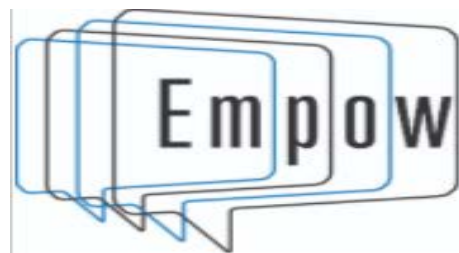


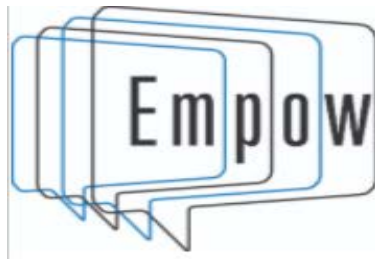


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Empowering the Participant Voice



Empowering the Participant Voice



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Motivation for Research Participant Surveys



The current lack of direct valid participant experience data to support evaluation of research practices and innovations, and guide their improvement, is a critical translational gap



The conduct of high-quality research is dependent on the ability to recruit and retain participants who are invested in, understand, and have confidence in the clinical research process.



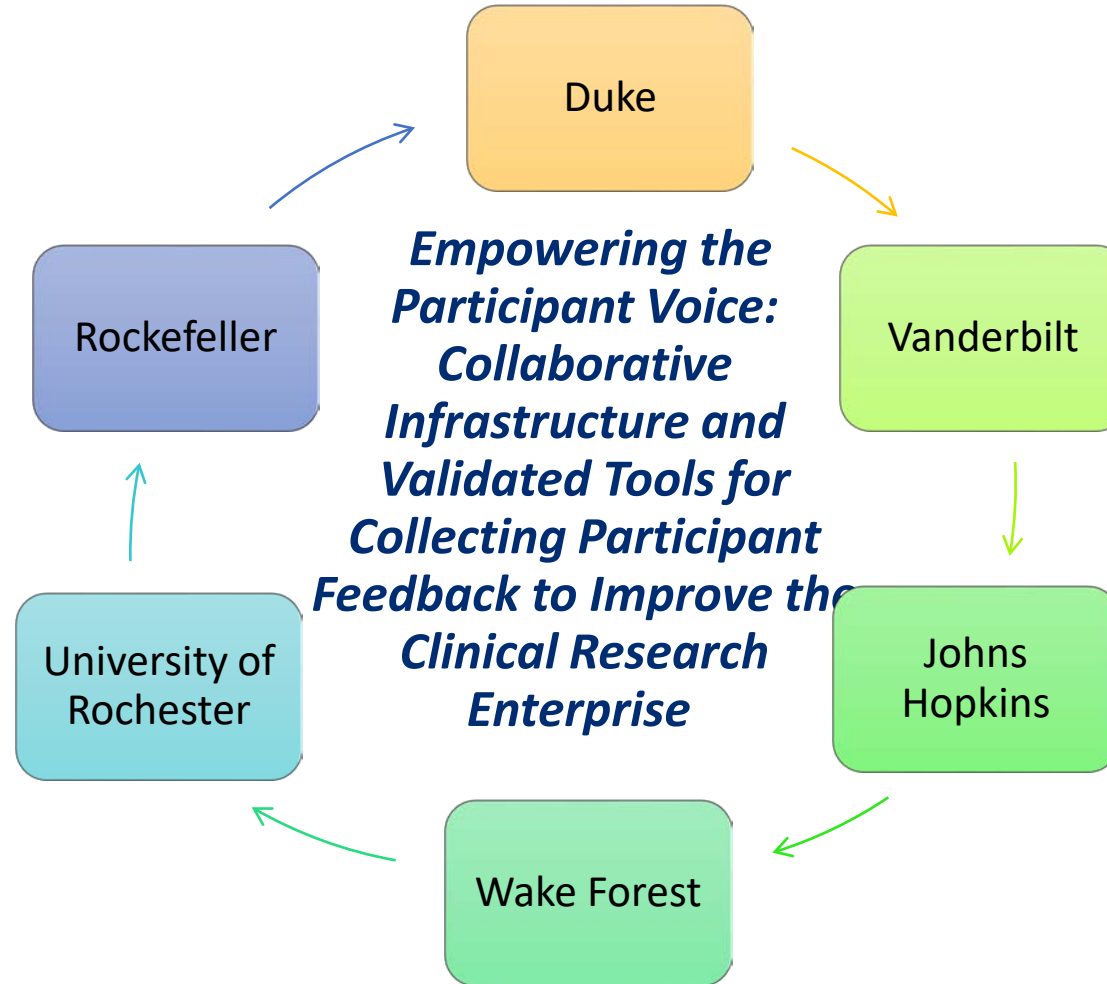
Understanding participants' experiences as research volunteers is critical to the continued improvement of the processes of clinical research and subsequently, to enhancing the participant's experience.

