Empowering the Participant Voice

Wouldn't you like to know what your participants are thinking? Empowering the Participant Voice, Update & Use Cases

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Vanderbilt University Medical Center

Wake Forest School of Medicine

University of Rochester Medical Center | CTSI Clinical & Translational Science Institute

Johns Hopkins Medicine

Duke Clinical & Translational Science Institute

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Support

Empowering the Participant Voice: Collaborative Infrastructure and Validated Tools for Collecting Participant Feedback to Improve the Clinical Research Enterprise is supported in part by a Collaborative Innovation Award from the National Center for Accelerating Translational Science #U01TR003206 to the Rockefeller University, and by Clinical Translational Science Awards UL1TR001866 (Rockefeller University), UL1TR002553 (Duke University), UL1TR003098 (Johns Hopkins University), UL1TR002001 (University of Rochester), UL1TR002243 (Vanderbilt University), and UL1TR001420 (Wake Forest University Health Sciences).

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EPV Project Overview

Site Use Cases

Technical Requirements

Invitation

Q&A

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A Brief History of the Research Participant Perception Survey (RPPS)

Identified the need for *participant-centered* measures of the research participation experience

Piloted a set of unvalidated questions, surveying participants at RU and NIH

Early data were presented to a group of Research Participant Advocates; very strong interest in using a common survey

Set out to design and validate a survey, developed with participant & other stakeholder input

2003 - 2006

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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

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2020

2023

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EPV Project 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.

Research Participant Perception Survey (RPPS-Short) asks about…

- Informed consent
- Listening/courtesy/respect
- Feeling valued
- Language/culture/privacy
- Communication with team
- Rate the Overall research experience
- Would you recommend to friends and family
- Demands of the study
- Demographics

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Example RPPS Survey Questions

Did the information and discussions you had before participating in the research study prepare you for your experience in the study?

- ○ No
- ○ Yes - somewhat
- ○ Yes - mostly
- ○ Yes - completely

When you were not at the research site and you needed to reach a member of the research team, were you able to reach him/her as soon as you wanted?

- ○ Never
- ○ Sometimes
- ○ Usually
- ○ Always
- ○ Did not need to reach the research team

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Value Proposition

Why Survey Research Participants with RPPS?

- Build participant trust
- Assess informed consent
- Tailor approach to participants
- Improve experience of underrepresented groups
- Identify best practices
- Improve recruitment and retention
- Identify high and low performing teams
- Understand COVID impact
- Establish benchmarks
- Develop participant-centered evidence base

Supported in part by NIH/NCATS Grant # U01TR003206

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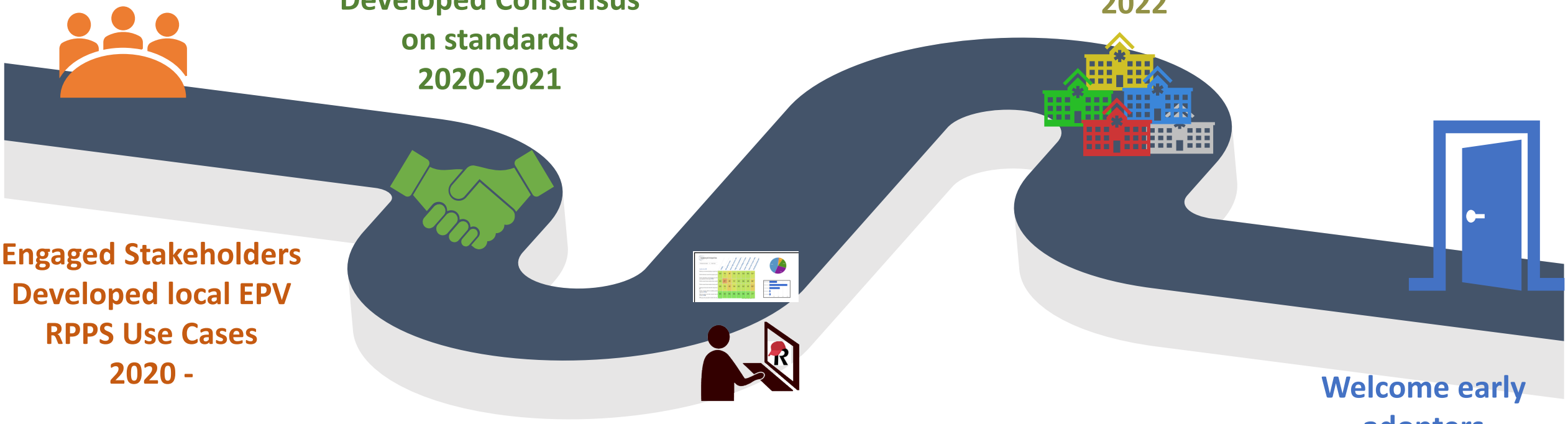
Implemented Use Cases
2022

