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

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

New Multi-institutional Collaborative Grant (NIH/NCATS funded)

4 year grant- June 2020 to May 2024

Rockefeller, Rochester, Vanderbilt, Duke, Wake Forest and Johns Hopkins

Develop a novel RPPS/REDCap collaborative infrastructure (dashboard) and instructions on how to implement the infrastructure

Demonstrate that the collaborative RPPS/REDCap infrastructure and implementation is an effective approach to collect institutional benchmarks and actionable data

Disseminate how to implement REDCap dashboard at other institutions

Survey Features

5-10 minutes

Collects information about

- Demands of the study
- Satisfaction with the research experience
- Informed consent, coercion
- Ability to reach research team
- Respect, courtesy, value
- General subject demographics

Requires person to have signed consent and had interactions with the study team

UR CTSI Implementation

Sent centrally by the CTSI

Given to research subjects enrolled in an interventional study in OnCore, not observational

After consent and at completion of participation

Anonymous, send by email or mail

Subjects can opt out of future emails or mailings

Reminder email sent 1 week after initial email

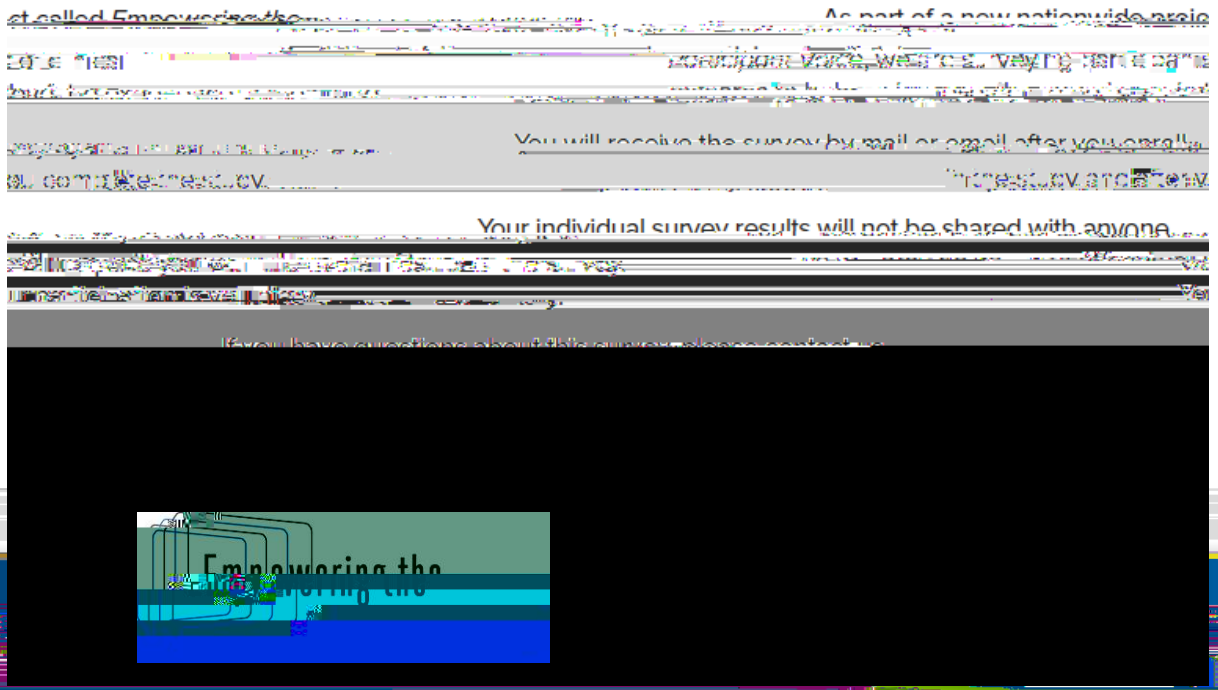
Collect 500 survey responses per year

De-identified data shared with Vanderbilt for inclusion in interactive dashboard

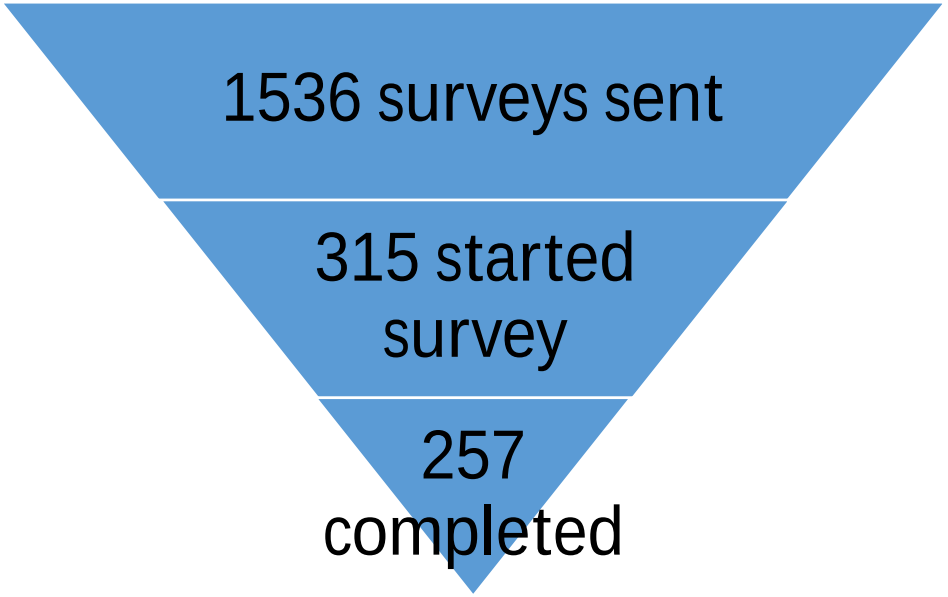
How to help

We will provide a Spanish and English flyer that describes the study.

Study teams should provide flyer to all subjects enrolled in interventional OnCore studies


Empowering the

Status Update



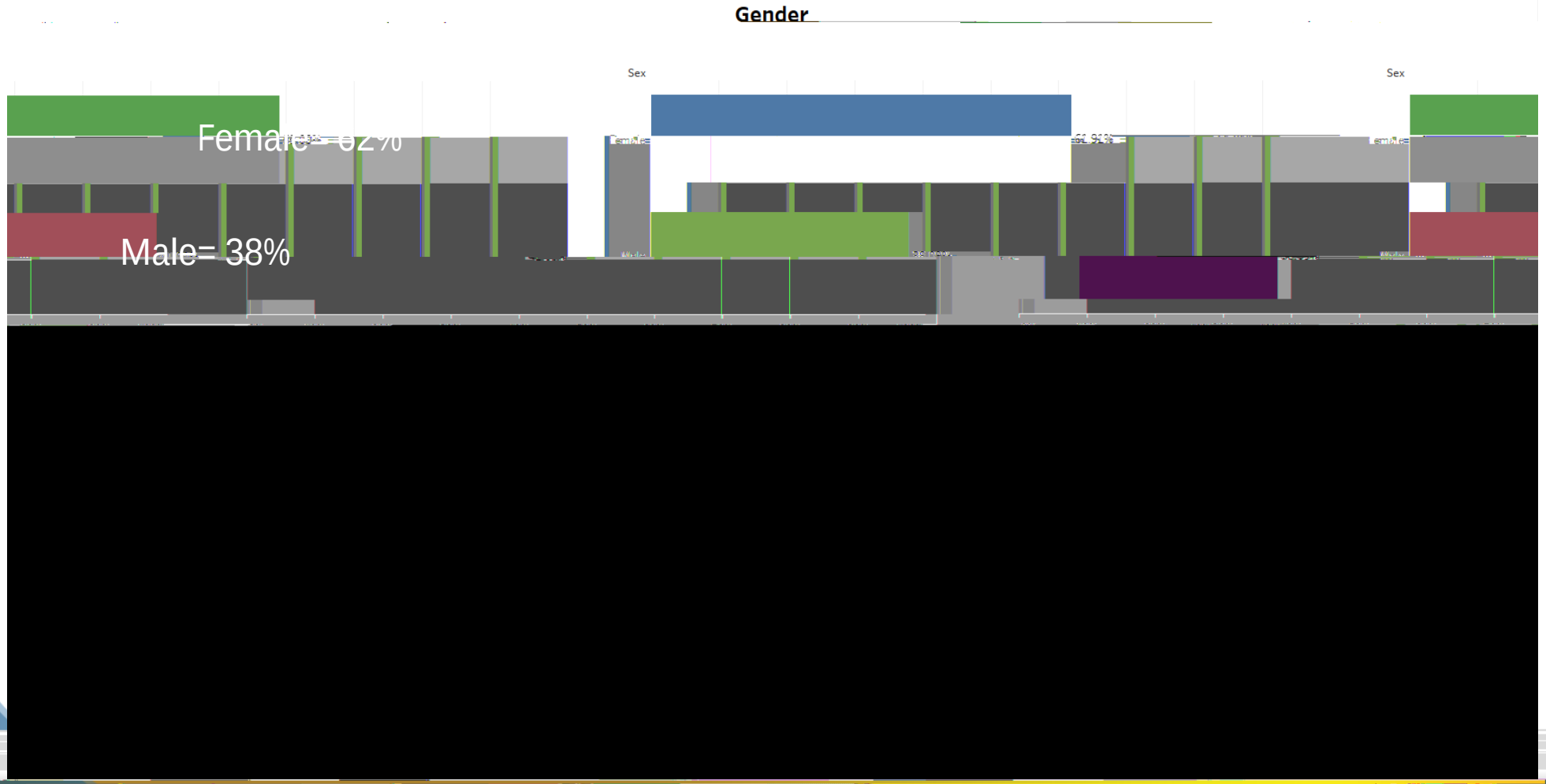
Subjects who enrolled or completed a study Jan-Aug 2021