Empowering the Participant Voice

Project Goals

- **DEVELOP** a novel Research Participant Perception Survey/REDCap (RPPS/REDCap) collaborative infrastructure and standard implementation models to enable widespread streamlined distribution of validated surveys for timely collection of participant feedback
- **DEMONSTRATE** that the collaborative RPPS/REDCap infrastructure and implementation model is an effective approach to collect institutional benchmarks and actionable data, balancing standardization and site autonomy
- **DISSEMINATE** the infrastructure, catalyze research-on-research and transform evaluation by empowering the participant voice to improve clinical research. Sites, investigators and other contributors using RPPS/REDCap infrastructure to evaluate research practices will share evaluation metadata to help refine the tools.

Multi-site CTSA Collaboration



***4 year grant
June 2020 to May 2024***

Current mechanisms to assess participant rights and safety

- High quality research relies on enrolling and retaining participants
- Regulations and ethics protect participant rights and safety
- Current mechanisms to assess if researchers achieve this are
 - Appropriate consent processes were documented
 - Informed consent forms signed
 - Regulatory guidelines followed
 - AAHRP requires processes for responding to participants' concerns

Goals of direct assessment of participant perceptions of research

- Provide robust, actionable information about processes
- Improve understanding of participant experience
 - Autonomy
 - Safety
 - Satisfaction
- Can help with
 - Enhancement of human subject protection
 - Recruitment and retention
 - Quality of research processes
 - Increase public trust in research

Validated Participant Survey Features

- 5-10 minutes to complete
- Collects information about
 - Demands of the study
 - Satisfaction with the research experience
 - Informed consent, coercion
 - Ability to reach research team
 - Respect, courtesy, value as a participant
 - General participant demographics
- Requires person to have signed consent and had interactions with the study team

Johns Hopkins Implementation of EPV

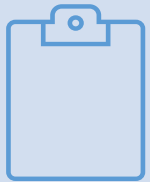
- Sent centrally by the ICTR
- Link to survey emailed to adults enrolled in a clinical trial in CRMS (non observational) and consented in the past 2-6 months
- Reminder email sent 2 weeks after initial email
- Send 500 survey invitations twice per year
- De-identified survey responses shared with Vanderbilt for inclusion in the EPV interactive dashboard

Results of Surveys Administered at Johns Hopkins



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JH has been surveying since 2016!!



Rhonda Kost worked with the Picker Foundation and multiple academic sites including Johns Hopkins to validate the survey (Kost et al Clin Trans Sci 2014 Dec;7(6):430-40.) The goal was to find a set of questions that was relatively brief but covered the important aspects of the research participant experience.



Some questions were modified to answer specific parameters that we wished to assess at Johns Hopkins.

JH has been surveying locally since 2016!