Developed Consensus on standards
2020-2021



Engaged Stakeholders
Developed local EPV
RPPS Use Cases
2020 -

Built tools & infrastructure
2021

Welcome early adopters
2023

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Data Flow Model

Download REDCap: .XML, RPPS, tool & forms

Participant contact and study information CTMS/EMR/Other

Study characteristics from CTMS

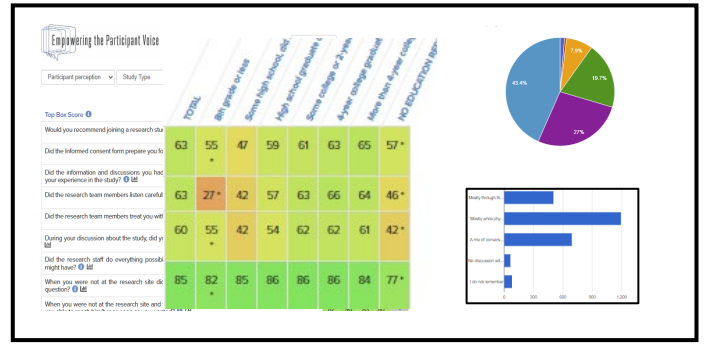
Create a REDCap Project

Set up data instruments using project creation tools

Data Collection

RPPS Project Data

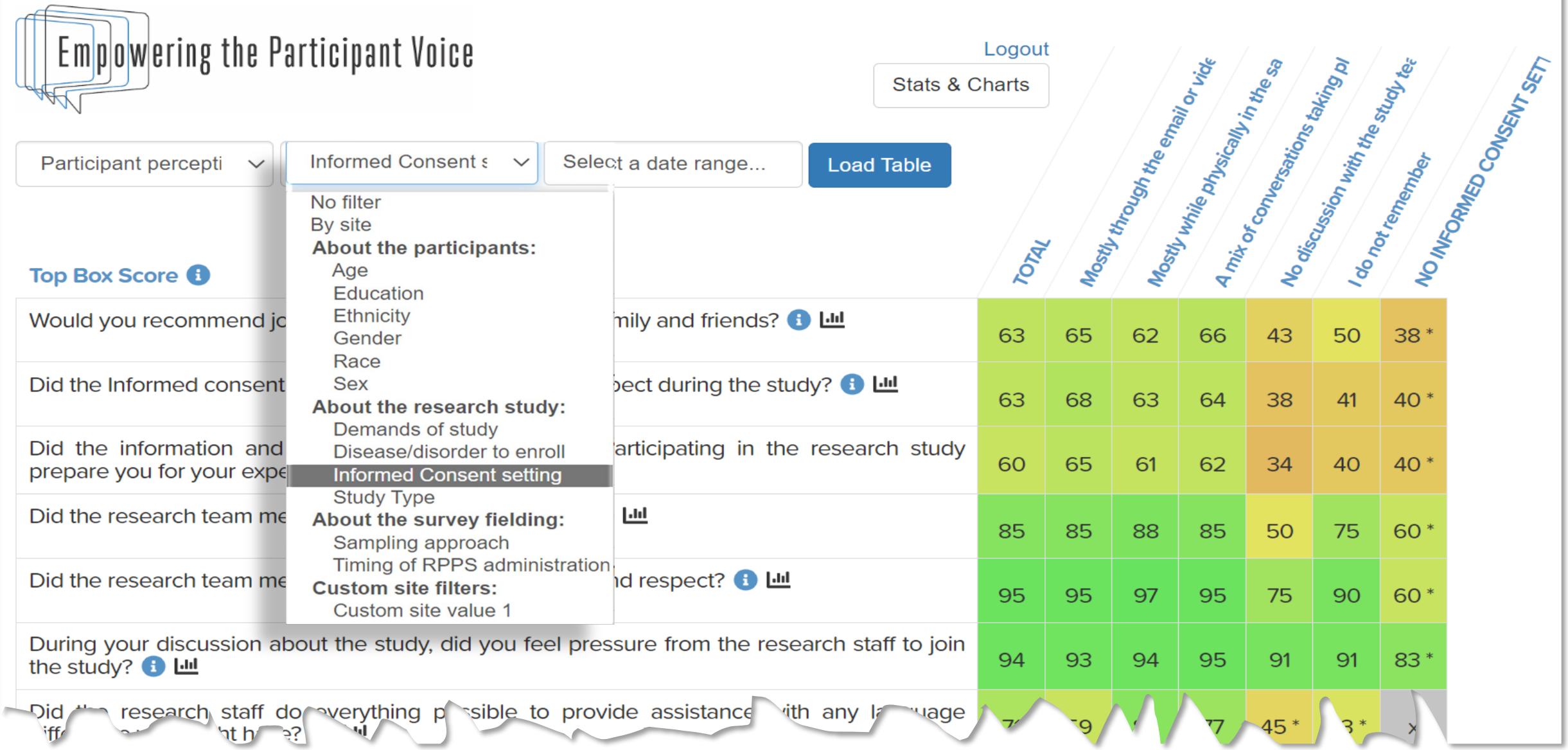
At-a-Glance Dashboard & Stats



Research Project Coordinator or REDCap administrator

Field through email/REDCap survey fxn

EPV Project manager, or Investigator or Department Chair, or stakeholder committee



Supported in part by NIH/NCATS Grant # U01TR003206

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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

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Planning Considerations

Institutional Support

- Align with Institutional initiatives

Team

- Dedicated project team to manage EPV

Engage stakeholders

- Leverage established structures and resources

Privacy

- De-identified data shared with Consortium

Scope of Implementation

- Enterprise-wide increases scale and sustainability

Sampling

- Census sampling recommended for broader reach and representation

Timing

- Administer post-consent, end-of-study, annually

Platform

- REDCap based infrastructure + email, EMR portal, SMS (Twilio)

Frequency

- Deploy survey at least semi-annually for efficient use of effort

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Alignment with Institutional Initiatives

Joseph E. Andrews, Jr.
PhD, MA, CIP, CCRP

Assistant Dean for Regulatory Affairs and Research Integrity at Wake Forest School of Medicine.

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Alignment with Institutional Initiatives

At WF we collect feed via:

- Surveys for patients following care
- Surveys for employees
- Surveys for students
- **Gap in the research area**

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Alignment with Institutional Initiatives

Pilot Study

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Alignment with Institutional Initiatives

- Looked at Phone, Mail, Email and Portal delivery
- Portal delivery:
  - Cost effective
  - Similar response rates to traditional methods
  - Offered opportunity to use participant data to drive initiatives
- WF was interested in rolling RPPS out, but needed to work on operational and technical details

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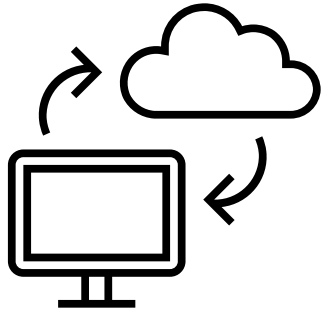
Alignment with Institutional Initiatives

Use of EPIC Metadata to understand communities' views



<u>EPV project</u>

- Listen to our participants
  - Examine differences in experience across study types, age, race, ethnicity, gender
  - Explore ways that we can ensure the best possible experience for all

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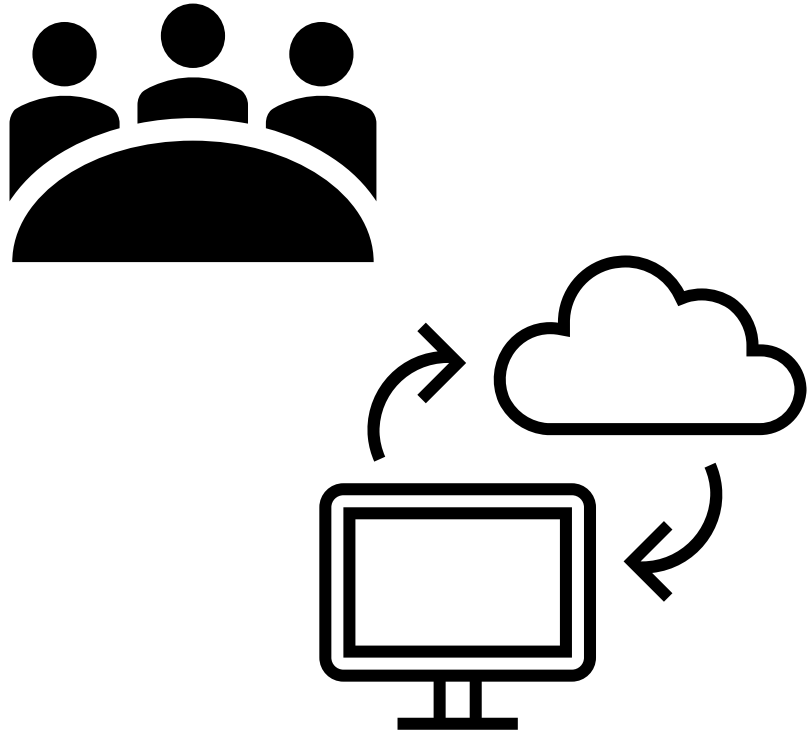
Alignment with Institutional Initiatives

Portal Use & DCOMMS

Research Community Enthusiasm

- Use of Portal for Research
- Show we care
- Improvement where possible
  - Better relationships
  - Retention
  - Word of mouth
  - Knowing what we are doing well



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Alignment with Institutional Initiatives

aLHS

Learning from what we do – Doing what we learn

- Had developed this model in clinical operations and academics
- EPV allowed us to implement this in research operations
  - Exploring findings related to language needs
  - Sending our second round of surveys out now to all participants in our CTMS

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Engaging Stakeholders

Ann M. Dozier
RN, PhD, FAAN

Professor and Chair, Department of Public Health Sciences
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Stakeholder Engagement - Rochester

- Enterprise-wide implementation of the survey for studies in our OnCore CTMS
  - Deemed performance improvement
- Chose to use existing groups rather than establish a new stakeholder panel specific to this project
  - Identified groups representing key stakeholders
  - Periodically attend their regularly scheduled meetings

