

# Empowering the Participant Voice

## Update

Carrie Dykes, PhD

SCORE

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# 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

# 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



# Let your voice be heard and help us improve clinical research!

As part of a new nationwide project called *Empowering the Participant Voice*, we are surveying participants of clinical research to help us improve the experience in the future.

You will receive the survey by mail or email after you enroll in the study and after you complete the study.

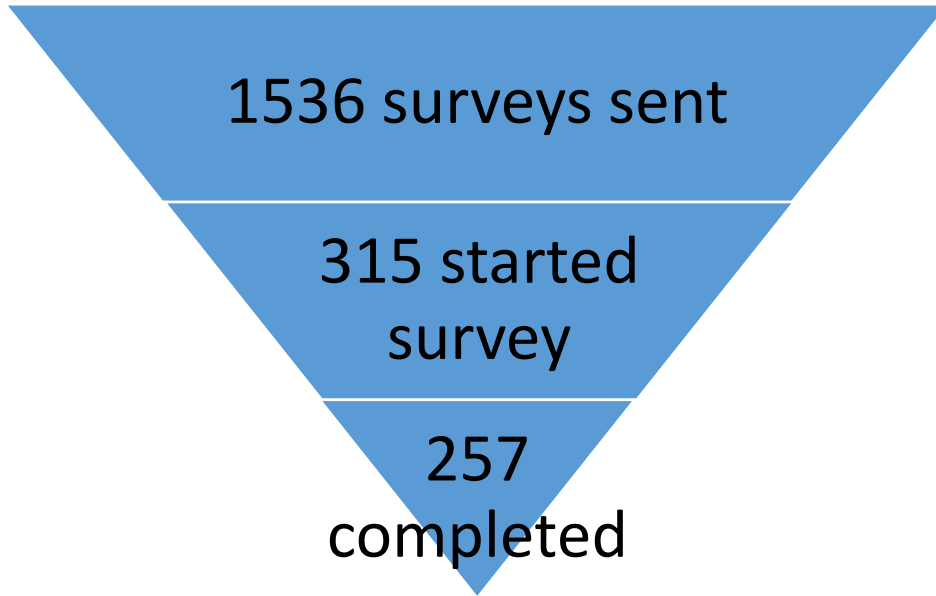
Your individual survey results will not be shared with anyone. We will provide you with the overall results of the survey. Your participation is voluntary.

If you have questions about this survey, please contact us by emailing [health\\_research@urmc.rochester.edu](mailto:health_research@urmc.rochester.edu) or calling 585-275-2107.





# Status Update



Subjects who enrolled or completed a study  
Jan-Aug 2021

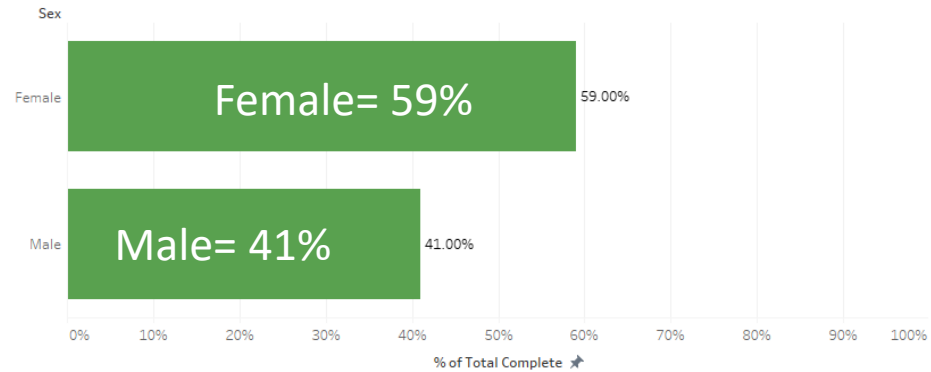
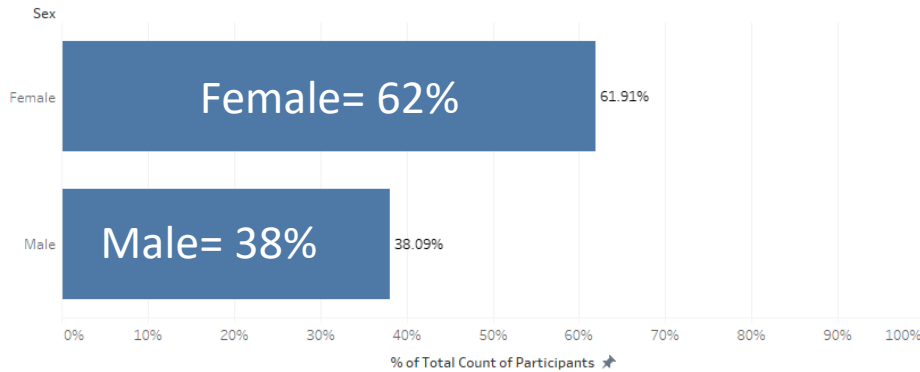
311 English  
4 Spanish