- Invitation letter with survey link is emailed to 500 adults randomly selected from those enrolled in a clinical trial in CRMS (non observational) 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 20%

Research Participant Satisfaction Survey Results

Survey Respondent characteristics 2016-2021

665 survey responses

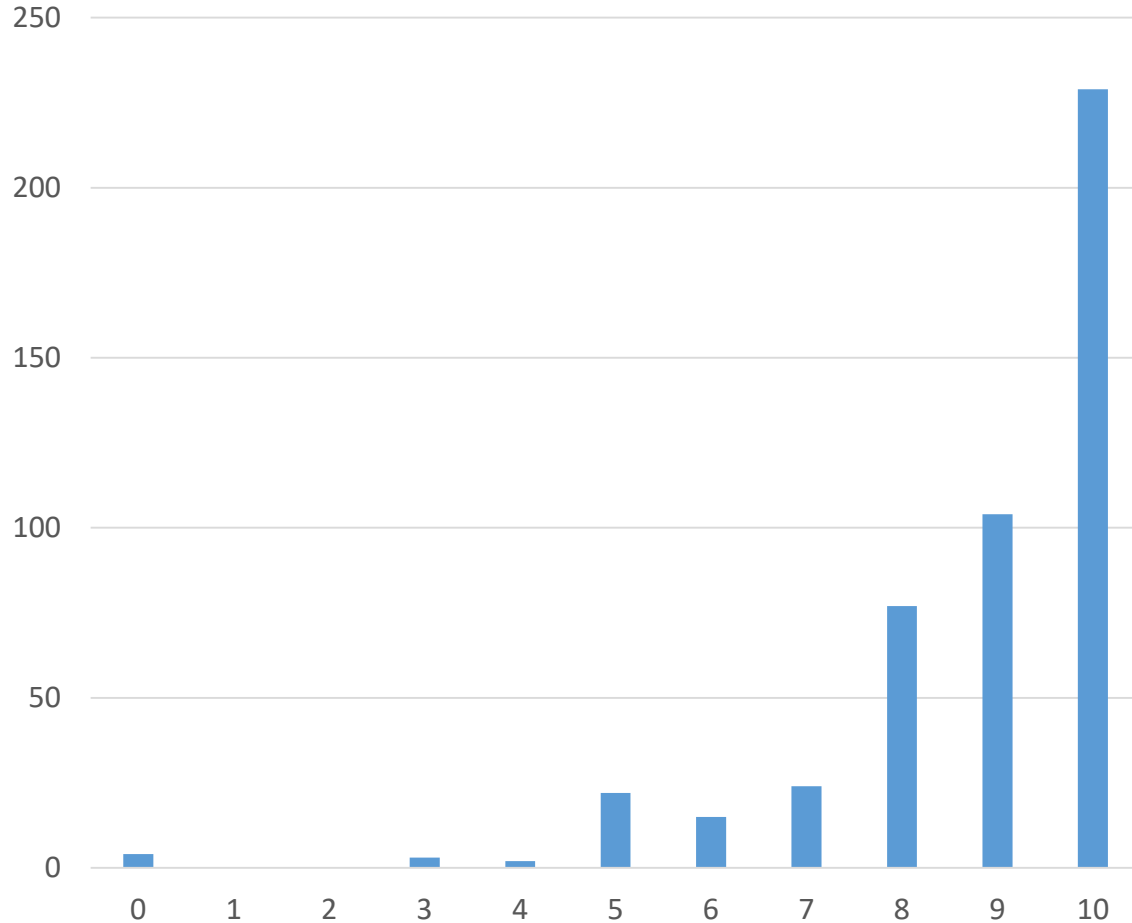
48% Female

80% White

17% Black or African American