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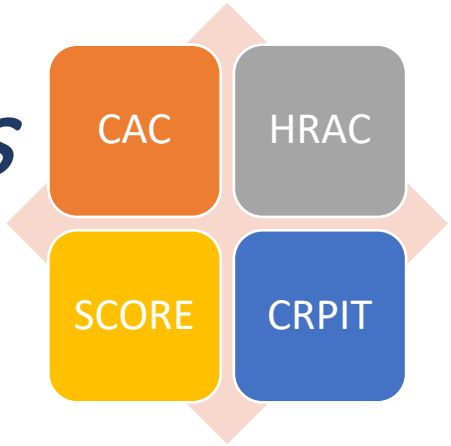
Stakeholder groups



- Community Advisory Council
- CTSI Leadership
- Health Research Advisory Committee (coordinators and investigators)
- Study Coordinator Organization for Research Education (SCORE)
- Clinical Research Process Improvement Team (institutional leadership)
  - (SADCR, CTSI, IRB, Office of Counsel, Office of Clinical Research, IT, ORPA, investigators)
- Wilmot Cancer Center Office of Clinical Research leadership

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Finding/Impact: Community Advisory Council

- Finding
  - Lower survey response rate for Hispanic and Black research subjects
- Action
  - Suggested we utilize the data we had to determine if there was evidence explaining why these groups of people might have a lower response rate
    - And if we could learn anything valuable/actionable from their responses
  - When posting results to the community, they suggested we discuss the historical injustice of research
  - Suggested sending hard copy of survey to Black and Hispanic subjects
- Impact
  - Analyzed the comments from Black and Hispanic respondents (n=23; n=13) and their answers to the RPPS items
  - Will test return rate from sending hard copies of surveys

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Finding/Impact: Health Research Advisory Committee

- Finding
  - Lower survey response rate for Hispanic and Black research subjects
- Action
  - Provide ways for coordinators and investigators to let subjects know they will get a survey
  - Also provide this survey to research subjects in studies not in OnCore (only billing risk studies are required to use OnCore)
- Impact
  - Created flyers in Spanish and English for teams to give to subjects when they consent
  - Shared with leadership that study teams that want to utilize the survey should be able to put their study in OnCore

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Finding/Impact: Wilmot Cancer Center

- Finding
  - Lower scores on consent related questions
    - Compared with other responses; compared with other sites (dashboard)
    - Lower scores on cancer center studies
      - Only the study PI is allowed to do the consent
- Action
  - Suggested looking at specific studies to see if some investigators have better scores than others
  - Recently implemented a new optional consent training program for new faculty
    - May shift to stronger language (strongly recommended vs. optional)
- Impact
  - Identified a two studies with better consent scores
    - Future plans to discuss with these study teams reasons their consent processes
  - Re-check scores after 6 months to see if scores improve as a result of the training program

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Enterprise Implementation

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Director, Institute for Clinical and Translational Research

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Enterprise Implementation - Johns Hopkins

JH has been surveying since 2016!

- Invitation letter with a survey link is emailed to 500 adults randomly selected from those enrolled in a clinical trial in CRMS and consented in the past 2-6 months.
- Reminder email sent 2 weeks after initial email
- 500 survey invitations sent twice per year July and January
- Responses are not linked to study participants
- Response rate average is about 23%

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Enterprise Implementation - Johns Hopkins

Research Participant Satisfaction Survey Respondents

Survey Respondent characteristics 2016-2021

665 survey responses
48% Female
80% White
17% Black or African American
47% 65 years of age or older

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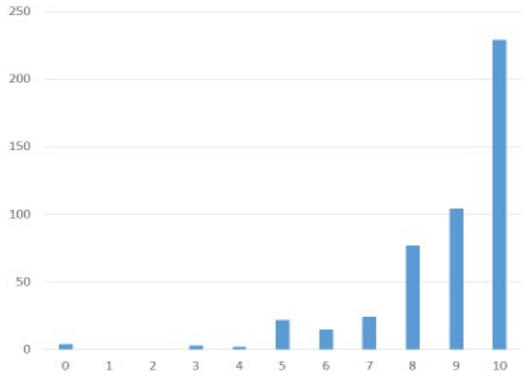
Enterprise Implementation - Johns Hopkins

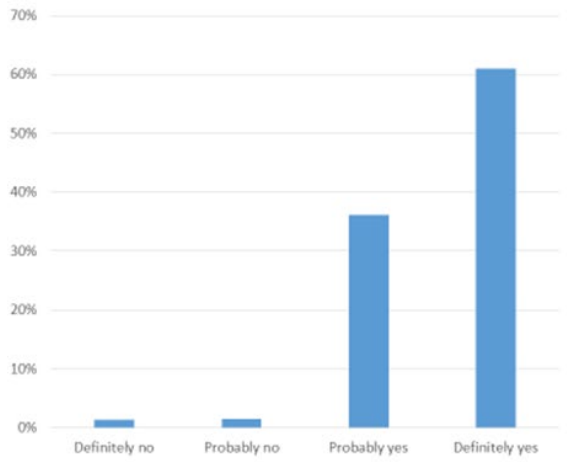
Rate your overall experience in the research study
(0 is the worst and 10 is the best)



90% of respondents rated their experience a 7 or higher

47% of respondents rated their experience as a 10

Would you recommend joining a research study to your family and friends?



61% of respondents said "definitely yes"

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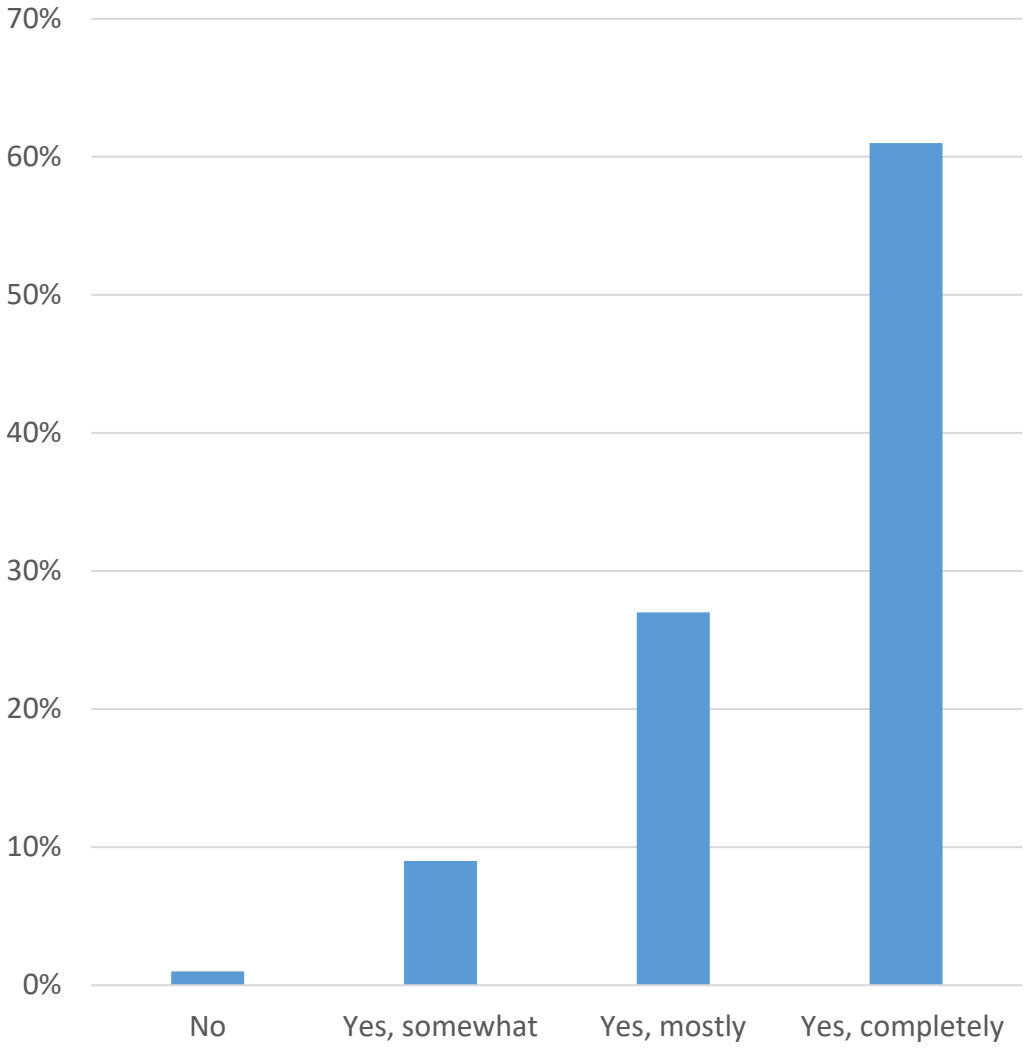
Did the informed consent to prepare you for what to expect during the study?