25 partially completed  
33 no questions answered

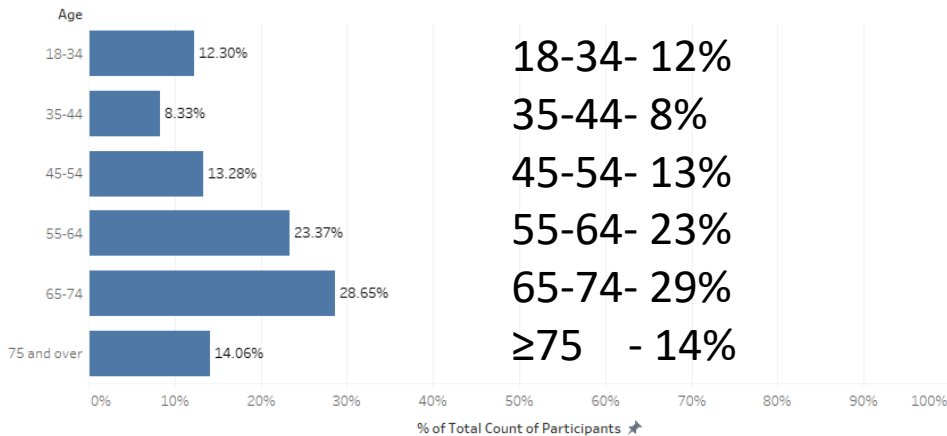
0/1536 opted out of future contact  
3/1536 responded to email they were not in a study

