WEBINAR

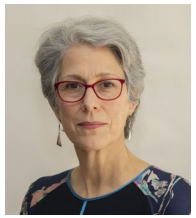
February 3, 2025

Who's at the Table? Bringing the Participant & Community Voice to Human Subjects Research

Moderator
Ann Johnson, PhD
Associate Vice Provost
Research Compliance
Stanford University

Stephen Falwell
IRB Administration Trainer
UC Davis

Heather Brown, MEd
IRB Administrator
University of Utah



Rhonda Kost, MD
Clinical Research Officer
The Rockefeller University

CARE-Q
Consortium for Applied Research Ethics Quality

care-q.org

General Information

- Please post questions in Q&A
- Link for continuing education credit will be posted in the chat at the end of the presentation

Complementary Roles of Community Engagement and IRB Review

Stephen Falwell
he/him/his
UC Davis IRB

CARE-Q®
Consortium for Applied Research Ethics Quality

Collaboration is Key

Transgender and Gender-Nonbinary Health: Development of Community-Generated Research Priorities

Miles Harris, Assistant Clinical Professor, Betty Irene Moore School of Nursing
Elizabeth Vasile, Director, Health Equity Resources & Outreach (HERO) Program, UC Davis Clinical and Translational Science Center
Stephen Falwell, Education, Training, and Outreach Lead, UC Davis IRB Administration
Community Partner: One Community Health

Vulnerable Populations per Regulations

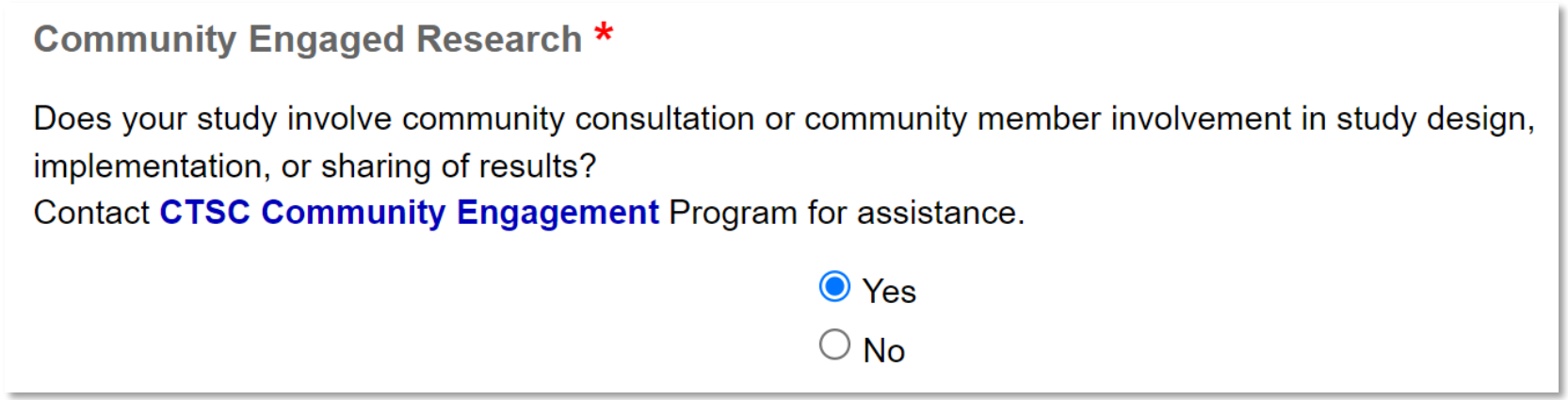
Based on vulnerability to **undue influence** and **coercion**

- Fetuses and neonates
- Incarcerated individuals
- Children

“Populations of Focus”

Identified by researchers in initial IRB application:

- Undocumented individuals
- Students or Direct Reports of the Principal Investigator
- Rural Communities
- Older Adults (65 years and older)
- Individuals from the LGBTQIA+ Community



Protection of Vulnerable Populations

Institutional Review Board

- Protection through **exclusion**
  - Regulatory requirements
- Is this population being exploited or used for convenience?
- Inclusivity is important in context of generalizability of results

Community Engagement

- Protection through **inclusion**
- Is community involved in:
  - Generation of research questions
  - Study design and implementation
  - Return of results

Benefits and Risks

Institutional Review Board

- Emphasis on individual risks:
  - Physical
  - Psychological
  - Emotional
  - Social
  - Financial
  - Privacy
  - Confidentiality

Community Engagement

- How may a community benefit from this research, not just the results of the research?
- What are risks to community?
- Does this community find risks more tolerable than the IRB does?

Recruitment

Institutional Review Board

- No promise of "free treatment"
- De-emphasis on compensation
- Does not imply investigational drug or device is safe, effective, or superior to an existing treatment
- Protection of participant privacy

Community Engagement

- Is this approach appropriate for this community?
- Will it result in diverse recruitment?
- Culturally appropriate and accessible language

Overcoming Language Barriers

Institutional Review Board

- Expectation that if a study has direct benefit, it will include those with limited English proficiency
- Encourage or require translated consent forms
- Short form consent forms in over 10 languages

Community Engagement

- Working with community partners to serve as bridge
  - Example: Promotores

Return of Results

Institutional Review Board

- Consent form to include information about return of results
- Legal limitations on return of clinical results from investigational assay or genetic results without qualified genetic counselor
- Process for treatment of abnormal results

Community Engagement

- Maximize return of results to individual participants
- How should results be returned to community
- How should results be communicated outside of community?

University of Utah Panel C

An Innovative Approach to Eliminating Barriers

Heather Brown, MEd.

University of Utah IRB Panel C

Panel C Mission

Establish an IRB Panel of Unaffiliated Non-Scientist community members to ***partner*** *&* ***provide*** *expertise for human subject research to be more* ***inclusive*** *and* ***representative*** *of diverse Utah.*

Panel C Purpose

Advance	Advance Human Research Protection Program and research community policies and practices to ensure respect for diverse Utah communities
Evaluate	Evaluate research projects and make determinations with unique community-based concerns
Review	Review participant study materials, such as consent forms and recruitment materials, to recommend improvements to literacy

Panel C
Foundation of Trust

Identify current and new relationships

- Attend community events
- Share meals
- Transparency
- Bi-Directional learning

Begin where the partners are **comfortable** learning all aspects of who, what, and how partners best work together

COMMUNITY ADVISORY IRB PANEL

UNIVERSITY OF UTAH

WHAT IS THE IRB?