61% of respondents said “Yes, completely”

27% of respondents said “Yes, mostly”

9% of respondents said “Yes, somewhat”

1% said “No”

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Satisfaction with Research Team Members

Participants report **high** satisfaction with the research team

84% reported the research team **always** listened carefully to them

93% reported research team **always** treated them with courtesy and respect

77% reported knowing how to **always** reach research team for questions

67% felt they were **always** a valued partner in the research process

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What would be important for participants in a future study

The highest number of participants rated the following four reasons as **important for future studies**

- Flexible schedule
- Accessible parking and study location
- Summary of overall research results shared with me
- Results of personal lab tests shared with me or my doctor

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Impact and Lessons Learned

- Overall, participant satisfaction was quite favorable, and this is quite reassuring.

- Important areas for improvement in the research experience:
  - participants want research results shared with them (80%)
  - and want their lab tests shared with them or their doctor (60%.)
  - billing issues
  - dissatisfaction with the participant payment process

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Impact and Lessons Learned

- Survey results are shared with the local community, the IRBs and the JH research community
- Findings are used in training programs for Research Coordinators and Principal Investigators
- Current and past survey results are always freely available on the ICTR website

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Enterprise Implementation

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Enterprise Implementation - Rockefeller

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We have been fielding RPPS since 2012

Enterprise –

- Bimonthly surveys
- To all adult participants, all studies
- IRB exemption, performance improvement
- Post-consent, end of study
- Include Lab group, protocol in metadata for return of results

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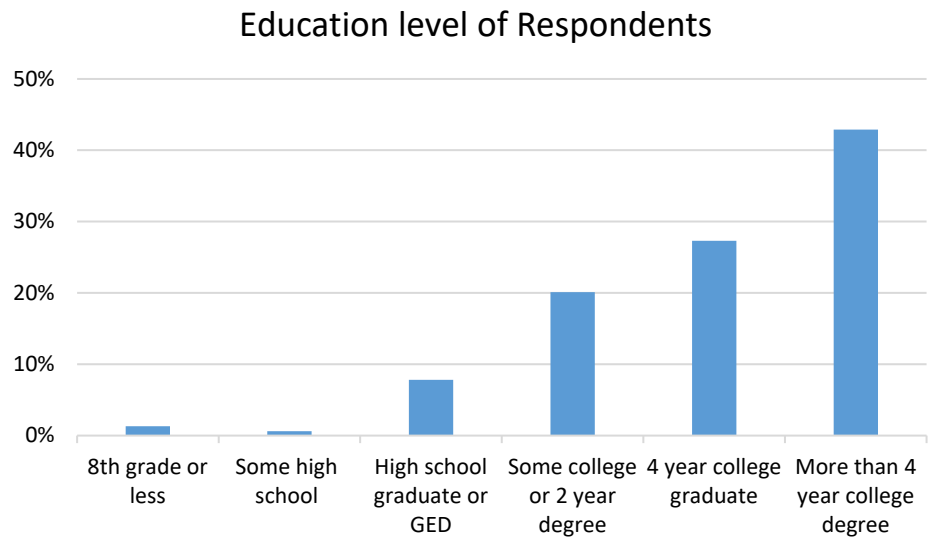
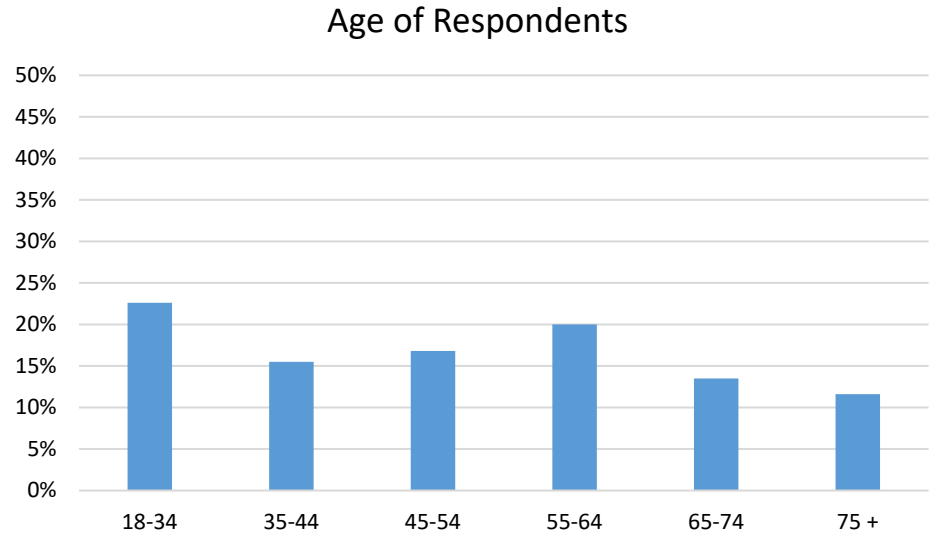
Enterprise Implementation - Rockefeller

Results

- Response rate 20% (14-27% by race)
- Demographics
  - Asian 4.5%; American Indian 2.6%; Black 24%; Hawaiian 1.3%; White 70.8%.
  - Female 49%; Male 50.3%; Prefer not to say 0.6%.
  - Latino/Hispanic 22%





Enterprise Implementation - Rockefeller

Findings and Impact

- A specific participant comment led to change of process for an already high scoring team
- Hospital CQI committee chose EPV RPPS as the 2023 and 2024 performance improvement activity.
- “Return of a summary of the results of the research” – is a highly rated factor (>50% “very important”) in deciding whether to join a future study
- Remote consent

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Did the information and discussions you had before participating prepare you for your experience in the research study?

