Empowering the Participant Voice (EPV): Design and Implementation of Collaborative Infrastructure to Collect Research Participant Experience Feedback at Scale

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Supplemental Materials

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Supplemental Appendix A - Longitudinal Stakeholder Tracking Form

Site Level Stakeholder Longitudinal Tracking

Evaluation Tool: Stakeholder Participation Longitudinal Tracking

Stakeholder engagement throughout the life of the project is one of several Evaluation parameters for this grant, Empowering the Participant Voice.*

This survey is meant to serve as a data collection tool for tracking:
- **engagement with stakeholders,**
- **the themes of their specific input,**
- **actions taken to incorporate their input, and**
- **the impact of those actions**

Please complete this form for each meeting engaging stakeholders for your local initiative related to the RPPS/REDCap project Empowering the Participant voice

Collaborating Site

- ◯ Duke
- ◯ Johns Hopkins
- ◯ University of Rochester
- ◯ The Rockefeller University
- ◯ Vanderbilt
- ◯ Wake Forest

Name of individual completing this form

_____
(First and last name)

Role, if not KSP

_____

Date of the meeting or stakeholder information-gathering event

_____

Meeting name (internal reference)

_____
(Optional field for site use)

Which stakeholders were present? (Choose all that apply)

- ☐ Institutional Leadership
- ☐ IRB/Human Research Protection Program
- ☐ Clinical Research Managers
- ☐ Investigators
- ☐ Research Coordinators / Practice Managers / Project Leaders
- ☐ Research Participants / Patients
- ☐ Community Members / Representatives
- ☐ Community liaison
- ☐ NCATS/NIH, & other CTSAs
- ☐ Others

Stakeholder category other, specify

_____

Approximately how many stakeholders were in attendance (excluding EPV team members)?

- ◯ 1-5
- ◯ 6-10
- ◯ 11-25
- ◯ 26-50
- ◯ More than 50

Stakeholders: Please select the titles or closest similar titles that reflect the authority, role or level of influence of the stakeholders at your site who attended the engagement/meeting/event.

When more than one stakeholder or role is involved, check all that apply.

Institutional Leadership

- ☐ University President/Provost
- ☐ AMC/Medical School President/Provost/Vice-Provost
- ☐ Health System Leadership (e.g Chancellor, etc.)
- ☐ CTSA PI/co-PI
- ☐ Research Center DIrector
- ☐ Department Chair
- ☐ VP or Director for Diversity and Inclusion
- ☐ Executive Committee
- ☐ Others

Leadership, other, specify:

_____

IRB/Human Research Protection Program

- ☐ IRB Chair/Vice-chair
- ☐ IRB administrators
- ☐ IRB Members
- ☐ HRPP University Official or Privacy Officer
- ☐ Other

Human research protections other, specify

_____

Clinical Research Managers

- ☐ Clinical Research Manager, research unit
- ☐ Clinical Research Manager, department/division
- ☐ Clinical Research Manager, Center or other organization
- ☐ Clinic Research Manager, CTSA Core
- ☐ Other

Clinical research manager other, specify:

_____

Investigators

- ☐ Medical Instructor
- ☐ Assistant Professor
- ☐ Associate Professor
- ☐ Professor
- ☐ Trainees
- ☐ Investigators studying populations under-represented in research
- ☐ Advance Practice/Extender Investigators (PA, Nurse Practitioner)
- ☐ Other

Investigators Other, please specify

_____

Clinical Research Coordinators	☐ Research Coordinator - direct contact with research participants ☐ Research Coordinator - no direct contact with research participants ☐ Research project lead or project portfolio manager ☐ Other
Coordinators other, specify:	_____
Research Participants / Patients	☐ Patients /Participants ☐ Patient /Participant advocates ☐ Patient/Participant Advisory board/members ☐ Respondents to previous surveys/Town Halls ☐ Others
Research participants other, specify:	_____
Community Members / Representatives	☐ CAB members ☐ CBO leaders ☐ Patient advocates ☐ Community leaders engaged in other projects ☐ Other
Community other, specify:	_____
How many attendees fulfill a COMMUNITY or CAB MEMBER or LIAISONor PATIENT or PARTICIPANT or similar role?	◯ 1-5 ◯ 6-10 ◯ 11-25 ◯ 26-50 ◯ More than 50 ◯ Not sure (Estimate the total)
NIH/NCATS & other CTSAs	☐ Program Officer ☐ PI Steering Committee ☐ CTSA (potential/Early Adopter) ☐ Other NIH/NCATS