IRB stands for Institutional Review Board. IRBs review research that studies living humans to make sure the studies are ethical and treat all people with respect. IRBs apply core ethical principles and practices for all human research.

Here are some examples of research IRBs review:

- Studies of medical treatments
- Studies of the human body
- Studies of human behavior, feelings, and relationships

There are a lot of institutions that conduct research with people: Universities, hospitals, schools, businesses, governments, and clinics.

The University of Utah has its own IRB that reviews research for the University, Primary Children's Hospital, the Salt Lake Veterans Affairs Medical Center, as well as many of our collaborators within Utah and across the country.

MISSION

The mission of the University of Utah Community Advisory IRB Panel is to **partner and provide** expertise for human research to be more inclusive and representative of the diverse Utah communities.

RESPONSIBILITIES

Advance the University's IRB, Human Research Protection Program, and research community policies and practices to ensure respect for diverse Utah communities and research participants.

Evaluate research projects and make determinations for studies with unique community-based concerns.

Review participant study materials, such as consent forms and recruitment materials, to recommend improvements to literacy.

CONTACT

University of Utah IRB
75 South 2000 East
Salt Lake City, UT 84112

irb@hsc.utah.edu

801-581-3655

www.irb.utah.edu
www.myirb.utah.edu

@myirbinutah
@lifeattheirb

THE UNIVERSITY OF UTAH

HOW THE COLLABORATION WORKS

Contribute 5 hours per month to complete determined assignments that fulfill the Community Advisory IRB Panel mission and responsibilities, which includes at least 75% attendance at monthly meetings each year.

Attend monthly 2 hour meetings at an agreed upon time by all members. Meetings may be in person or via a web conferencing app like Zoom. In person meetings are facilitated at the most accessible locations in Salt Lake Valley and meals are provided.

Participate in an initial training and annual training related to the field of research ethics and how to most efficiently complete assignments. The initial training is 2-3 hours. The annual training is 3 hours, which can be completed over the whole year.

Connect with the Panel's IRB Administrator and Chair each month when assistance is needed.

Use University electronic systems to support completion of assignments.

Receive a $200 monthly stipend, paid by check quarterly. These payments constitute taxable income from the University of Utah.

Commit to a 3-year term of service, with the option to continue for additional terms.

Panel C
Foundation of Trust

ENSURE ACCESSABILITY FOR ALL:

Engaging in preferred location and communication

Evaluating training processes for continued growth via bi-directional learning

Continuing efforts for building knowledge and maintaining relationships of trust

Recognize time and practice are required

Panel C Formation

1. **Recruitment:**	TRUST
2. **Onboard:**	One-on-one with IRB Administrator
3. **Post onboard:**	One-on-one check-in with IRB Administrator
4. **Kick-Off:**	One whole group “practice” study review with paired panel members and assigned IRB Primary Reviewer Mentor
5. **Convened Board #1:**	One whole group “real” study review with paired panel members and assigned IRB Primary Reviewer Mentor

Panel C Formation

6. Convened Board #2:

- One whole group “real” study review with each panel member and assigned IRB Primary Reviewer Mentor on call

7. Convened Board #3:

- Two whole group studies review with paired board members and IRB Administration support as needed

8. Convened Board #4:

- Two whole group studies review with paired board members and IRB Administration support as needed

9. Convened Board #5:

- One study per board member

10. IRB Administrator

- Board member check-ins ongoing

Lessons Learned

TIME

TRAINING

FLEXIBILITY

Panel C
Highlight

IRB Spanish Inclusion Policy

Spanish Inclusion Guidelines

https://irb.utah.edu/about/news/2023/03-06-2023-spanish.php

Chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://irb.utah.edu/_resources/documents/pdf/00igs-bmgs/igs-including_spanish_speakers_in_research_072224.pdf

CARE-Q. Consortium for Applied Research Ethics Quality care-q.org

Institutional Review Board
THE UNIVERSITY OF UTAH

Investigator Guidance Series

INCLUDING SPANISH-SPEAKING INDIVIDUALS IN RESEARCH

Definitions

A. A ***certified interpreter*** is an individual who has passed a certification exam given by an accredited entity to verify his/her professional interpretation skills in a certain language.

B. A ***certified translator*** is an individual who has passed a certification exam given by an accredited entity to verify his/her professional translation skills in a certain language.

C. ***Interpretation*** is the spoken exchange of communication between two languages.

D. A ***person who speaks Spanish*** is a person for whom a) Spanish is their native or only language spoken, and/or b) Spanish is their preferred language for communication.

E. A ***qualified interpreter*** is a person who speaks English and Spanish and facilitates communication either through virtual, in-person or over the phone. NOTE: for the purposes of this guidance document, the interpreter will be a Spanish interpreter.

F. A ***qualified translator*** is person who speaks and writes in both languages, English and Spanish, and converts a document into the target language. NOTE: for the purposes of this guidance document, the translator will be a Spanish translator.

G. **Translation** is the change of written materials from one language into another.

Description

Spanish is the second-most common language spoken in the state of Utah. The principles of justice and equitable selection of participants compels the University of Utah IRB and research community to make adequate provisions for including Utahns who speak Spanish in research. **This policy is effective July 1, 2023.**

For all prospective research with participant interaction conducted by University of Utah researchers within the state of Utah, the University of Utah IRB requires each non-exempt study to have provisions for including people who speak Spanish. Provisions must include the following:

a) Recruitment methods for people who speak Spanish, including translated recruitment materials and interpretation services if individuals would like to discuss the study.
b) Consent processes for people who speak Spanish, including translated consent documents and interpretation services during the consent process and discussion.
c) Methods for ongoing communication with and data collection from participants who speak Spanish, including translated study materials and interpretation services for ongoing communication.