# Recipients vs Respondents- Sex and Age

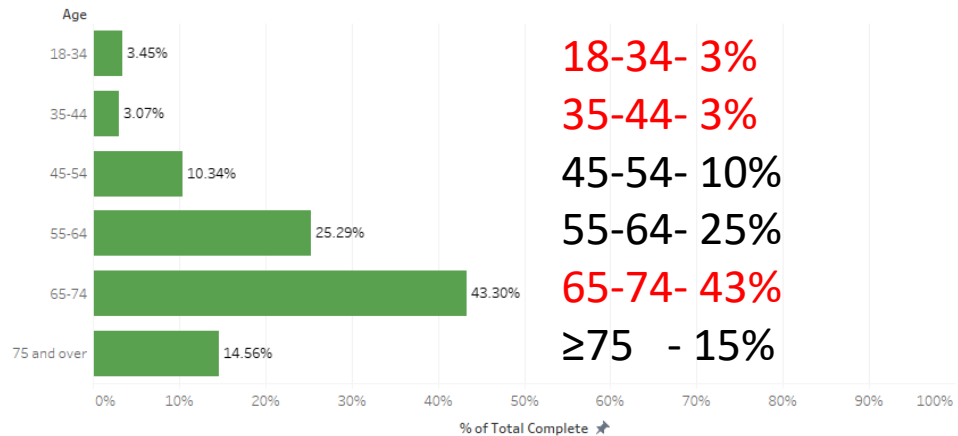
## Gender



## Age



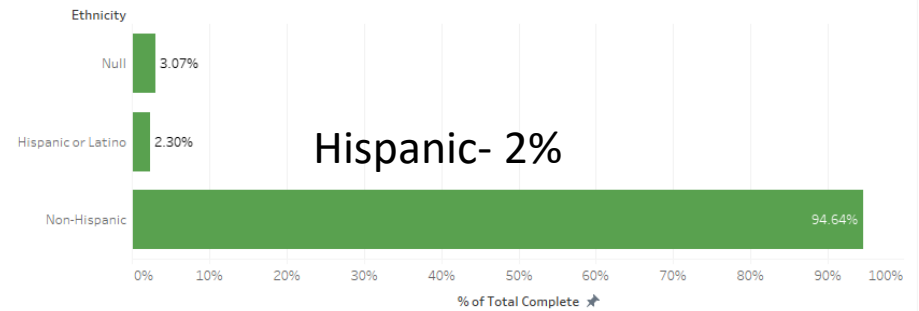
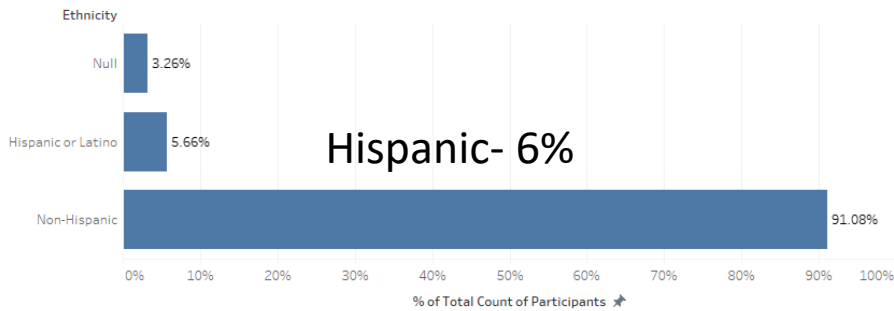
18-34- 12%  
 35-44- 8%  
 45-54- 13%  
 55-64- 23%  
 65-74- 29%  
 ≥75 - 14%



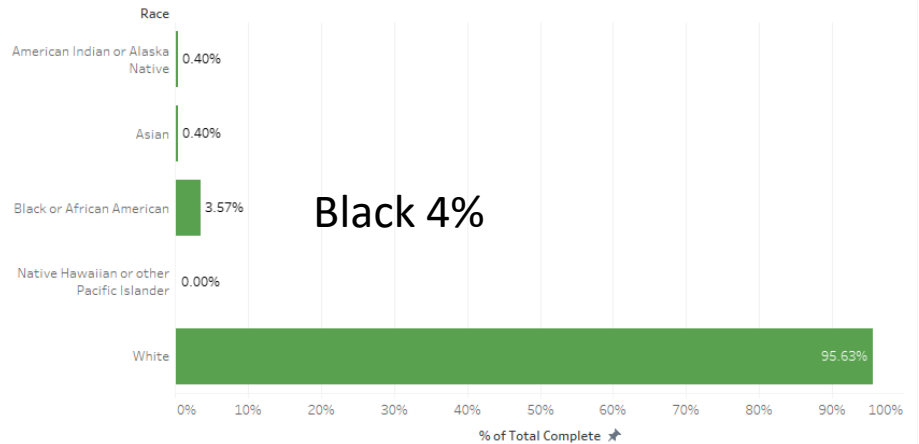
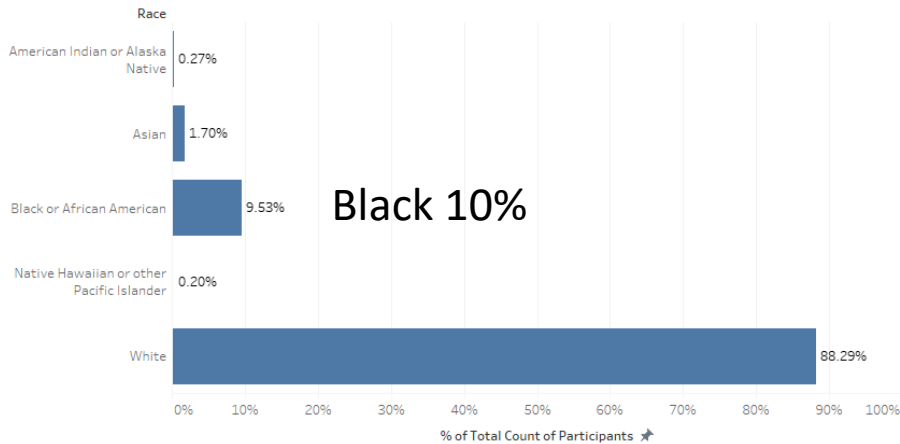
18-34- 3%  
 35-44- 3%  
 45-54- 10%  
 55-64- 25%  
 65-74- 43%  
 ≥75 - 15%