Comparing where the consent discussion took place:

Remote: ….mostly by email, video or telephone

79% completely

In-person……mostly while physically in the same place as the study team

68% completely

Hybrid….both physically in the same place & over telephone/video/computer

76% completely

Overall rating (Topbox)

Remote consent: 90%

In-person consent: 79%

Hybrid consent: 79%

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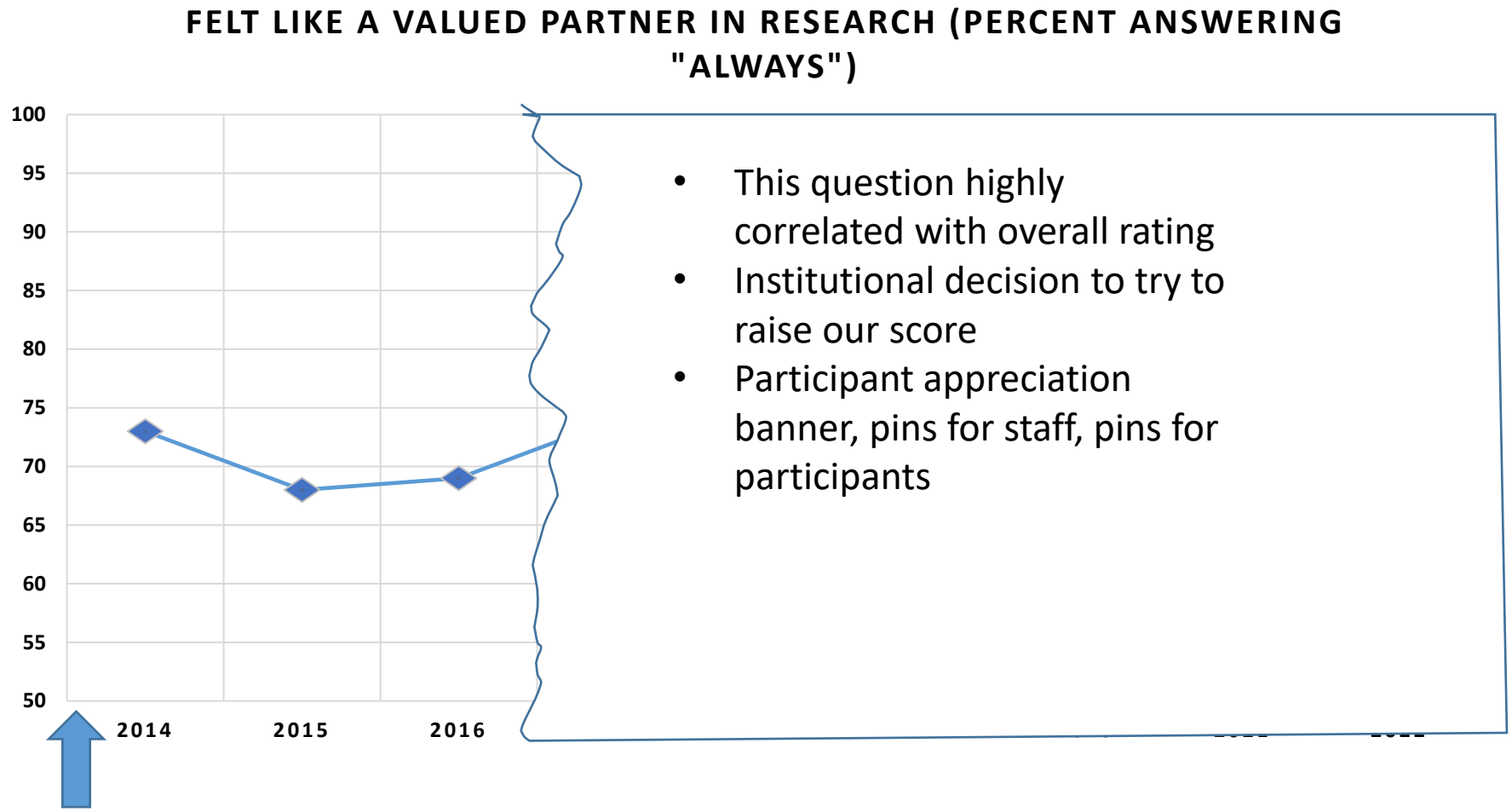
Partnership, a decade-long focus



- This question highly correlated with overall rating
- Institutional decision to try to raise our score
- Participant appreciation banner, pins for staff, pins for participants

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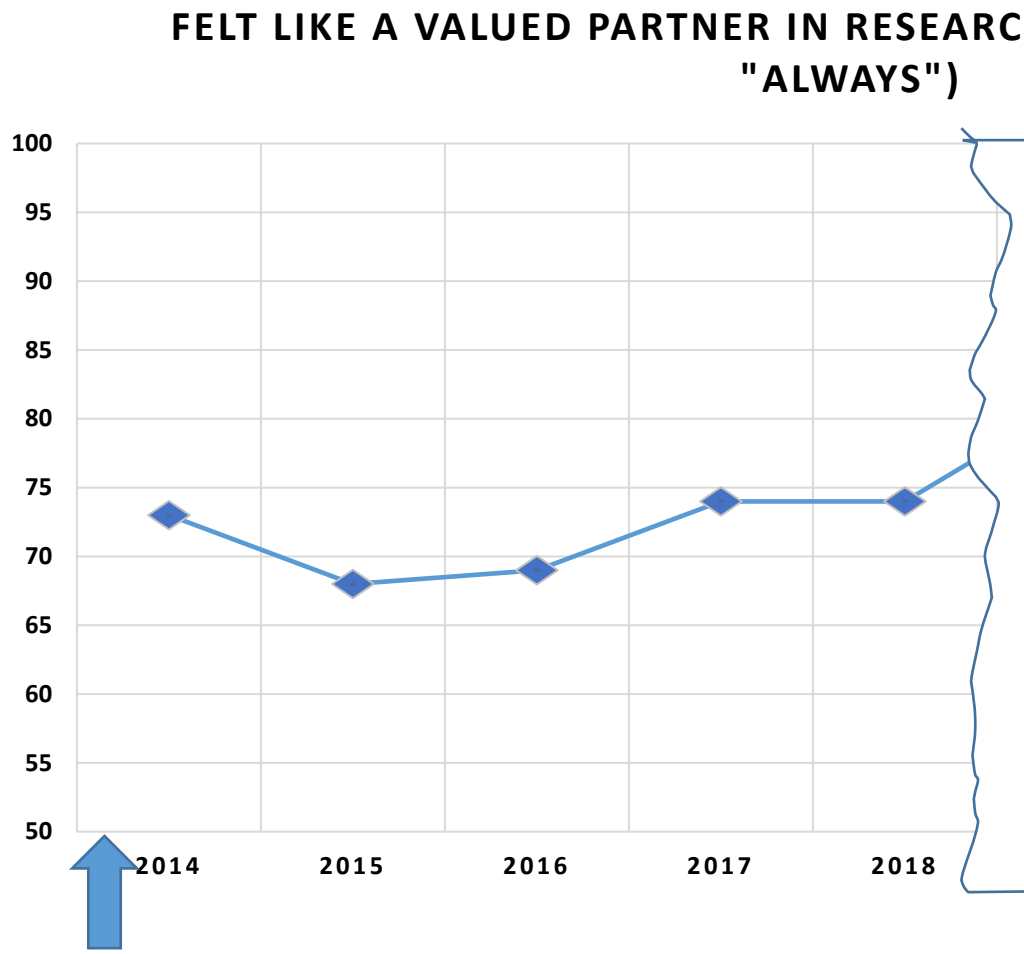
Partnership, a decade-long focus



- Incorporate the value into:
  - Trainings for new investigators
  - Protocol development navigation process
  - Recruitment strategy
  - Community engagement
  - Return of Results initiative