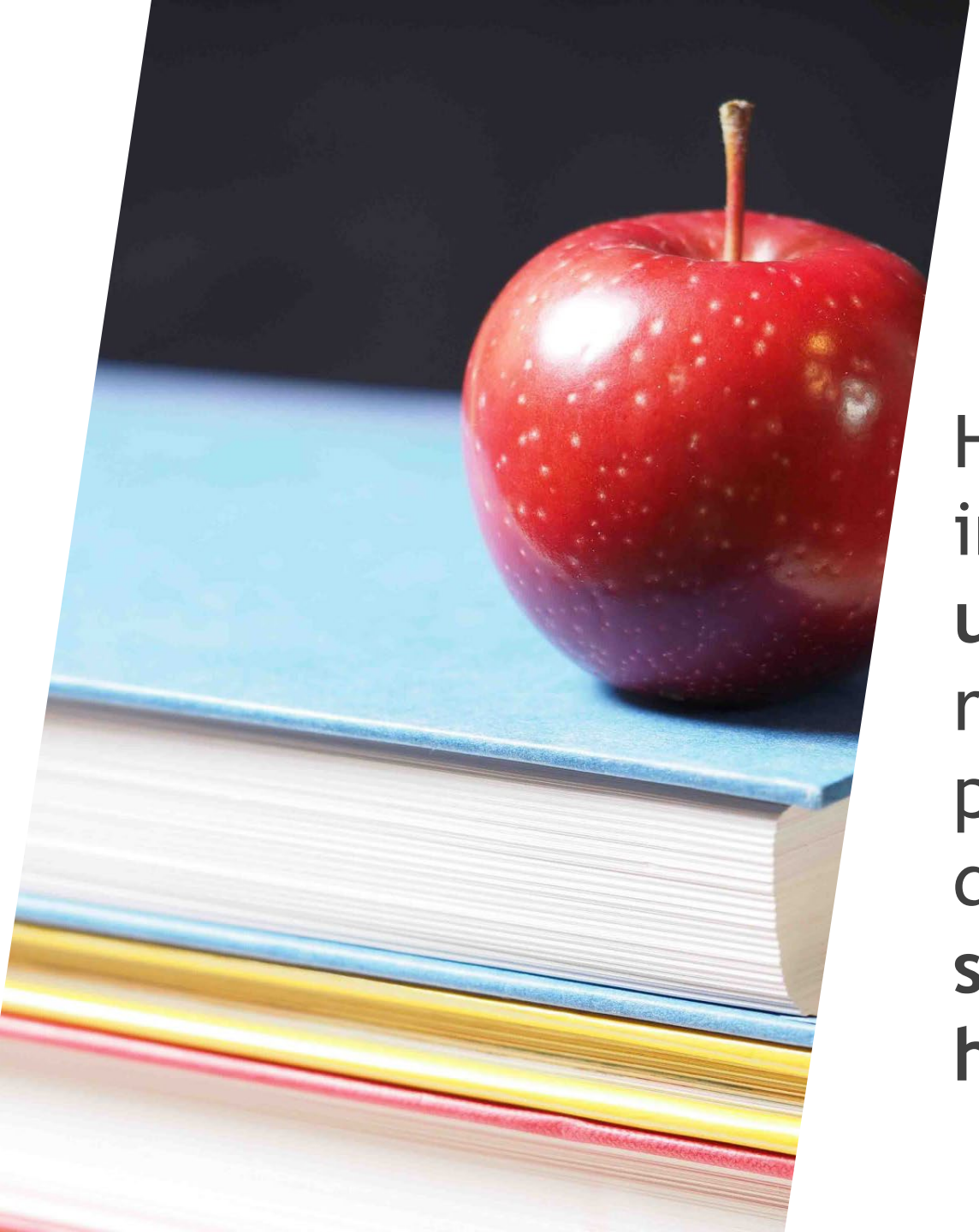
It may be reasonable to modify study procedures for Spanish-speaking participants to facilitate efficient, effective communication and data collection. For example, English-speaking participants may be asked to record side effects they experience in writing, where Spanish-speaking participants may be asked to provide answers orally through an interpreter so that their responses can be recorded by the study team in English.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Panel C Outcome:

Promotion of Community Engagement

- Health Literacy
- Research
- Consultation



Health Literacy

Health literacy is the **ability** of individuals to easily **access**, **understand**, and **apply** health-related information, **empowering** people to make **informed health** decisions while **reducing** the **stress** associated with making **healthcare choices**.

Research Consultation Prevention

- Prevention of having the study returned for modifications, changes, or tabled
- Contact methods
- Engagement Process
- Additional Information

Voices of Panel C

The IRB gives me the opportunity to…

- "Provide unique **insights** to critical medical studies that can make all the difference in health outcomes for my Pacific Island community."

  -Richard Wolfgramm

- "Look out for my friends in marginalized groups and help them have **equal** access to research and medical advancements."

  -Dalton Peery

- "Partner with an incredibly diverse group of individuals who are committed to inclusive **ethical** research."

  -Ruth Gerritsen-McKane

Voices of Panel C

The IRB gives me the opportunity to…

- "Work with a team that represents specialized communities and cares about the world of human research. **HOPE.**"

  -Liesl Jacobson

- "Collaborate and determine research studies that need to **engage** the community in more meaningful ways."

  -Reverend France A. Davis

- "Give people a **voice** for communities in research to be more inclusive by informing and integrating community engagement practices."

  -Sara Carbajal

THANK YOU!

Using the Research Participant Experience Survey to Elicit Participant Feedback and Drive Improvements to Clinical Research

Rhonda G. Kost MD
Associate Professor of Clinical Investigation
Center for Clinical Translational Research
The Rockefeller University

Why Survey Research Participants?