47% 65 years of age or older

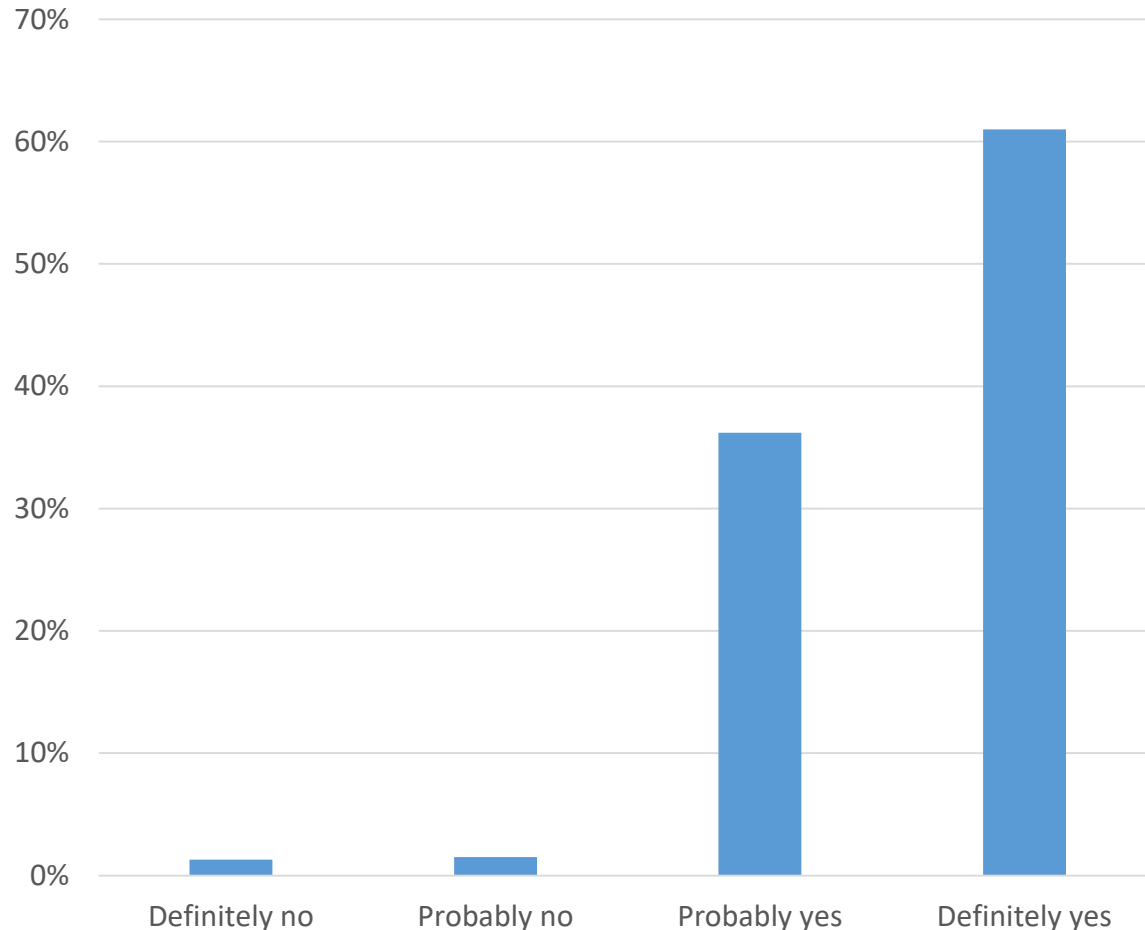
Rate your overall experience in the research study (0 is the worst and 10 is the best)



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”

Reasons majority respondents voted “Very Important” for joining a research study

50% or more of the respondents rated five reasons for joining a research study as “**very important**”