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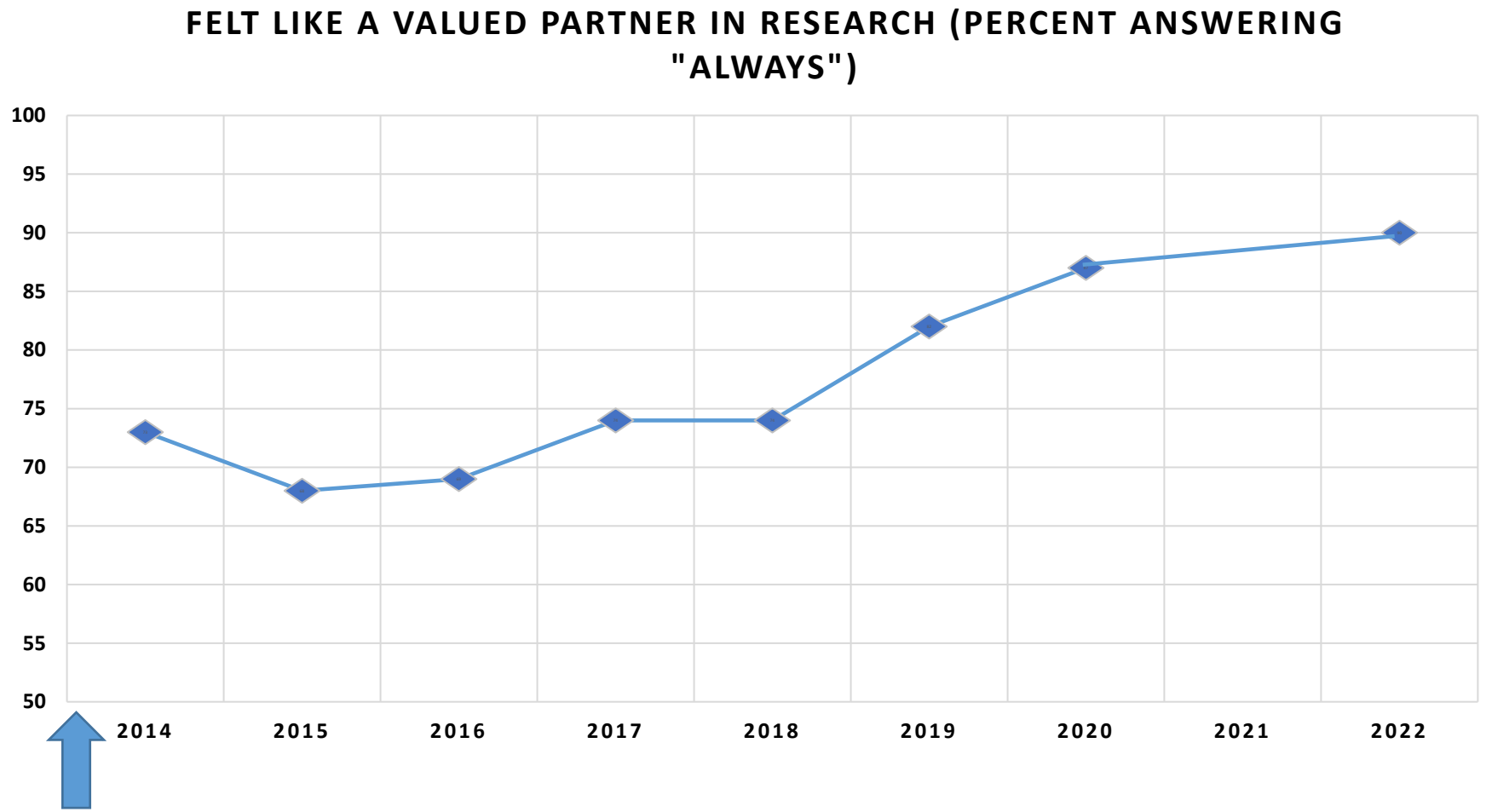
Partnership, a decade-long focus



A sustained institutional value

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Study-Level Implementation

Sierra Lindo
MPH
Project Manager
Duke Clinical
and
Translational Science
Institute

Duke Clinical & Translational Science Institute

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Study level Implementation – Duke

- QI, Central Distribution and management
- Project by project with volunteer pilot study teams
- Inclusive of all study types
  - Interventional
  - Observational
  - Population health based (later)
  - University based (later)

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Study Level Challenges

- Many relate to increasing the efficiency of how we add studies
  - Time-intensive with individual personalized surveying
- Duke has piloted processes designed to distinguish survey results at a study level. Previously, the consortium design provides only had means to report results at an institutional level but study-level view is coming in the next iteration of the Dashboard
- We are piloting a way for research teams to add questions for their individual studies, requiring an increasingly flexible design

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PERT Study Intervention

Colorectal Cancer Screening

SPR 0028 - PERT Study
Performance of Epi proColon® in Repeated Testing in the Intended Use Population

Thank you for your participation in this study! Please keep this for your records, and contact us if you have any questions.

The Study Team

Taylor Harris
(919) 668-3663

Morgan Mangum
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Jhoanna Aquino
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Study Email: PERT-Study@dm.duke.edu

Pro000855544

Duke Primary Care Research Consortium

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Durham, NC 27701

epi pro colon®

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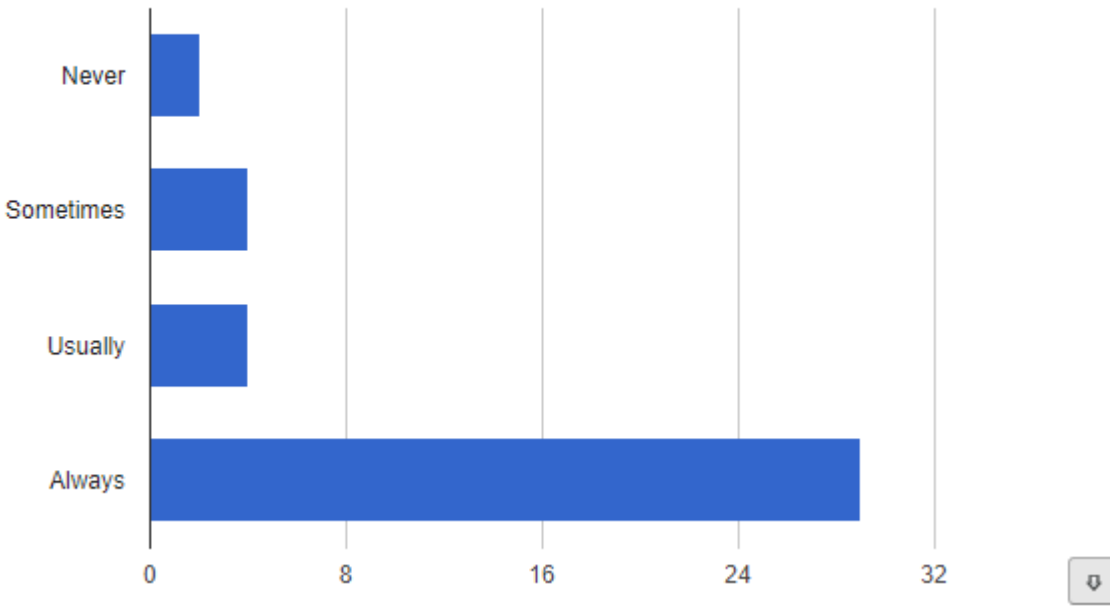
Measuring Impact