- Is consent effective?
- Are participants having a positive experience?
- Which experiences impact recruitment, retention?
- Do research experiences among groups differ?
- What is the experience of minorities and underrepresented groups?
- How effective or impactful are current initiatives?
- How do we compare to other sites? Are there opportunities to collaborate?
- Build trust by asking participants for feedback
- Earn trust by engaging communities and acting on results
- Identify high scores, elucidate and share better/best practices
- Identify lower scores as opportunities to improve practices

Supported in part by NIH/NCATS Grant # U01TR003206

Stakeholders engaged in developing the RPPS from the start

Focus Groups, n=129

Participants

45% male
50 yrs old (19-86)

58% white
28% African American
2% Asian
2% Native American
9% Not reported

13% ≤ high school
28% some college
31% college graduate
26% graduate education

1-20 protocols experience

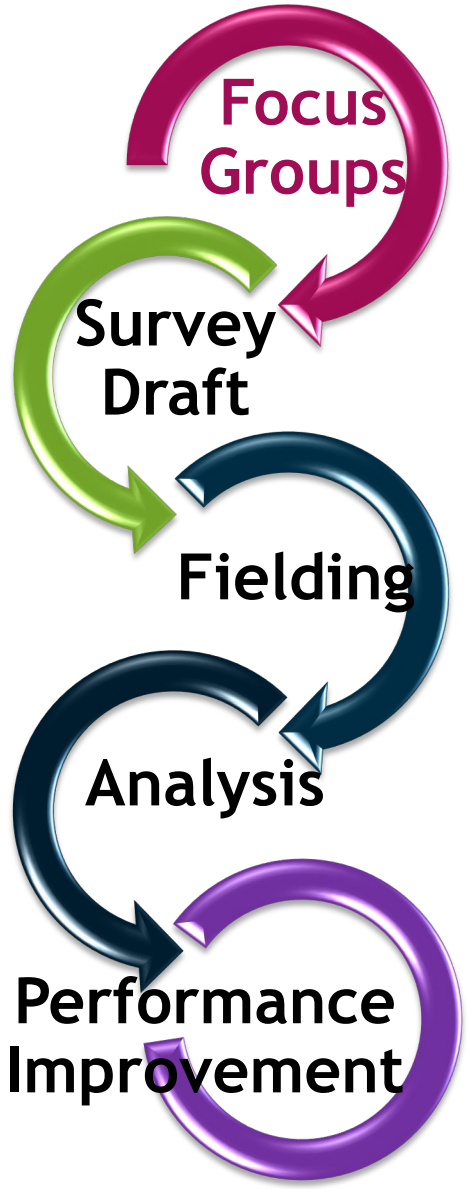
Kost, et. al., *Clin Transl Sci* 2011 4,403-413

Research Participant Perception Survey Project - Methods

Part I

Part II

Part III



- Participants & stakeholders identify key themes
- "Actionable" questions designed
- Initial validation steps
- Broad Sampling – representative of research population
- Validated with participants at 15 NIH-supported research centers
- Psychometric Analyses
- Instrument Reliability, validation
- Local & Aggregate Outcomes
- Benchmarking, improvement cycle

What does the survey ask about? (RPPS)

- Informed consent
- Listening/courtesy/respect
- Feeling valued
- Language/Culture/Privacy
- Communication with the research team
- Rate the Overall Research Experience
- Would you recommend research participation

- Demands of the Study
- Demographics
- Factors affecting the decision to join future research
- Open text box for comments…

Top Box Scoring

Yessis et. al. Clin Transl Sci 2012 Dec;5(6)452-60.

Example RPPS Survey Questions

Did the research team members listen carefully to you?

- ◯ Never
- ◯ Sometimes
- ◯ Usually
- ◯ Always

Did the research team members treat you with courtesy and respect?

- ◯ Never
- ◯ Sometimes
- ◯ Usually
- ◯ Always

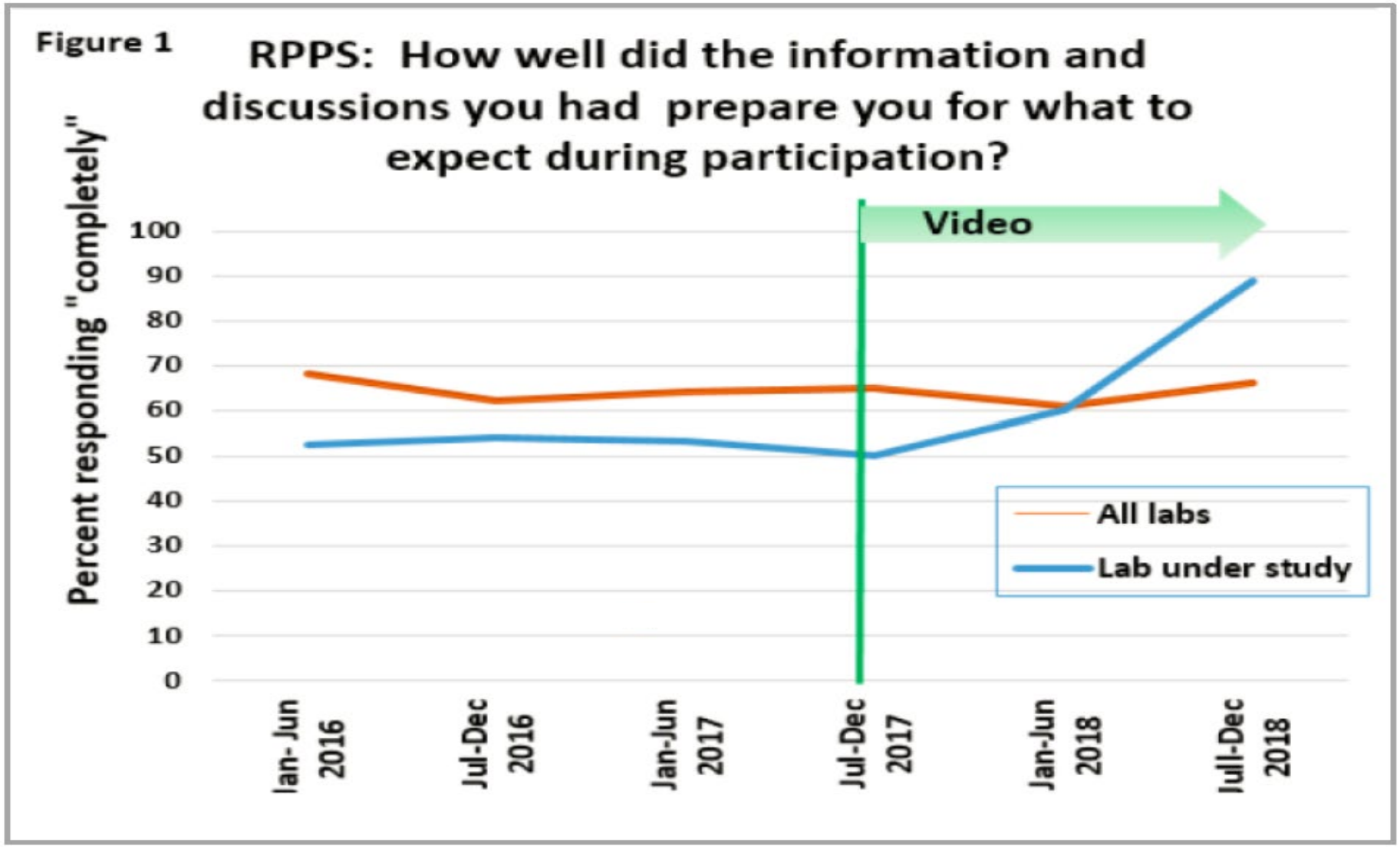
Do you have confidence and trust in the study team?