CTSA(s) (potential/Early Adopters) - Select all that apply

- ☐ None
- ☐ ALBERT EINSTEIN COLLEGE OF MEDICINE, BRONX, NY
- ☐ BOSTON UNIVERSITY, BOSTON, MA
- ☐ CASE WESTERN RESERVE UNIVERSITY, CLEVELAND, OH
- ☐ CHILDREN'S RESEARCH INSTITUTE, WASHINGTON, DC
- ☐ COLUMBIA UNIVERSITY HEALTH SCIENCES, NEW YORK, NY
- ☐ DUKE UNIVERSITY, DURHAM, NC
- ☐ EMORY UNIVERSITY, ATLANTA, GA
- ☐ GEORGETOWN UNIVERSITY, Washington, DC
- ☐ HARVARD MEDICAL SCHOOL, BOSTON, MA
- ☐ INDIANA UNIV-PURDUE UNIV AT INDIANAPOLIS, INDIANAPOLIS, IN
- ☐ JOHNS HOPKINS UNIVERSITY, BALTIMORE, MD
- ☐ MAYO CLINIC ROCHESTER, ROCHESTER, MN
- ☐ MEDICAL COLLEGE OF WISCONSIN, MILWAUKEE, WI
- ☐ MEDICAL UNIVERSITY OF SOUTH CAROLINA, CHARLESTON, SC
- ☐ NEW YORK UNIVERSITY SCHOOL OF MEDICINE, NEW YORK, NY
- ☐ NORTHWESTERN UNIVERSITY AT CHICAGO, CHICAGO, IL
- ☐ OHIO STATE UNIVERSITY, COLUMBUS, OH
- ☐ OREGON HEALTH & SCIENCE UNIVERSITY, PORTLAND, OR
- ☐ ROCKEFELLER UNIVERSITY, NEW YORK, NY
- ☐ RUTGERS BIOMEDICAL/HEALTH SCIENCES-RBHS NEW BRUNSWICK, NJ
- ☐ SCRIPPS RESEARCH INSTITUTE, LA JOLLA, CA
- ☐ STANFORD UNIVERSITY STANFORD, CA
- ☐ STATE UNIVERSITY OF NEW YORK AT BUFFALO, AMHERST, NY
- ☐ TUFTS UNIVERSITY BOSTON, BOSTON, MA
- ☐ UNIV OF ARKANSAS FOR MED SCIS LITTLE ROCK, AR
- ☐ UNIV OF MASSACHUSETTS MED SCH WORCESTER, WORCESTER, MA
- ☐ UNIV OF NORTH CAROLINA CHAPEL HILL, CHAPEL HILL, NC
- ☐ UNIVERSITY OF ALABAMA AT BIRMINGHAM, BIRMINGHAM, AL
- ☐ UNIVERSITY OF CALIFORNIA AT DAVIS, Sacramento, CA
- ☐ UNIVERSITY OF CALIFORNIA LOS ANGELES, LOS ANGELES, CA
- ☐ UNIVERSITY OF CALIFORNIA, SAN DIEGO LA JOLLA, CA
- ☐ UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, SAN FRANCISCO, CA
- ☐ UNIVERSITY OF CALIFORNIA-IRVINE, IRVINE, CA
- ☐ UNIVERSITY OF CHICAGO, CHICAGO, IL
- ☐ UNIVERSITY OF CINCINNATI, CINCINNATI, OH
- ☐ UNIVERSITY OF COLORADO DENVER, AURORA, CO
- ☐ UNIVERSITY OF FLORIDA, GAINESVILLE, FL
- ☐ UNIVERSITY OF ILLINOIS AT CHICAGO, Chicago, IL
- ☐ UNIVERSITY OF IOWA, IOWA CITY, IA
- ☐ UNIVERSITY OF KANSAS MEDICAL CENTER, KANSAS CITY, KS
- ☐ UNIVERSITY OF KENTUCKY, LEXINGTON, KY
- ☐ UNIVERSITY OF MIAMI SCHOOL OF MEDICINE, MIAMI, FL
- ☐ UNIVERSITY OF MICHIGAN AT ANN ARBOR, ANN ARBOR, MI
- ☐ UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN
- ☐ UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR, ALBUQUERQUE, NM
- ☐ UNIVERSITY OF PENNSYLVANIA PHILADELPHIA, PA
- ☐ UNIVERSITY OF PITTSBURGH AT PITTSBURGH, PITTSBURGH, PA
- ☐ UNIVERSITY OF ROCHESTER, ROCHESTER, NY
- ☐ UNIVERSITY OF SOUTHERN CALIFORNIA Los Angeles, CA
- ☐ University of Texas Health Science Center San Antonio SAN ANTONIO, TX
- ☐ UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON, HOUSTON, TX
- ☐ UNIVERSITY OF TEXAS MED BR GALVESTON, GALVESTON, TX
- ☐ UNIVERSITY OF UTAH, SALT LAKE CITY, UT
- ☐ UNIVERSITY OF VIRGINIA, CHARLOTTESVILLE, VA
- ☐ UNIVERSITY OF WASHINGTON, SEATTLE, WA
- ☐ UNIVERSITY OF WISCONSIN-MADISON, MADISON, WI
- ☐ VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, TN
- ☐ VIRGINIA COMMONWEALTH UNIVERSITY, RICHMOND, VA
- ☐ WAKE FOREST UNIVERSITY HEALTH SCIENCES, WINSTON-SALEM, NC
- ☐ Washington University in St. Louis, SAINT LOUIS, MO
- ☐ WEILL MEDICAL COLL OF CORNELL UNIV , NEW YORK, NY
- ☐ YALE UNIVERSITY, NEW HAVEN, CT