# Recipients vs Respondents- Ethnicity and Race

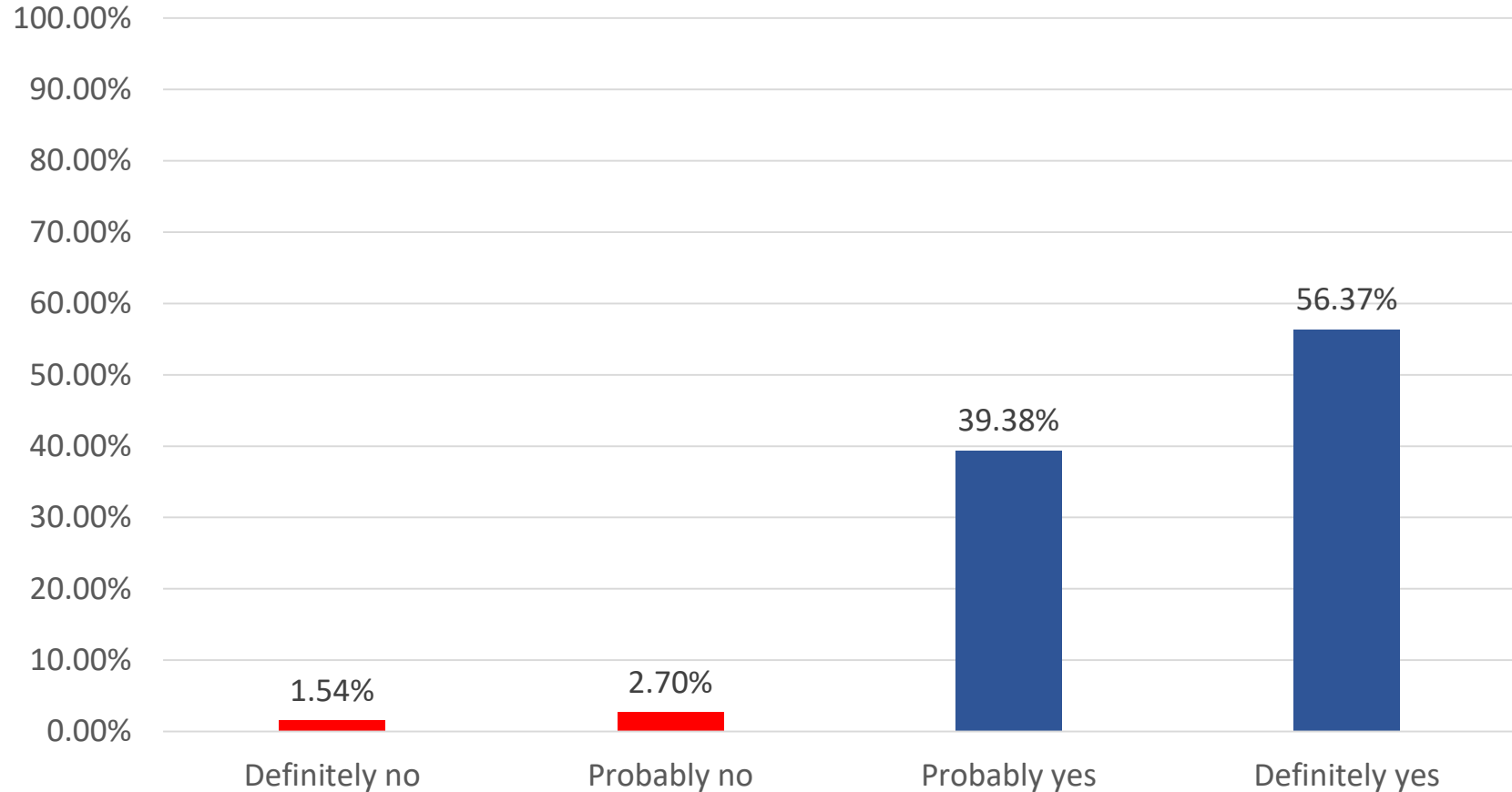