- ◯ Never
- ◯ Sometimes
- ◯ Usually
- ◯ Always

During your discussion about the study, did you feel pressure from the research staff to join the study?

- ◯ Never
- ◯ Sometimes
- ◯ Usually
- ◯ Always

Acting on Findings/Actions/Impact



Engaged Stakeholders, Developed Validated RPPS-Long
One-time national benchmarks 2008-2011

Continuous monthly surveying at RUH 2012 - present

Developed *Shorter* validated RPPS-S 2018

TIN Collaboration Webinar Prep-to-grant February 25, 2019

Empowering the Participant Voice

2020
2024

Empowering the Participant Voice (EPV) - Aims

1. **Develop** a novel Research Participant Perception Survey/REDCap (RPPS/REDCap) collaborative infrastructure, tools, and standard implementation models.

2. **Demonstrate** that the collaborative RPPS/REDCap infrastructure and implementation model is an effective approach to collect local and national benchmarks and actionable data.

3. **Disseminate** the infrastructure, catalyze research-on-research and transform evaluation by empowering the participant voice.

The Rockefeller University 1901 · Duke Clinical & Translational Science Institute · Johns Hopkins Medicine · Wake Forest School of Medicine · University of Rochester Medical Center CTSI Clinical & Translational Science Institute · Vanderbilt University Medical Center · University of Michigan · Columbia University Irving Medical Center

Participants

Rockefeller

Duke

JHU

Wake Forest

Rochester

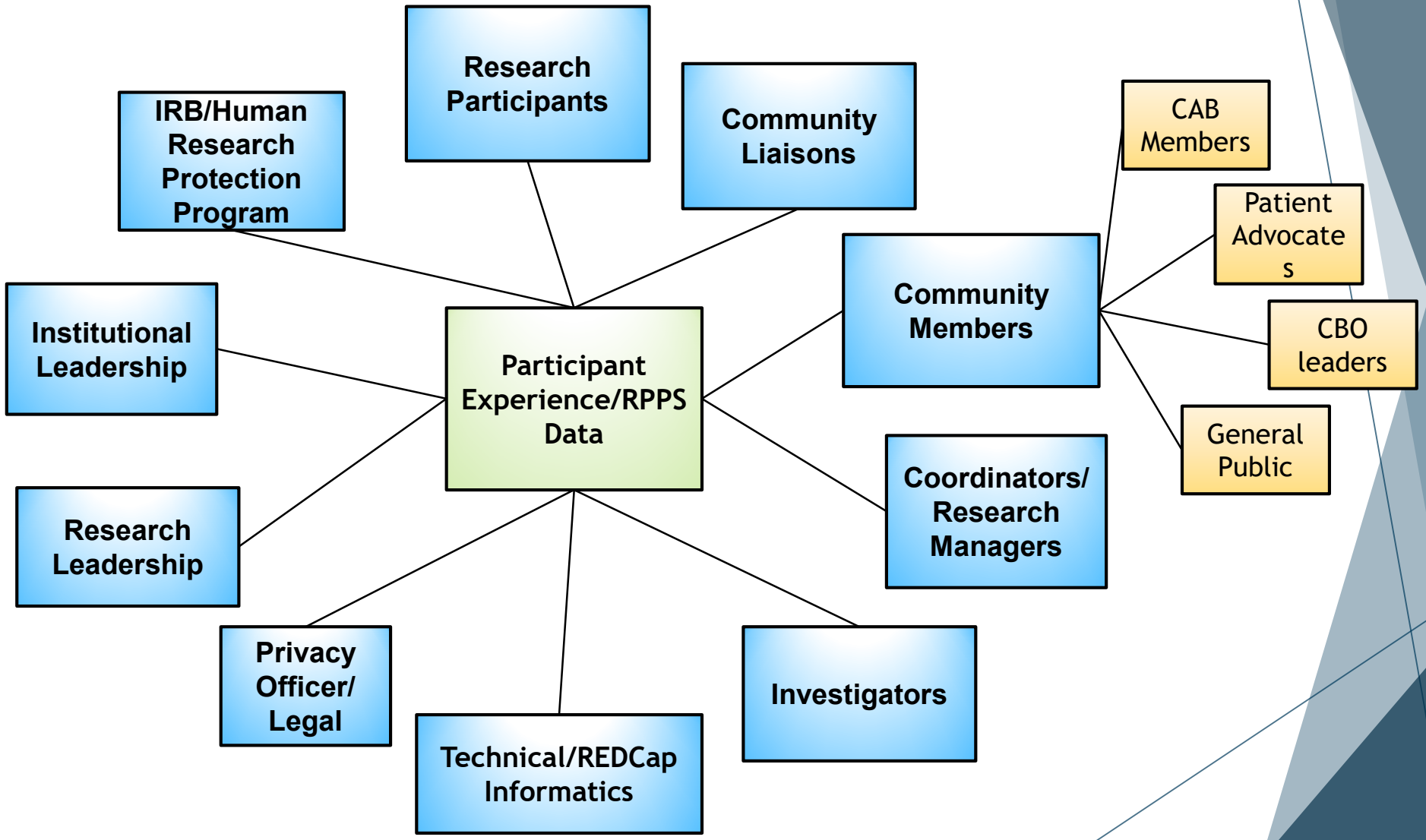
+

EPV Consortium
Inter-Institution Dashboard
(RU/VUMC)