To find out more
about my disease

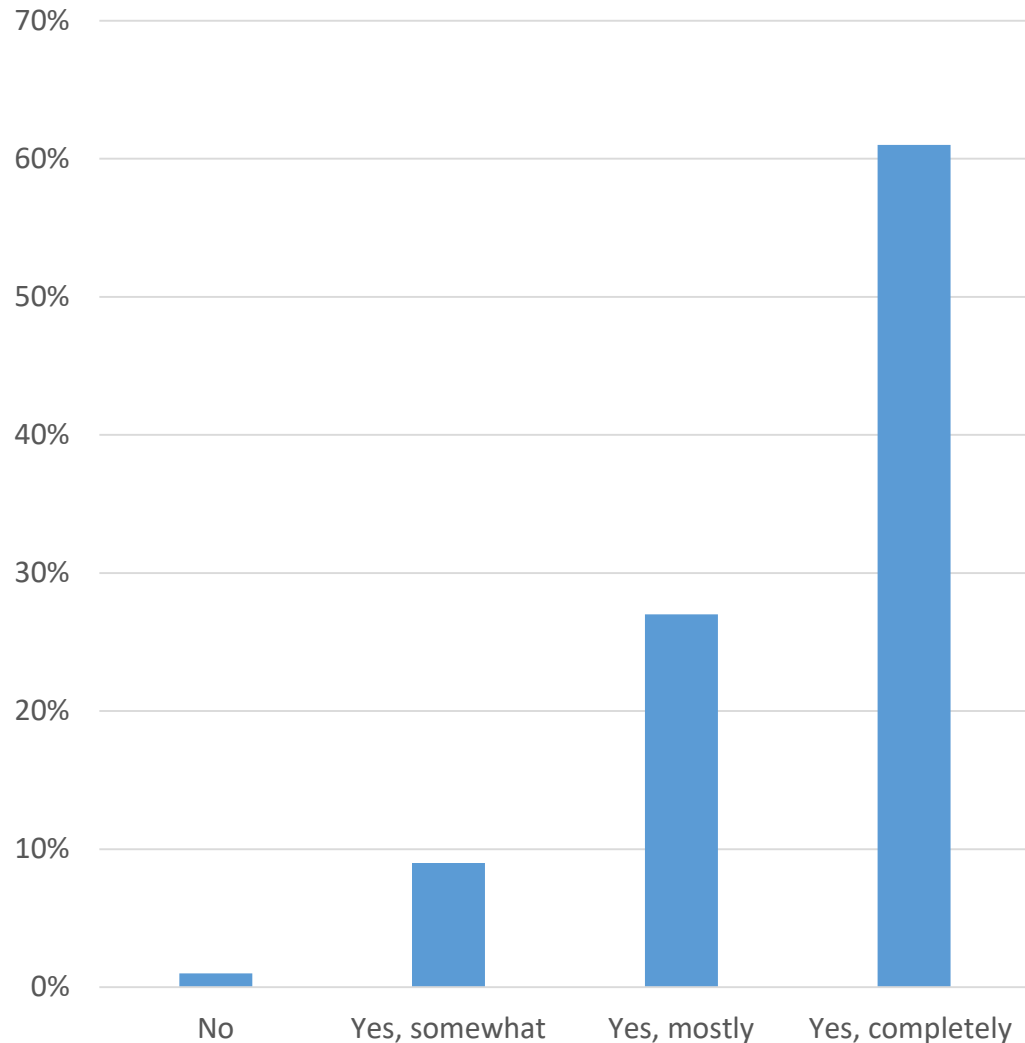
To gain new access
to therapy

To help others

Because of the
Research/Health
Center’s
reputation

Because I am
concerned about
the topic of the
study

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



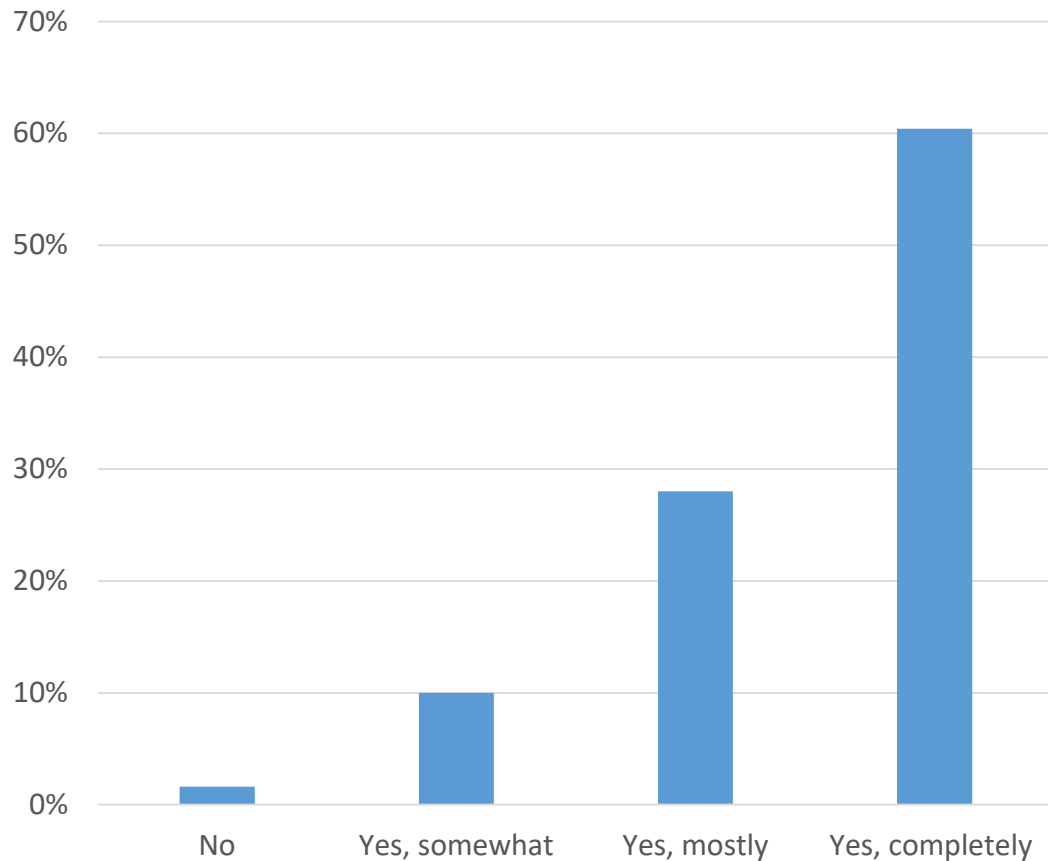
61% of respondents said “Yes, completely”

27% of respondents said “Yes, mostly”

9% of respondents said “Yes, somewhat”

1% said “No”

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



60% of respondents said “Yes, completely”

28% of respondents said “Yes, mostly”

10% of respondents said “Yes, somewhat”

1.6% said “No”