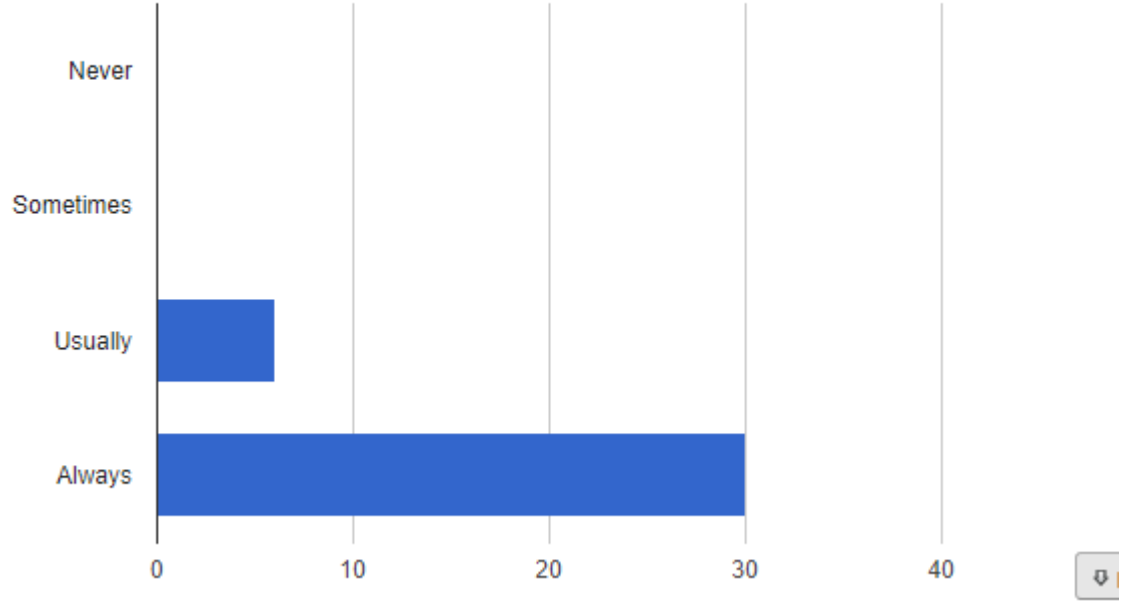
When you were not at the research site ***did you know*** how to reach the research team if you had a question?

Counts/frequency: Never (2, 5.1%), Sometimes (4, 10.3%), Usually (4, 10.3%), Always (29, 74.4%)



Pre-Intervention

Counts/frequency: Never (0, 0.0%), Sometimes (0, 0.0%), Usually (6, 16.7%), Always (30, 83.3%)



Post-Intervention

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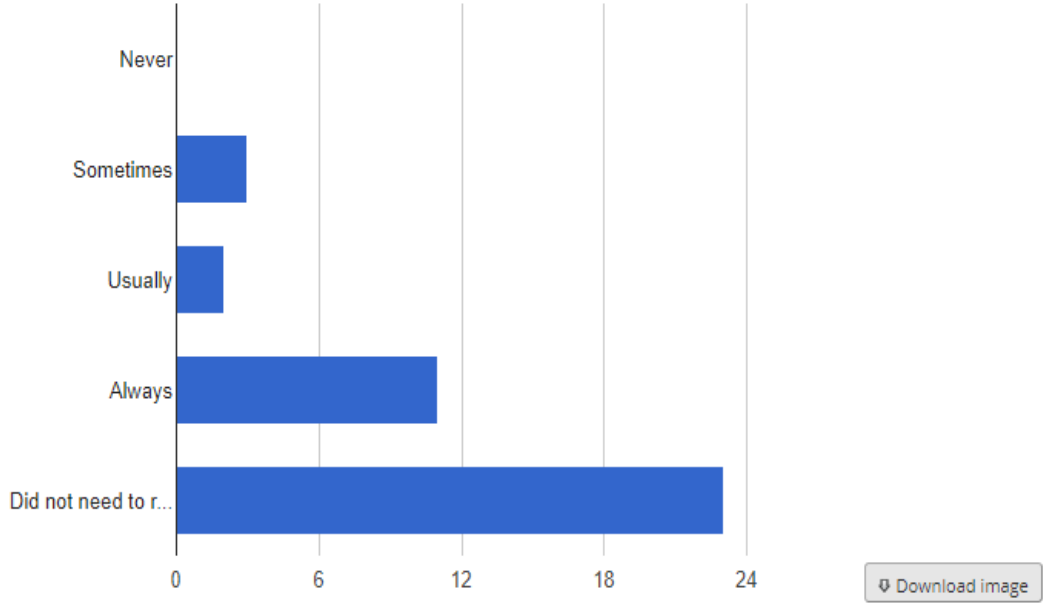
Measuring Impact

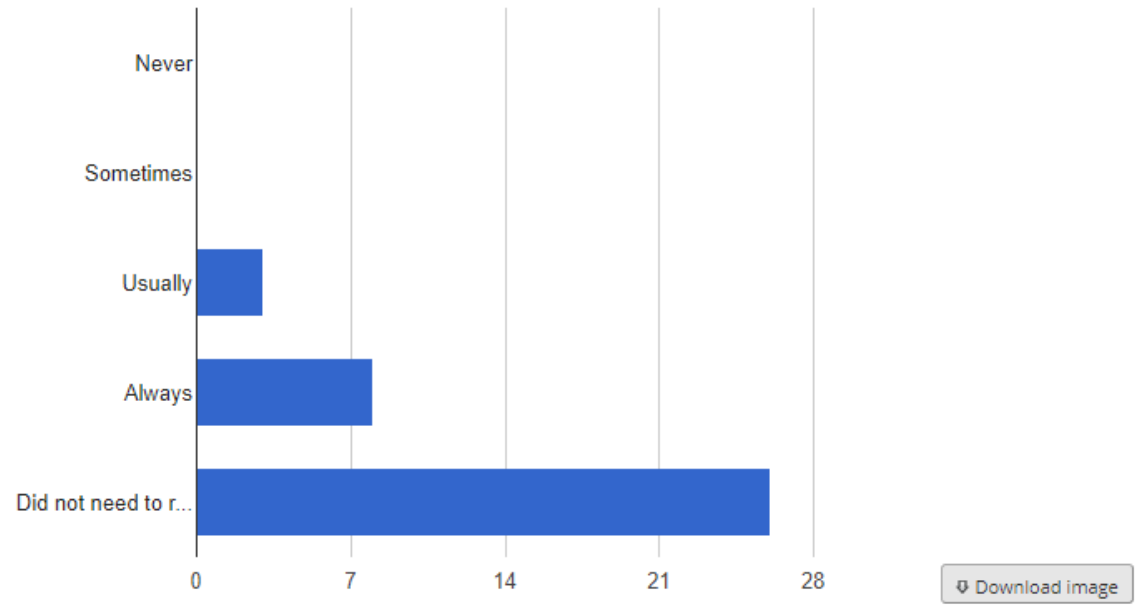
When you were not at the research site and you needed to reach a member of the research team**, *were you able to*** reach him/her as soon as you wanted?