NIH/NCATS Other (please specify)	_____
Other CTSAs, attendee roles	☐ CTSA PI ☐ Pediatric CTSA PI or faculty or peds other ☐ Recruitment/Outreach/CE Core ☐ Faculty/PI/Trainees ☐ Program/core manager ☐ IT/REDCap specialist ☐ HRPP, IRB, or Privacy Officer ☐ Other role/group
CTSA Consortium Members Other, please specify	_____
Non-CTSA institutions, & potential/Early Adopters. Chack all that apply	☐ institutional leadership ☐ research/clinical leadership ☐ IRB/Privacy/HRPP ☐ clinical research manager/coordinators ☐ investigator/research team members ☐ participant/patients ☐ community liaison/advocate/representative ☐ Agency (e.g. AAHRPP, FDA, CMS, etc.) ☐ Not -for-profit (advocay group, philanthropy) ☐ Other
Name of institutions (EPV Webinars only)	_____

What was discussed at the stakeholder meeting? Please describe the focus, details, and highlights of the discussion, including differences of opinion and any resolution or actions decided.

Consider the categories below to organize the themes of the meeting. Thank you.

Discussion specific to early-adoption planning, onboarding, DUA, technical alignement, other issues.	_____
THE DASHBOARD: Ease-of-use, utilty, challenges interpreting the data, best feature(s), missing feature(s)	_____
RESPONSE RATES AND DEMOGRAPHICS: Outreach, how to encourage reutrn of the surveys from specific communities/partiicpants.	_____
Review of POTENTIALLY ACTIONABLE FINDING(S); How was it decided what might be "actionable"?	_____
Did the group have PROPOSED INNOVATIONS AND CHANGES for improving on a specific actionable finding?	_____

What are the stakeholders lookng for (VALUE) in considering the data and the effort/cost of the survey?	
Were there TECHNICAL OR OPERATIONAL ISSUES regarding the survey infrastructure or operational challenges?	
SOMETHING ELSE was discussed.	
Stakeholder comment/suggestion theme 1:	
Stakeholder comment/suggestion theme 2:	
Stakeholder comment/suggestion theme 3:	
Stakeholder comment/suggestion theme 4:	
Stakeholder comment/suggestion theme 5:	
Stakeholder comment/suggestion theme 6:	
Comments about the design of this form: missing information, revisions, other.	

Empowering the Participant Voice is supported in part by a grant from the National Center for Accelerating Translational Science U01TR003206 to the Rockefeller University, and Clinical Translational Science Awards UL1TR002553 (Duke University), UL1TR003098 (Johns Hopkins University), UL1TR002001 (University of Rochester), UL1TR001866 (Rockefeller University), UL1TR002243 (Vanderbilt), and UL1TR001420 (Wake Forest University Health Sciences).

Supplemental Appendix B - EPV Research Participant Perception Survey (EPV-RPPS-Short)

Research Participant Perception Survey - Empowering the Participant Voice

Please complete the survey below.

Thank you!

Languages:

◯ English
◯ Español

Survey Date and Time

_____

Welcome!

The purpose of this survey is to collect feedback about research participant experiences.

At this time, we are asking about your experiences in the study that you most recently joined or completed (or stayed with more than a year). To protect your privacy, we provide this hint and not the full study title: [study_title_for_privacy] .