311 English
4 Spanish

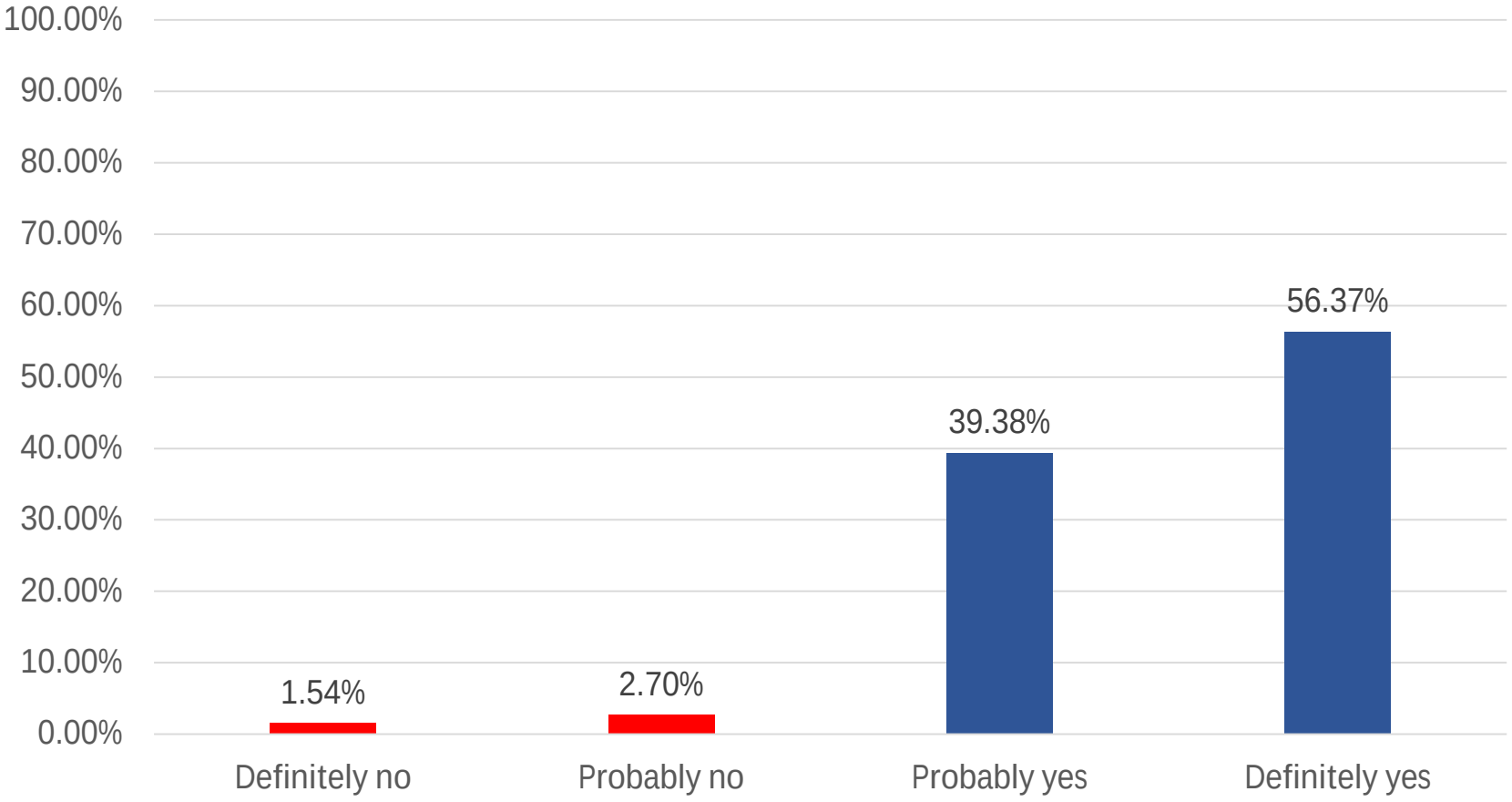
25 partially completed
33 no questions answered