Each site has its own RPPS dashboard and ability to aggregate and analyze its local data

Supported in part by NIH/NCATS Grant # U01TR003206

Broadly Engaging stakeholders



Kost et al JCTS 2024, PMID: 38476242

Concerns from Stakeholders

Concerns	Action
Confidentiality	
Will groups engage?	
How to prioritize findings?	
Will benchmarks compare apples-to-apples?	
Risk of negative scores	
Team might perceive scores as punitive.	
Are the questions relevant to participants? **C**	
Lack of transparency and accountability from the institution. **C**	
Potential for tokenism **C**	

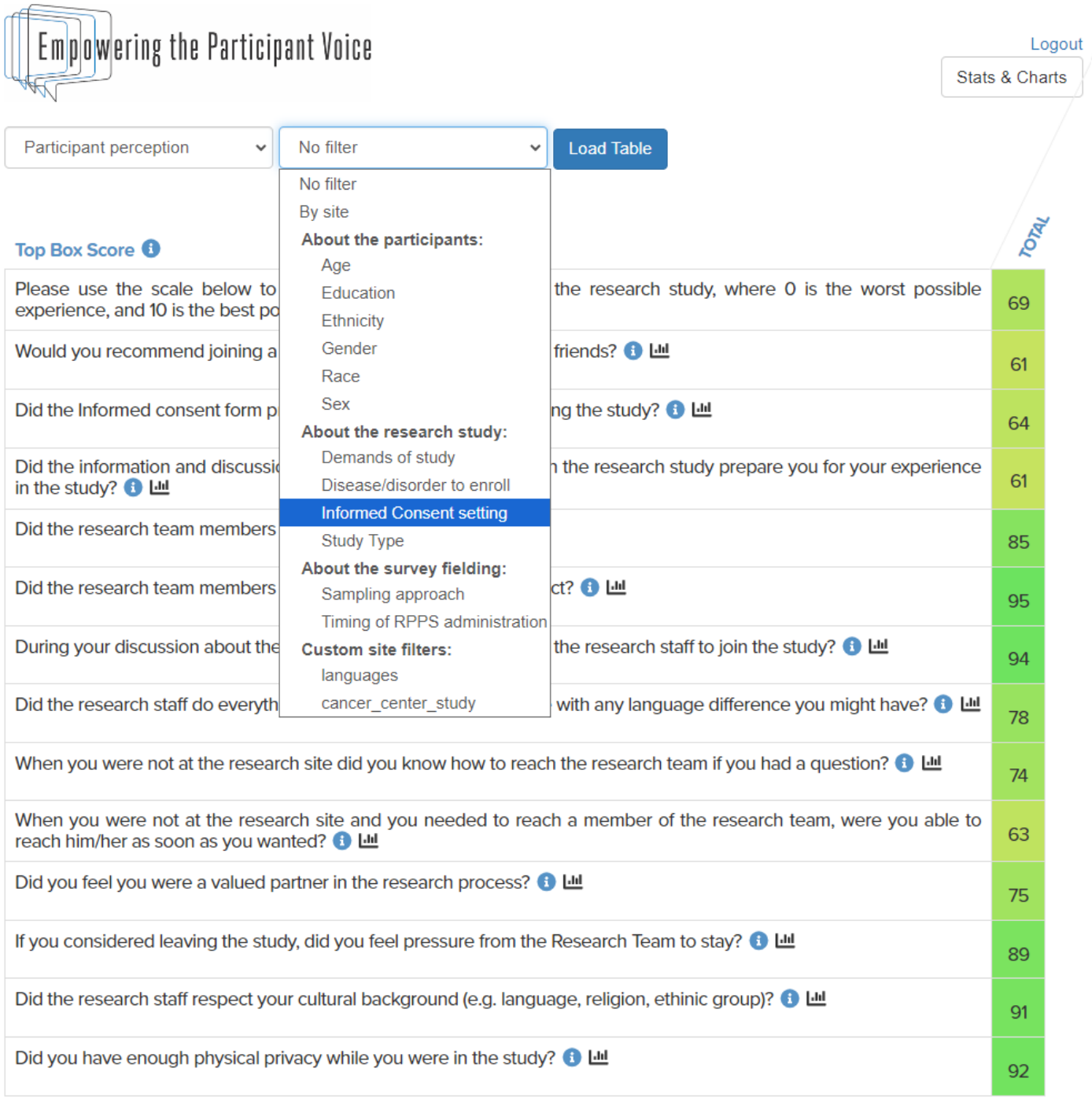
Adapted from: Kost et al JCTS 2024, PMID: 38476242