The results will help us understand how to improve the experience in the future.

This survey is being used nationwide as part of the Empowering the Participant Voice project.

The survey will take 2-3 minutes to complete.

Survey responses are analyzed as a group. We do not share any individual survey responses to staff or research teams or in any reports or publications.

Your participation is voluntary.

Please answer the questions below regarding the research study you enrolled in within the past year. If you enrolled in more than one study, answer for the most recent study.

When the survey questions refer to "the study," we are asking about your experiences enrolled in that clinical research study, not this online survey study.

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

◯ Definitely no
◯ Probably no
◯ Probably yes
◯ Definitely yes

Please use the scale below to rate your overall experience in the research study, where 0 is the worst possible experience, and 10 is the best possible experience.

◯ 0 worst
◯ 1
◯ 2
◯ 3
◯ 4
◯ 5
◯ 6
◯ 7
◯ 8
◯ 9
◯ 10 best

Did the study require that you already have a disease or condition in order to enroll?

◯ Yes - required a disease or condition to enroll
◯ No

Did the study involve taking a drug or a supplement or the use of a new medical device, or undergoing a new medical procedure, or lifestyle or behavioral change?

◯ Yes - drug, supplement, device or procedure involved
◯ No
◯ Not sure

How much did the study demand of you? (Pick the answer that most closely describes your experience)

◯ Simple (for example: a few visits or simple tests or surveys)
◯ Moderate (for example: multiple visits or a short inpatient stay; only a few procedures, not risky or intense)
◯ Intense (for example: long or multiple inpatient stays or many visits; procedure(s) that are intense, risky, or complex)

Before you joined the study, how did the study team discuss the details of the study with you?

◯ Mostly through the email or video or telephone conversations
◯ Mostly while physically in the same place with a member of the study team
◯ A mix of conversations taking place both physically in the same place and over telephone/video/computer
◯ No discussion with the study team before joining the study
◯ I do not remember

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

◯ No
◯ Yes - somewhat
◯ Yes - mostly
◯ Yes - completely

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

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

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

◯ Never
◯ Sometimes
◯ Usually
◯ Always

Did the research staff do everything possible to provide assistance with any language difference you might have?

◯ Never
◯ Sometimes
◯ Usually
◯ Always
◯ No language difference

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

◯ Never
◯ Sometimes
◯ Usually
◯ Always

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

Did you feel you were a valued partner in the research process?

◯ Never
◯ Sometimes
◯ Usually
◯ Always

If you considered leaving the study, did you feel pressure from the Research Team to stay?

◯ Never
◯ Sometimes
◯ Usually
◯ Always
◯ Did not consider leaving the study

Did the research staff respect your cultural background (e.g. language, religion, ethinic group)?

◯ Never
◯ Sometimes
◯ Usually
◯ Always
◯ No cultural issues

Did you have enough physical privacy while you were in the study?

◯ Never
◯ Sometimes
◯ Usually
◯ Always

What is the highest grade or level of school that you have completed?

◯ 8th grade or less
◯ Some high school, did not graduate
◯ High school graduate or GED
◯ Some college or 2-year degree
◯ 4-year college graduate
◯ More than 4-year college degree

What is your age?

◯ 18-34
◯ 35-44
◯ 45-54
◯ 55-64
◯ 65-74
◯ 75 and over

What is your race? (Please choose one or more)

☐ Asian
☐ American Indian or Alaska Native
☐ Black or African American
☐ Native Hawaiian or other Pacific Islander
☐ White

Are you of Spanish or Hispanic or Latino/a/x origin or descent?

◯ No - not Spanish/Hispanic/Latino/a/x
◯ Yes - Puerto Rican
◯ Yes - Mexican, Mexican American, Chicano
◯ Yes - Cuban
◯ Yes - other Spanish/Hispanic/Latino/a/x

What is your sex? (Assigned at birth).

◯ Female
◯ Male
◯ Intersex
◯ Prefer not to say

How would you describe your gender identity?

◯ Woman
◯ Man
◯ Non-binary
◯ None of these terms describe me
◯ Prefer not to say

Is there anything else you would like to share about your experience in the study you most recently joined?

Which of the following things would be important for you in a future study? Please check all that apply.

