelle Liu<sup>4</sup>, Tiffany Israel<sup>5</sup>, Sara L. Van Driest<sup>2,6</sup>  and Digna R. Velez Edwards<sup>1,3,7,8,\*</sup>

Most pharmacogenetic research is conducted in adult, non-pregnant populations of European ancestry. Study of more diverse and special populations is necessary to validate findings and improve health equity. However, there are significant barriers to recruitment of diverse populations for genetic studies, such as mistrust of researchers due to a history of unethical research and ongoing social inequities. Engaging communities and understanding community members' perspectives may help to overcome these barriers and improve research quality. Here, we highlight one method for engaging communities, the Community Engagement Studio (CES), a consultative session that allows researchers to obtain guidance and feedback based on community members' lived experiences. We also provide an example of its use in pharmacogenetic studies. In designing a survey study of knowledge and attitudes around pharmacogenetic testing among children with chronic conditions and pregnant individuals, we sought input from diverse community stakeholders through CESs at Vanderbilt University Medical Center. We participated in two CESs with community stakeholders representing study target populations. Our goals were to learn specific concerns about pharmacogenetic testing and preferred recruitment strategies for these communities. Concerns were expressed about how genetic information would be used beyond the immediate study. Participants emphasized the importance of clarity and transparency in communication to overcome participation hesitancy and mistrust of the study team. Recruitment strategy recommendations ranged from informal notices posted in healthcare settings to provider referrals. The CES enabled us to modify our recruitment methods and research materials to better communicate with populations currently under-represented in pharmacogenetics research.

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- Michelle Liu, PharmD
- Sarah Osmundson, MD

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- Digna Velez Edwards, PhD, MS

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- Tiffany Israel
- Jasmine Bell
- Leah Dunkel
- Devan Ray
- Community Experts

**Comments or  
questions?**

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