Concerns from Stakeholders

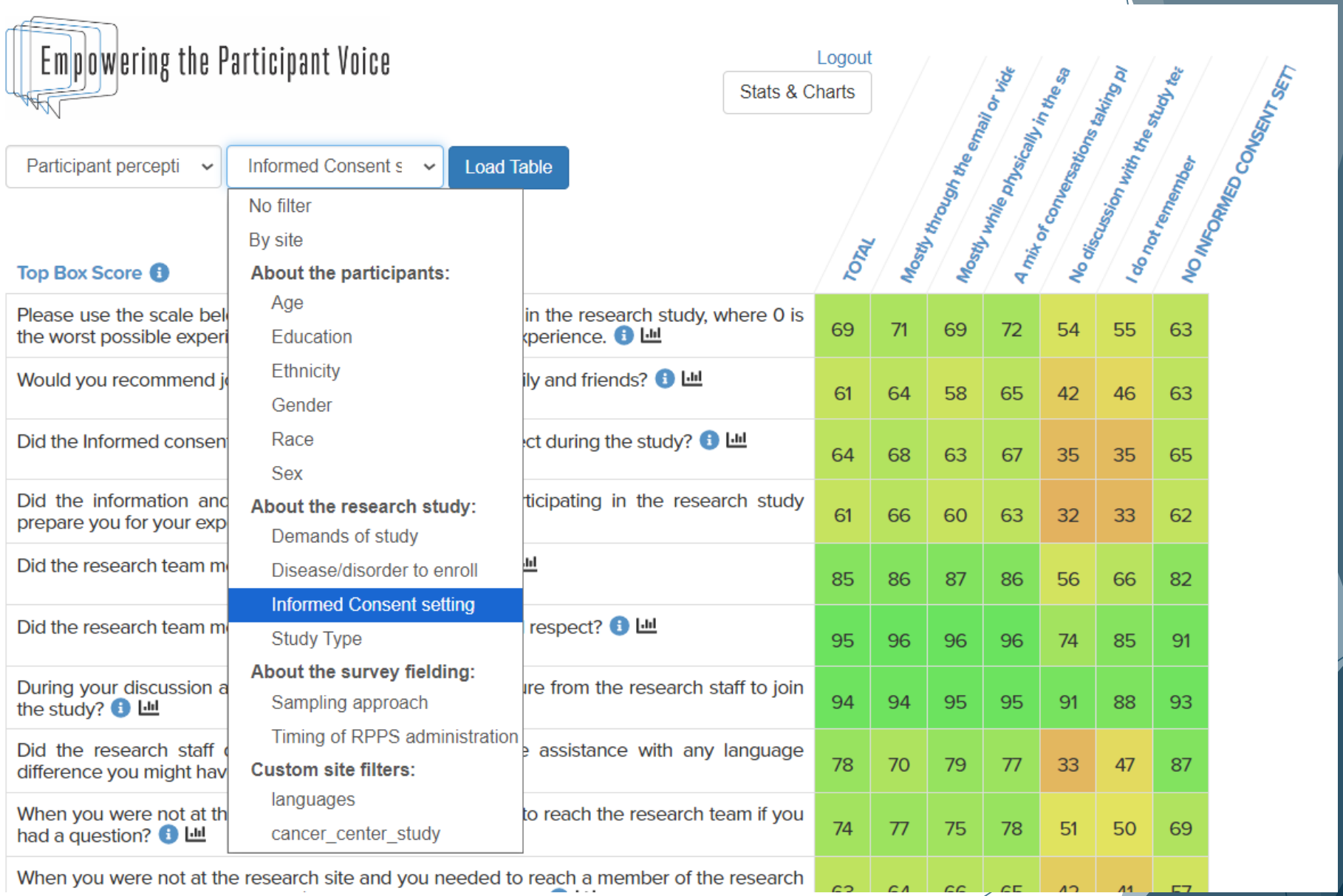
Concerns	Action
Confidentiality for participants and teams	Results are anonymized; data governance local
Will groups engage?	Engage early, address fears with policy, leverage community relationships, and share results
How to prioritize findings?	Develop performance improvement plan with stakeholders
Will benchmarks compare apples-to-apples?	Standards and variables optimize comparability
Risk of negative scores, reputational harm to investigator or institution.	Local data governance about data-sharing; study level variables; confidentiality.
Team might perceive scores as punitive.	Constructive performance improvement models
Are the questions relevant to participants? **C**	Questions developed with participants; free text option
Lack of transparency and accountability from the institution. **C**	Communicate plan for return of results; engage stakeholders in analysis and actions; be accountable.
Potential for tokenism **C**	Engage communities and trusted proxies; be accountable.

Adapted from: Kost et al JCTS 2024, PMID: 38476242

At-a-Glance-Dashboard



At-a-Glance-Dashboard



[Links to At-a-Glance Dashboard demo, and Hands-on-test-dashboard](#).

Selected Local RPPS Findings/Actions/Impact

(Site) Findings	Actions	Impacts
(A) 74% of respondents were able to reach the study team when needed	Distributed contact cards at POC	✓83% of respondents were able to reach the study team when needed

Selected Local RPPS Findings/Actions/Impact

(Site) Findings	Actions	Impacts
(A) 74% of respondents were able to reach the study team when needed	Distributed contact cards at POC	✓83% of respondents were able to reach the study team when needed
(A) 53% of respondents said a flexible visit schedule “Very Important” for future studies	Add Saturday appts one week out of each month	✓Enrollment increased 60% in weeks with Saturday appointments (from 3.6 to 6/wk.)

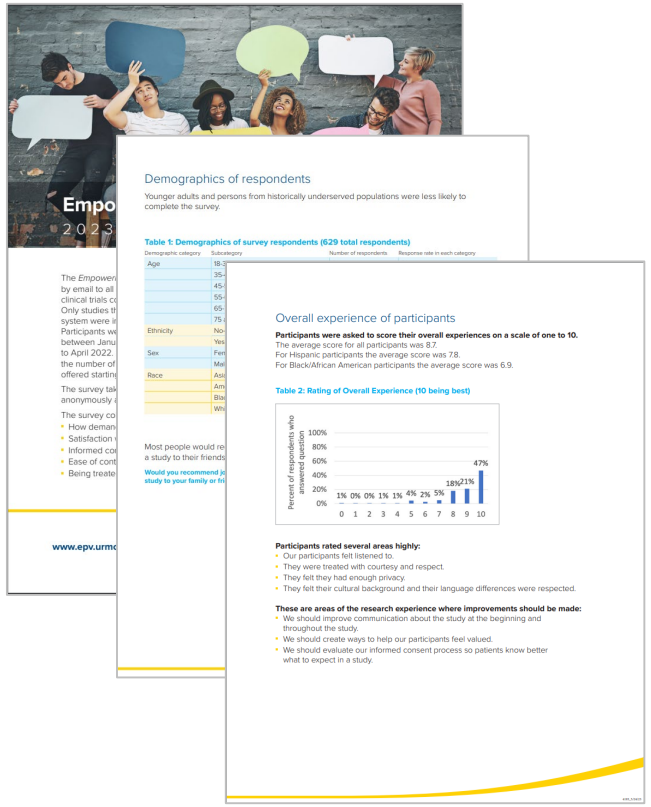
Selected Local RPPS Findings/Actions/Impact