0/1536 opted out of future contact
3/1536 responded to email they were not in a study

Recipients vs Respondents- Sex and Age

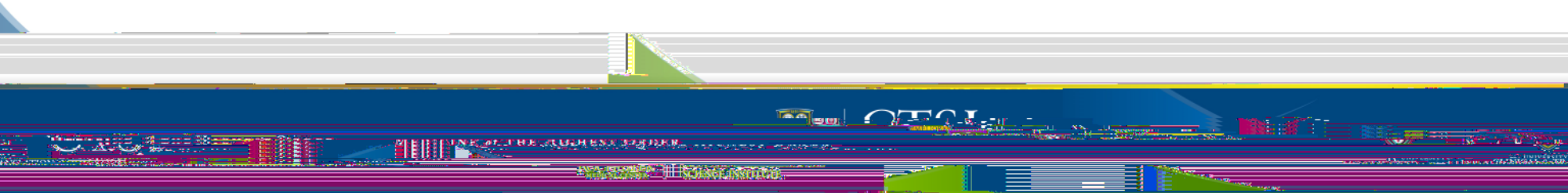


Would you recommend joining a research study to your family and friends?

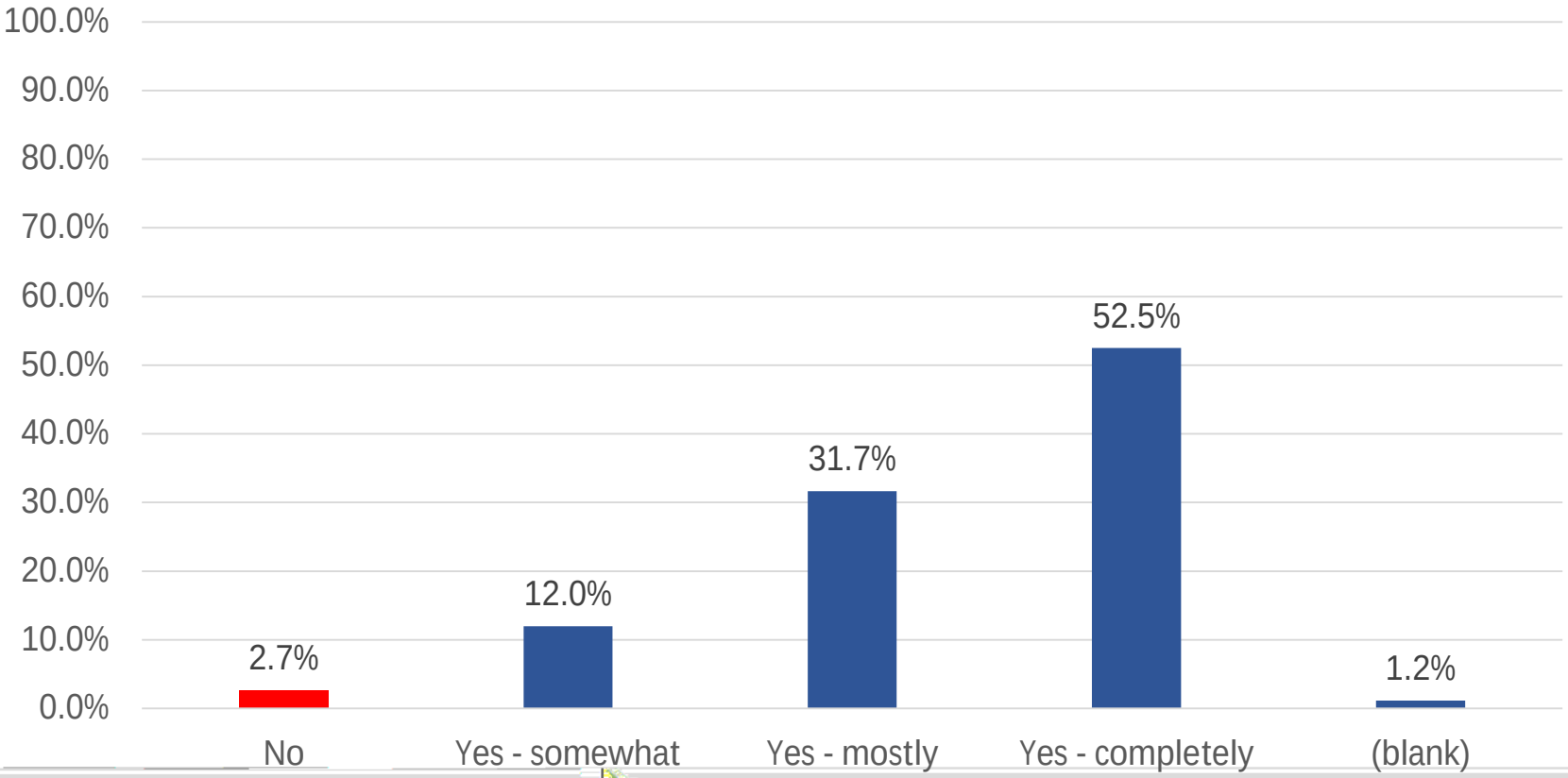


Please use the scale below to rate your overall experience in the research study, where 0 is the worst possible experience, and 10 is the best possible experience.