☐ Access to computer, internet, and television
☐ Access to comfortable bed
☐ Payment/More Payment
☐ Support groups
☐ Volunteer appreciation
☐ Flexible Schedule
☐ Accessible parking and study location
☐ Planned discharge and proper goodbye to research team
☐ Summary of overall research results shared with me
☐ Results of personal lab tests shared with me or my doctor
☐ Other (please specify)

Please specify other important things:

_____

Thank you for completing the survey. Your responses will help us to improve the research experience for participants. Empowering the Participant Voice is supported in part by a grant from the National Center for Accelerating Translational Science U01TR003026 to The Rockefeller University, and Clinical Translational Science Awards UL1TR002553 (Duke University), UL1TR003098 (Johns Hopkins University), UL1TR002001 (University of Rochester), UL1TR001866 (Rockefeller University), UL1TR002243 (Vanderbilt), and UL1TR001420 (Wake Forest University Health Sciences).

Time spent on survey (minutes)

_____

Supplemental Appendix C – Statistical Considerations

Supplemental Appendix C - Statistical Considerations comparing RPPS scores

The Dashboard displays the Top-Box score, that is, the percentage of respondents that selected the optimal answer (e.g., “always”). Formal statistical analyses of local dashboard data are left to individual sites, programs, and investigators to implement by downloading de-identified data from the REDCap database and using third-party software (e.g., SAS, STATA, R) to conduct analyses of interest. However, in the spirit of ease of use, the team presents simple guidelines on how to informally evaluate the data presented in the Dashboard, particularly comparing a filtered column value to the aggregate score.

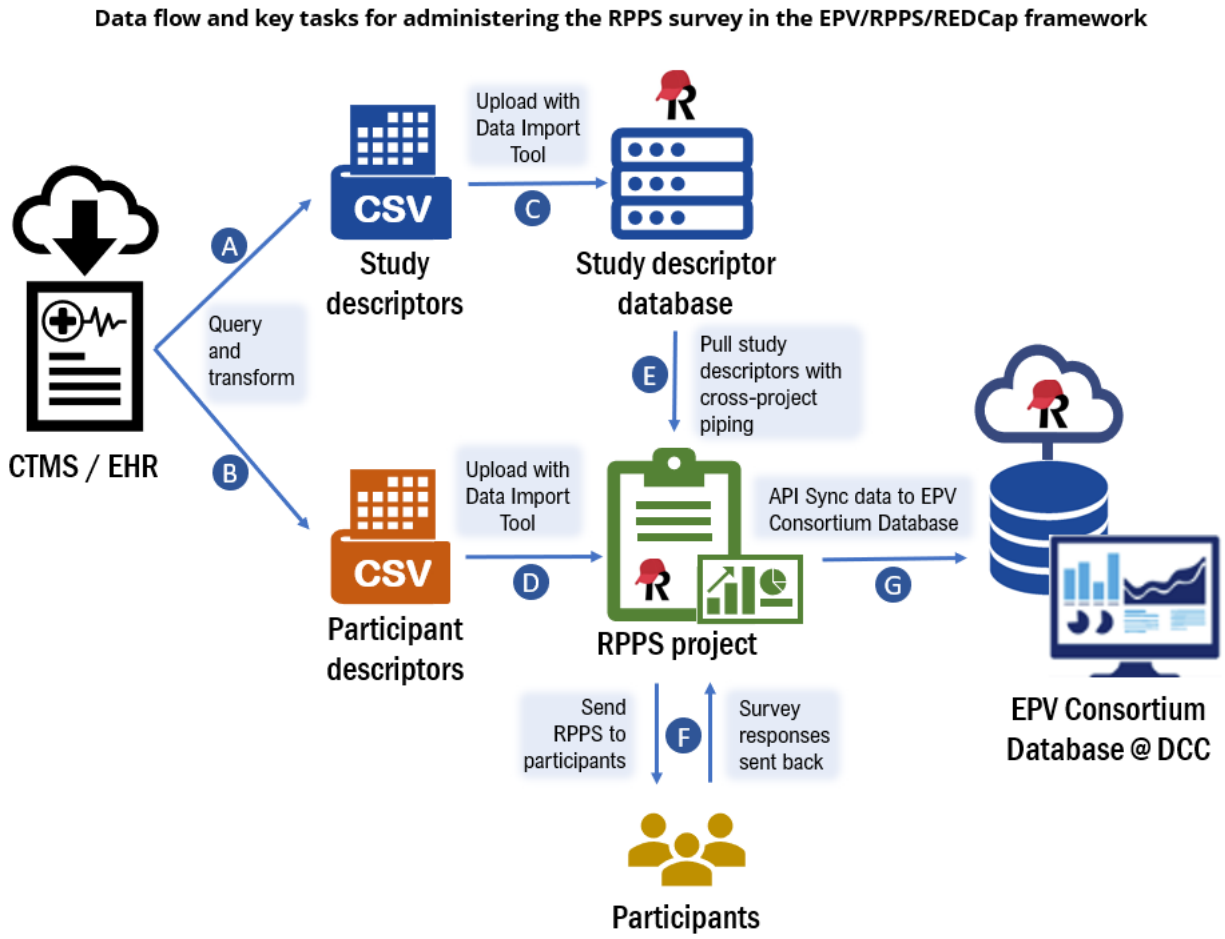
Users often want to know whether value A is “significantly different” from value B. Users should also consider whether the value of a “statistically significant” finding versus an observed difference would help investigators drive policy, take remedial action, or declare success. Relying simply on “statistical significance” to determine importance or trigger action is not the best use of information, as the ability to declare “statistical significance” is primarily a function of sample size; large sample sizes result in the ability to declare significant very small (and likely unimportant) differences, while small sample sizes often result in “missing” important differences, limited by the need for very large differences to attain significance. Common sense also dictates that results reflecting a very negative experience by even a small set of participants, while not statistically significant, would be worthy of further investigation. Therefore, in our discussions, we focused on determining the smallest difference that generally would be worthy of attention, concern, or remedial action. Through iterative discussion, and consideration of examples of statistically analyzed results, the team arrived at a value of 10 percentage points as a reasonable informal estimate of a minimum important difference. This difference would also be declared to be statistically significant using a two-sample t-test assuming equal variances, using the recommended cell sample size of 20 (assuming a Type I Error of 5% and 80% power), which is the analytic sweet spot : observing an agreed upon important difference and declaring it statistically significant.