Satisfaction with Research Team Members

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

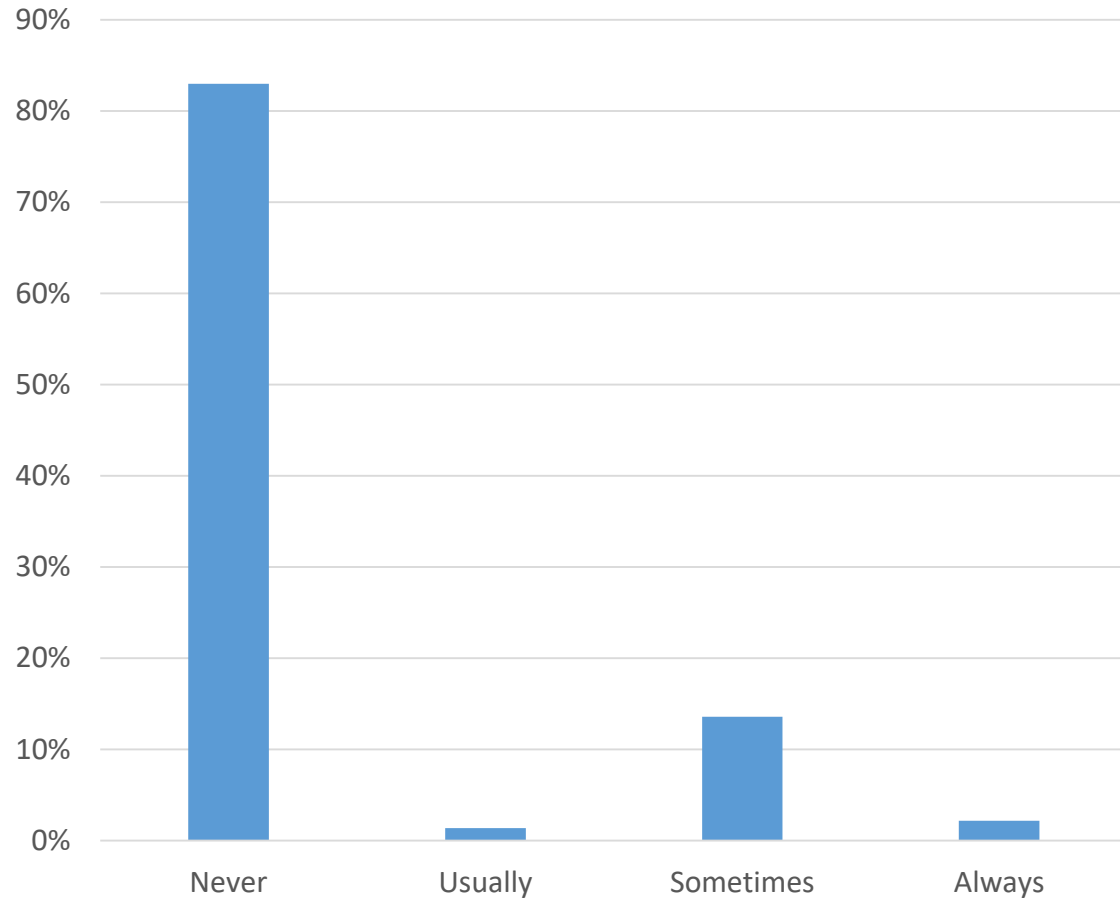
84% reported the research team **always** listened carefully to them

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

Were you ever concerned with your safety and health during the study?



83% of respondents reported “never”

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

Impact and Lessons Learned

- Impact on translational research at Hopkins: Results from the surveys are shared with the local community, the IRBs and the research teams. Findings are discussed in Research Coordinator Training Program and PI ReWards Program. Results are freely available on the ICTR website.
- Lessons Learned: Overall, participant satisfaction was quite favorable. Important areas for improvement of the research experience:
 - participants want research results shared with them (80%)
 - and want their lab tests shared with them or their doctor (60%).

Impact and Lessons Learned

- Interesting finding: overall, about 16% of respondents reported they “have not participated in a research study” in the past 6 months.
 - Concern: consent issue? Patients confusing research with standard care? Incorrect person getting the invite?
- Recurring free text responses: Far more positive comments! Issues with billing/insurance being charged for study procedures and difficulties in receiving payment for participation.

Engaging Institutional, Community and Patient Stakeholders



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Project Stakeholders at Each Site



Stakeholder engagement goals

- Understand and address expectations and concerns
- Refine the value proposition
- Gather input on implementation, and reaching hard-to-reach populations
- Approaches to sharing data, analyzing results, returning results to the community
- Goals of fostering trust and partnership

Forming Stakeholder Committee at Hopkins

We value honest feedback about the project and how we can improve our research participant experience!

We have engaged often with our Community Research Advisory Council (C-RAC) about this project and continue to engage with them.

We have also formed a stakeholder committee that has met about the project and will meet again this spring.



Stakeholder Engagement Feedback Survey

Some of the questions we have asked our stakeholders

- What do they think of the results we have gotten so far?
- How would you use this survey?
- Do you have any concerns about the survey?
- Are there weaknesses in the data?
- Should we sample in a different way?
- How can we assure these results are broadly communicated?
- Who are the target audiences?
- What can we gain by working in the broader consortium?

What can our research teams do?

- We need your help to **INTRODUCE** the survey to your research participants. Let them know they may hear from us!
- We need you to help us **TAKE ACTION** based on findings!
- Help **DIRECT** people considering research to the survey results on the ICTR webpage
- Consider **FUTURE** potential for individual research projects or teams to use the survey for the participants in their studies.



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