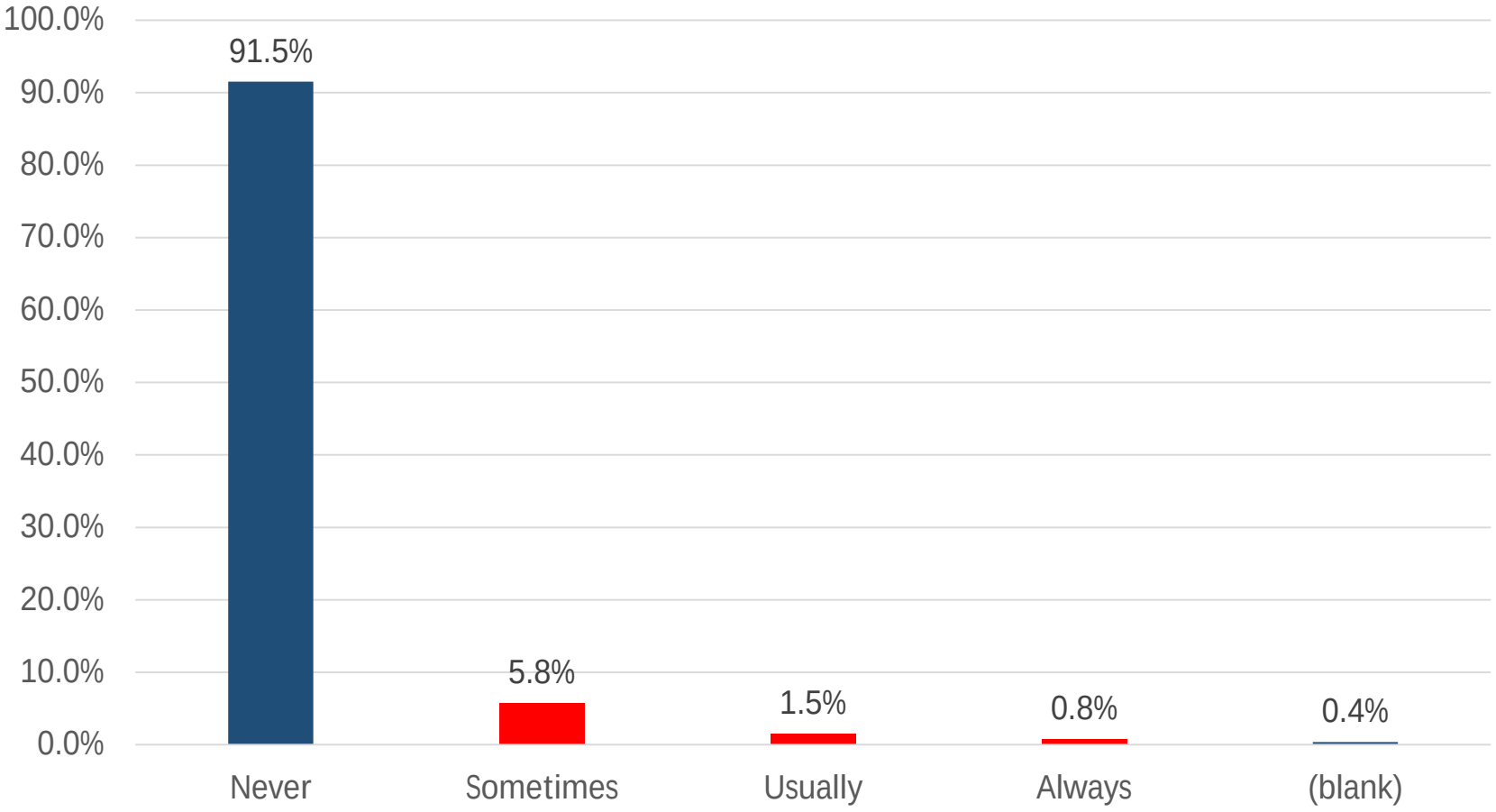
Before you joined the study, how did the study team discuss the details of the study with you?