Supplemental Figure S1 - Implementation Schematic

Implementing the Research Participant Perception Survey

1. Engage stakeholders and plan project
2. Implement technical infrastructure
3. Identify participants/ Extract descriptors
4. Import study/site data to project
5. Send RPPS surveys & receive responses
6. Share local data to Consortium database
7. Analyze data/Identify actionable findings with stakeholders
8. Design/Implement performance improvement
9. Re-survey to evaluate impact
10. Disseminate to stakeholders, consortium, and community

Supplemental Figure S2 -
Data Flow for collecting research participant experience data using the using developed infrastructure



Supplemental Figure S2. Data Flow for collecting and aggregating participant feedback in the Empowering the Participant Voice, Research Participant Perception Survey project;(EPV/RPPS). Extract study descriptors (A) and participant descriptors (B) from institutional data sources, e.g. clinical trial management system (CTSM) or electronic health record (EHR). Using the REDCap Data Import Tool, upload study descriptor data to the Study descriptor database (C) and pipe to the Research Perception Survey (RPPS) Project in REDCap (E). Import participant descriptors to RPPS project (D). Send personalized RPPS survey links to participants and receive survey responses data to the RPPS project database (F). Sync local project data to the Empowering the Participant Voice (EPV)Consortium Database at the data coordinating center (DCC) using an application programming interface (API).

Supplemental Table S1 -
Characteristics of All Participants Sent a Research Participant Perception Survey Including Non-Resonders

Supplemental Table S1. Characteristics of Research Participants who were sent the Research Participant Perception Survey (RPPS) including non-responders. Total and Range Across Sites, February 2022 – May 2023

	Total, % N = 13850	**Site Ranges N=904-6614**
Age		
18 - 34	13	3 – 33
35 - 44	12	2 – 14
45 - 54	16	9 – 25
55 - 64	22	15 – 35
65 - 74	24	6 – 30
>75	14	6 – 16
Sex		
Female	63	46 – 94
Male	37	6 – 48
Intersex	0.0	0
Prefer not to Say	0.0	0
Gender		
Woman	40	20 – 60
Man	25	10 – 40
Non - binary	0.0	0 – .1
Prefer not to say	35	0 – 53
Race		
Asian	2	1 – 10
American Indian/Alaska Native	0.3	0 – 1
Black/AA	18	9 – 28
Native Hawaiian/Other Pacific Islander	0.1	0 –.1
White	74.1	49 – 85
More than one race	2.3	0 – 5
Decline to answer/unknown	3.5	0.4 – 13
Ethnicity		
Hispanic/Latina/o/x	4.5	2 – 17

*Data regarding Gender for some or all participants who were sent a survey was incomplete or missing for three of five sites.