(Site) Findings	Actions	Impacts
(A) 74% of respondents were able to reach the study team when needed	Distribute contact cards at POC	✓83% of respondents were able to reach the study team when needed
(A) 53% of respondents said a flexible visit schedule “Very Important” for future studies	Add Saturday appts one week out of each month	✓Enrollment increased 60% in weeks with Saturday appointments (from 3.6 to 6/wk.)
(B) Multiple complaints about delays to study compensation	Took data to the committee reviewing whether to invest in debit card system	✓Committee passed debit card proposal & proceeded with implementation
(C) Scores for consent from respondents in cancer center studies << than others	Mandatory consent training for CC investigators; request for CC variable	- Impact pending on scores; CC variable implemented in EPV 2024
(D) Comments about specific interactions, study procedures	Shared w/ clinical leadership; staff retraining; revision to vendor contract	✓No related complaints in ensuing 11 months
(E) Informed consent and language assistance disparities, >75, males, <HS education, email/video consent process	Formation of permanent *Equity in Research Committee; addressing each element of findings*	- Comprehensive Institutional response
(F) Low response rate from Latino/x population (significant % of participants)	Developed lower literacy materials n English and Spanish, including RPPS	✓40% of response cohort Latino/x (compared to aggregate 6%).

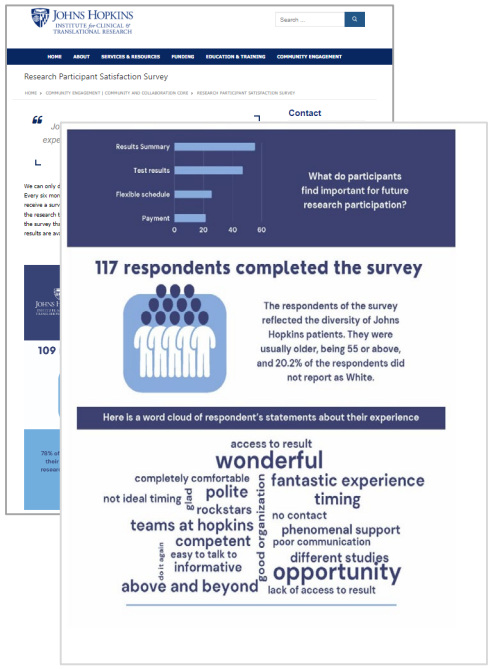
Participant Preferences & Comments

- Common themes reported by sites to the Steering committee
  - Praise for study teams, individuals
  - Gratitude for the level of attention and care
  - Complaints about specific interactions
  - Complaints about specific study procedures
  - Unexpected out-of-pocket expenses
  - Delays in receiving payment
  - Difficulty parking
  - Desire for more flexible visit schedules
- 63% of participants said receiving an overall summary of the results of the study would be “Very important” to enrolling in a future study

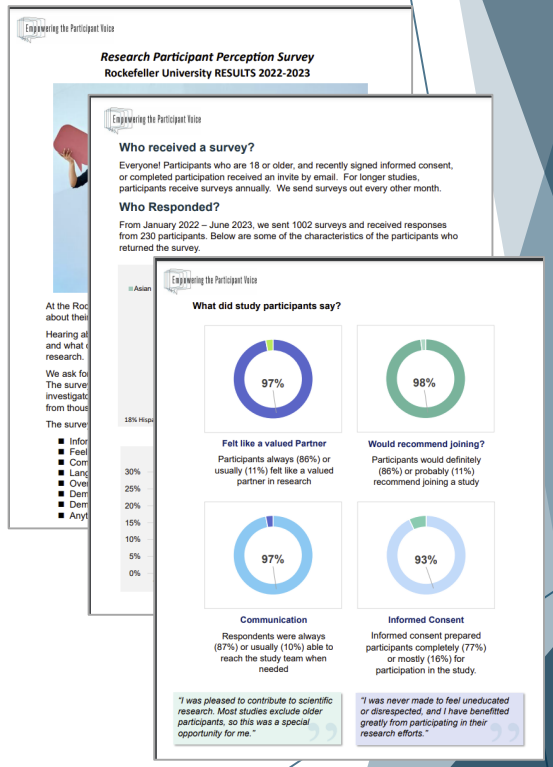
Community-Informed Return of Results Websites



[University of Rochester Survey Results website]



[Johns Hopkins University Survey Results Website]



[Rockefeller University Survey Results Website]

Resources for Adopting RPPS survey

Tools, software, anecdotes, and links shared freely on EPV Website

- Survey, Data dictionary, Implementation Guide, Dashboard
- Filters – participant & study characteristics, custom variables
- Consortium Dashboard - Benchmarks, confidential site-site comparisons
- Learning Collaborative
- Bibliography -Research Participation Perception Survey publications (8+)

Contact Rhonda G. Kost MD, kostr@rockefeller.edu

EPV Project Collaborating Site Teams

The Rockefeller University
- Rhonda Kost
- Natalie Schlesinger
- Cameron Coffran
- Adam Qureshi
- Barry Coller
- Roger Vaughan

The Johns Hopkins University
- Dan Ford
- Liz Martinez
- Scott Corey
- Cassie Lewis-Land

Duke University
- Ranee Chatterjee
- Jamie Roberts
- James Goodrich
- Sierra Lindo
- Michael Musty
- Sameer Cheema
- Schuyler Jones

The University of Rochester
- Ann Dozier
- Carrie Dykes
- Pavithra Punjala

Wake Forest University
- Joseph Andrews
- Lynn Wagenknecht
- Issis Kelly-Purmarol
- Derek Burgin
- Janet Shuping

Vanderbilt University
- Alex Cheng
- Paul Harris
- Ellis Thomas
- Eva Bascompte-Moragas
- Lindsey O'Neill
- Nan Kennedy

University of Michigan*
- Sana Shakour
- Lisa Connally Powell
- Kathie Wilcox-Pelzer
- Julie Lumeng

Columbia University*
- Nancy Green
- Karen Marder
- Siddiq Mohamed
- Sheila O'Byrne

* Early adopter sites, added in 2023.

Questions and Discussion

Continuing Education

To receive certificate(s), complete the questionnaire at the link posted in the Zoom chat:

https://ucsd.co1.qualtrics.com/jfe/form/SV_bsCdDsO6hEi8wZg

Questions? Email us at info@care-q.org