Counts/frequency: Never (0, 0.0%), Sometimes (3, 7.7%), Usually (2, 5.1%), Always (11, 28.2%), Did not need to reach the research team (23, 59.0%)



Pre-Intervention

Counts/frequency: Never (0, 0.0%), Sometimes (0, 0.0%), Usually (3, 8.1%), Always (8, 21.6%), Did not need to reach the research team (26, 70.3%)



Post-Intervention

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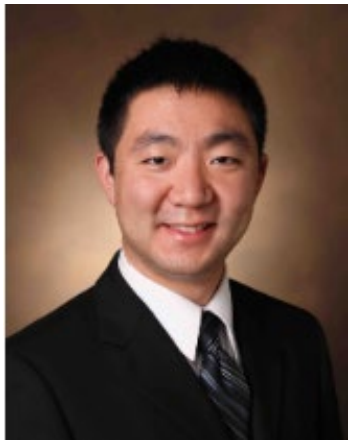
Empowering the Participant Voice

Technical Implementation

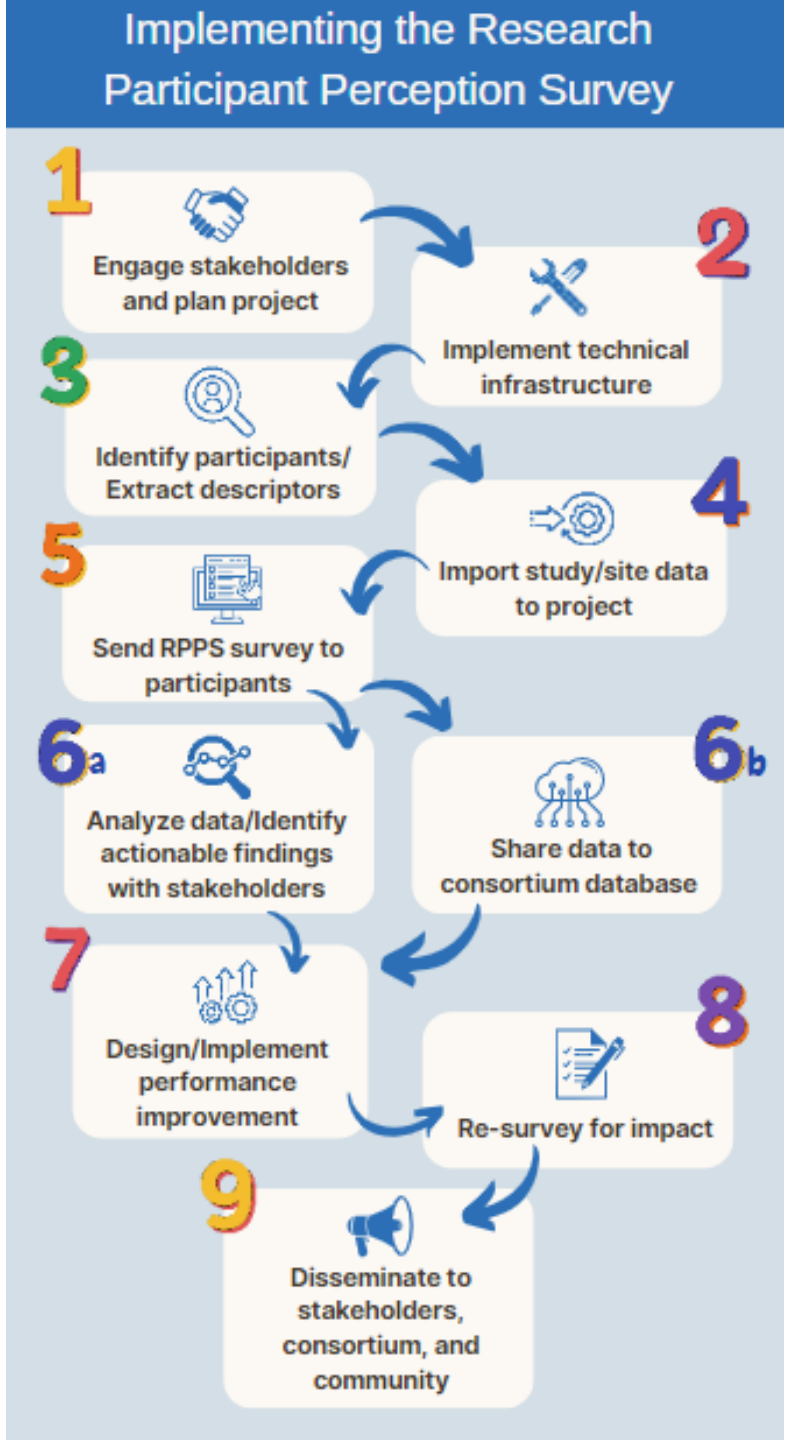


VANDERBILT UNIVERSITY MEDICAL CENTER

Alex Cheng
PhD
Technical Lead
Research Assistant Professor, Department of Medical Bioinformatics, Vanderbilt University Medical Center

Empowering the Participant Voice

Implementation



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Technical Requirements RPPS/REDCap

- ❑ Install or update REDCap to version 10.0 or later
- ❑ Create an EPV RPPS Project in REDCap
- ❑ Create a Research Study Database Project in REDCap (*Optional)*
- ❑ Create an Intra-Institutional Aggregator Project in REDCap (*Optional)*
- ❑ Connect your institution's RPPS Project with the EPV Consortium Database
- ❑ Install REDCap external modules:
  - ❑ EPV At-a-Glance Dashboard module 1.7 or later
  - ❑ Multilingual 1.9.8 or later
  - ❑ Cross project piping 1.4.5 or later

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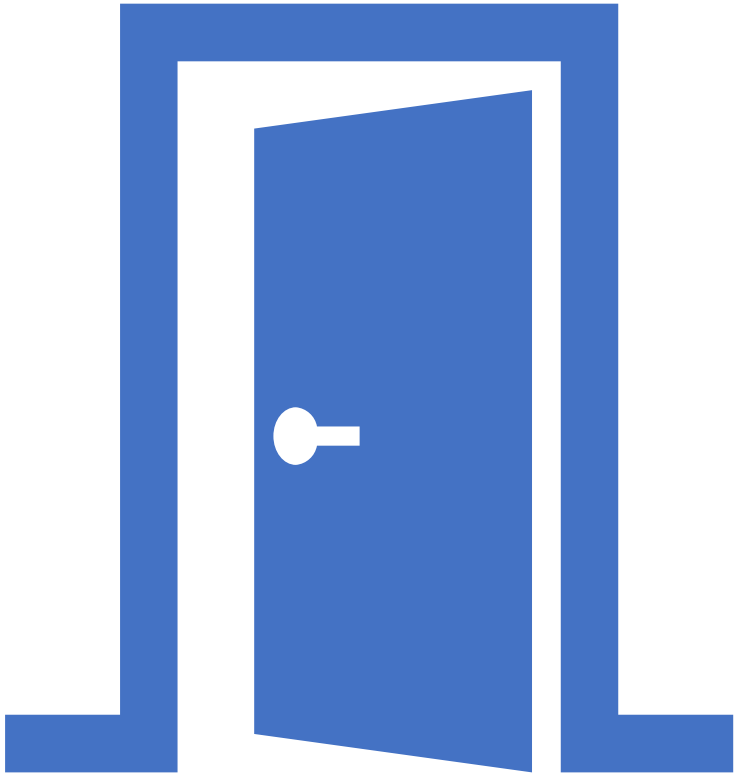
EPV learning collaborative



The Rockefeller University 1901

Johns Hopkins Medicine

Your site here!

Vanderbilt University Medical Center

University of Rochester Medical Center | CTSI Clinical & Translational Science Institute

Wake Forest School of Medicine

Duke Clinical & Translational Science Institute

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Ready to share…

Next, broad dissemination of the EPV RPPS/REDCap infrastructure to early-adopter institutions

- Learning Collaborative
- Comprehensive EPV Implementation Guide
- Biweekly technical calls
- New Pediatric RPPS working group

EPV website (https://www.Rockefeller.edu/research/epv

Sign up for project updates at epv@rockefeller.edu

Contact PI at kostr@rockefeller.edu if your institution is interested in implementing EPV infrastructure.

Please complete the *post-webinar poll*….we are evidence driven!

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Questions

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Process Improvement

- Analyze data
- Design improvement
  - Include stakeholders! (e.g, participants, staff: research, HSR, clinical)
  - Identity risk points prospectively (e.g, failure mode and effects analysis)
- Implement change
- Measure impact