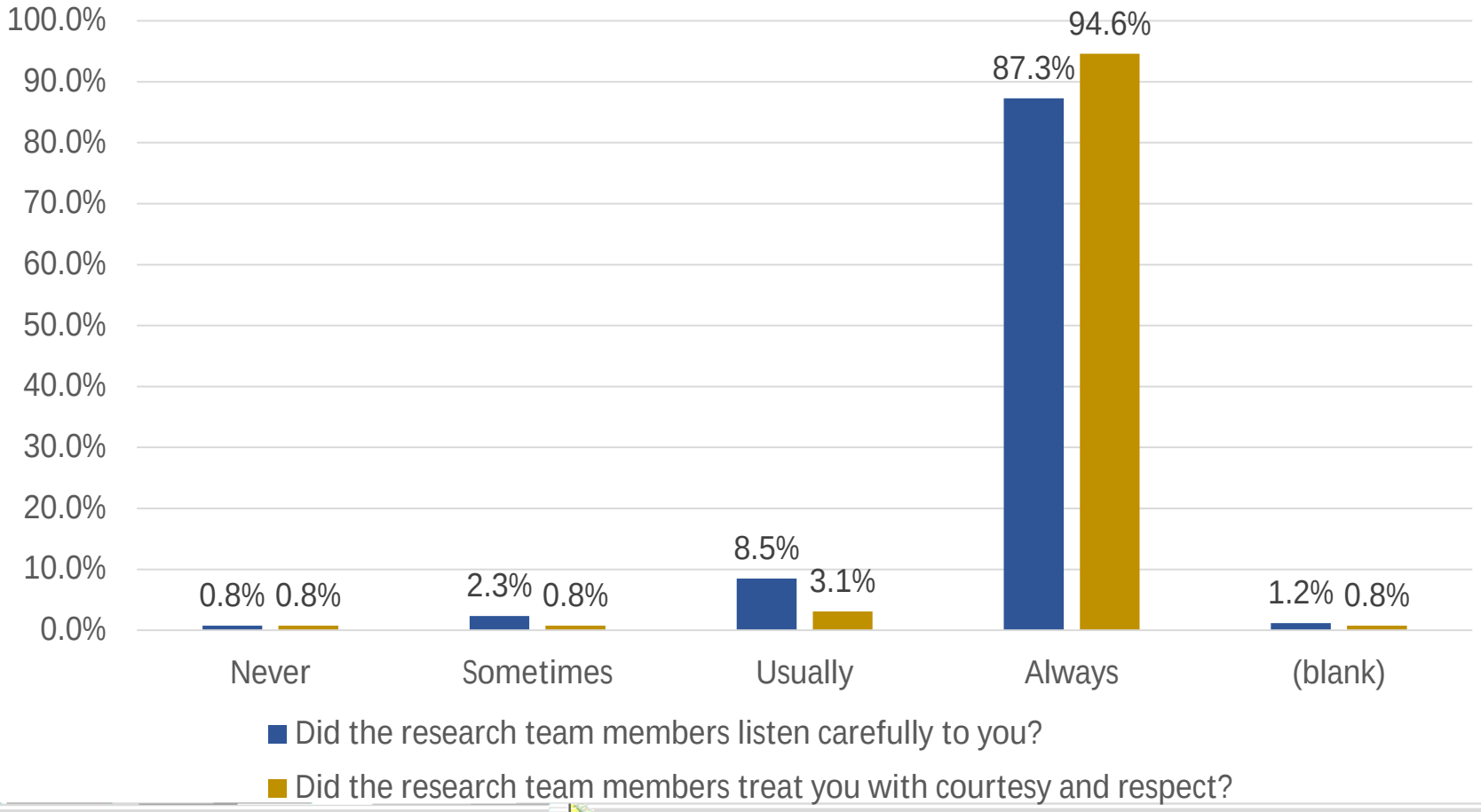
Did the information and discussions you had before participating in the research study prepare you for your experience in the study?



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



Listening/Respect and Courtesy



Question	Percent with perfect score
Did the research staff do everything possible to provide assistance with any language difference you might have?	95
When you were not at the research site did you know how to reach the research team if you had a question?	83
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?	73
Did you feel you were a valued partner in the research process?	74
If you considered	

67 Comments

At all times I felt safe, being treated with respect, and I appreciate being with my group of professionals.

Dr. X made me feel like I was his most important patient. (I know I am not)!

Expectations about activity level / frequency of participation not communicated to me at the start…

Have not received any feed back on how the study effected me

I think the patient should be told how much HIS COST would be up front before he signs up. The cost was astronomical given the insurance I provided.

I believe this study saved my life while not subjecting me to highly toxic levels of medication.

Future Analyses

- Individual study team response?
  - Yes depending on number of responses
- Look at demographics for each question
- Timing of survey
- Response rate by department, disease, type of study

Future Activities

- Share with other stakeholder groups
- Creation of public website with annual posting of results
- Test the impact of incentives
- Use interactive dashboard to compare between CTSA institutions

Collaboration Survey

Purpose: to get feedback about how we are doing with collaborating/communicating you on this project

It will be emailed to all attendees after this meeting