**Ethnicity**



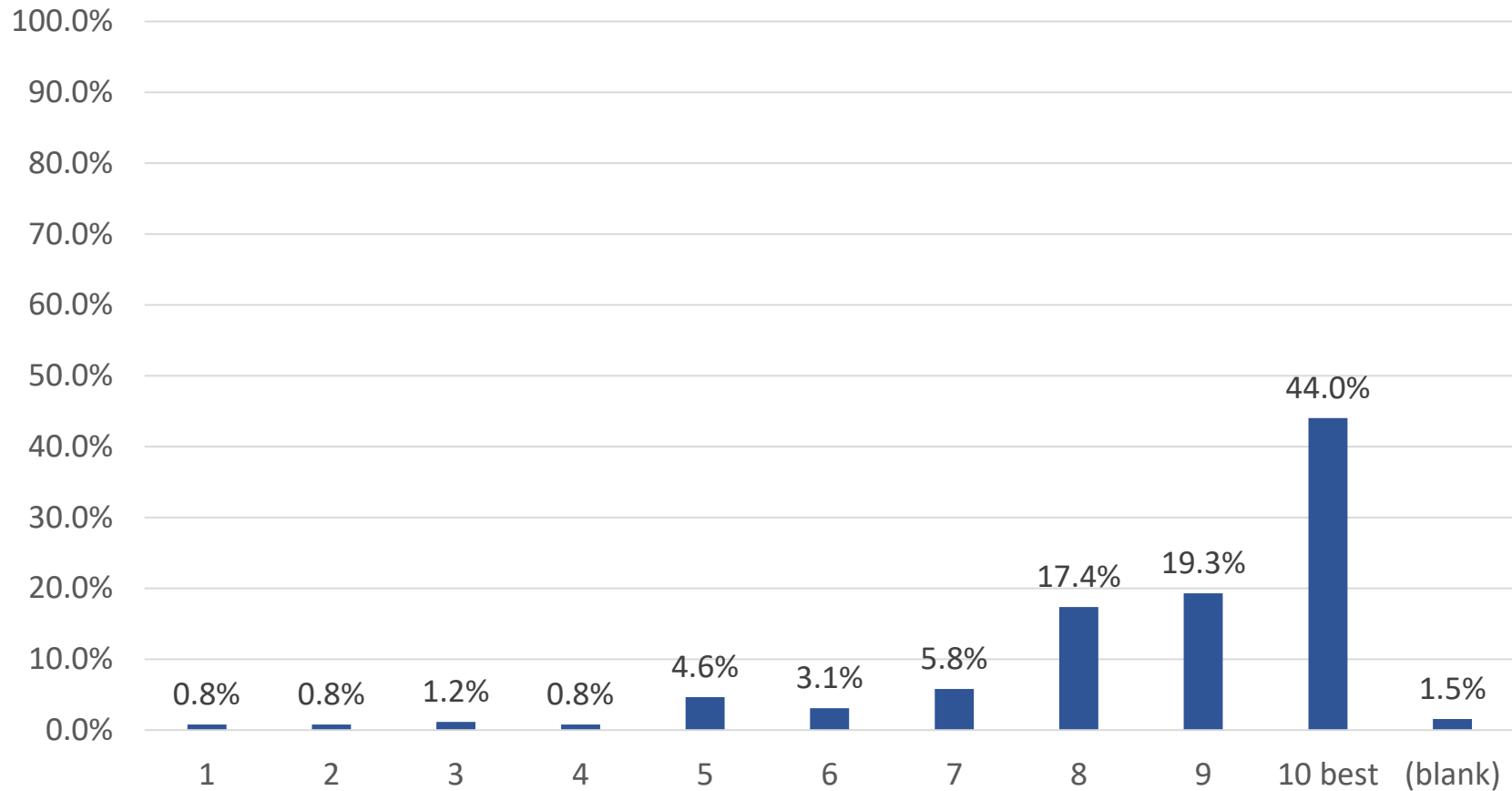
**Race**



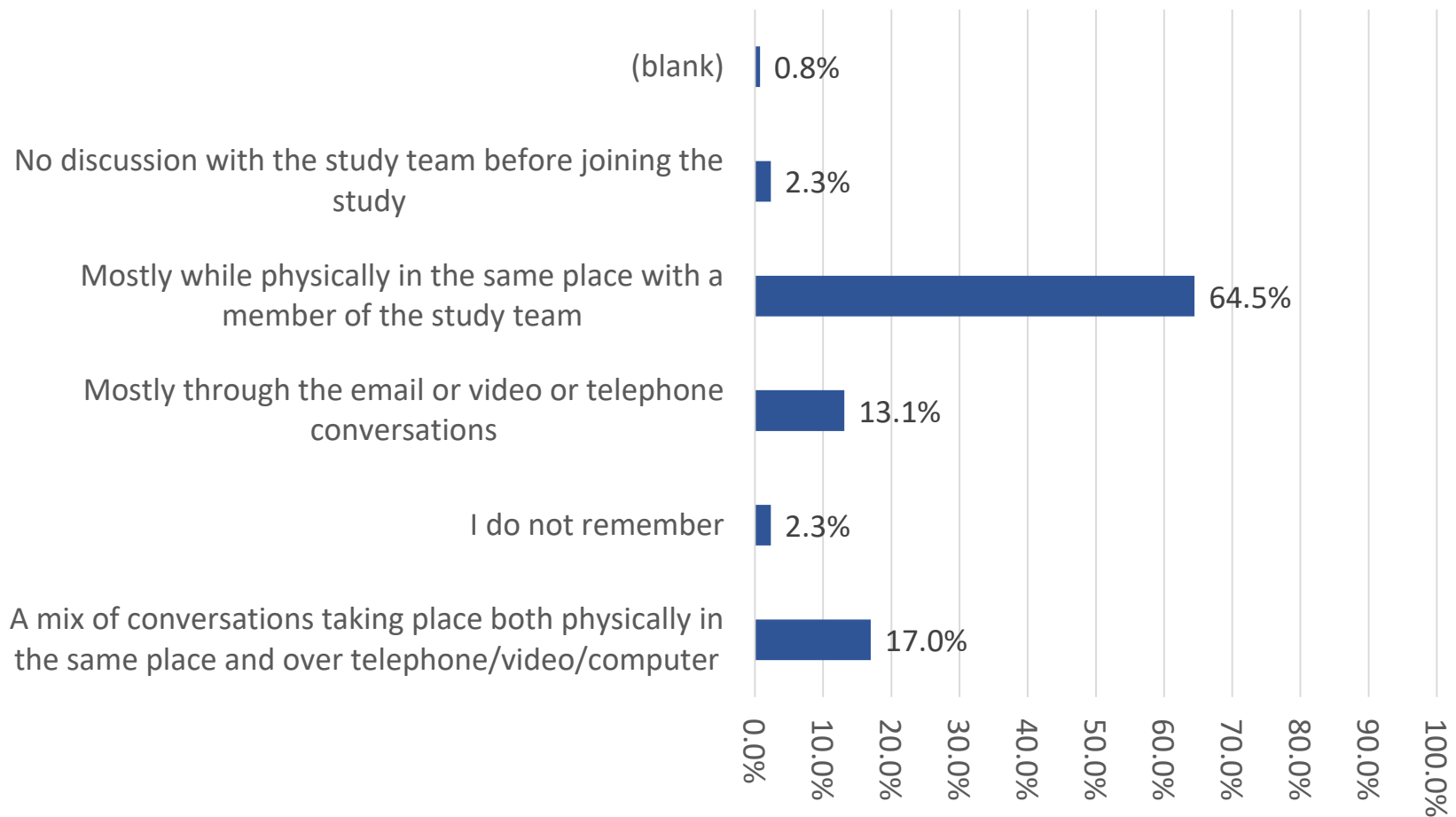
# Would you recommend joining a research study to your family and friends?



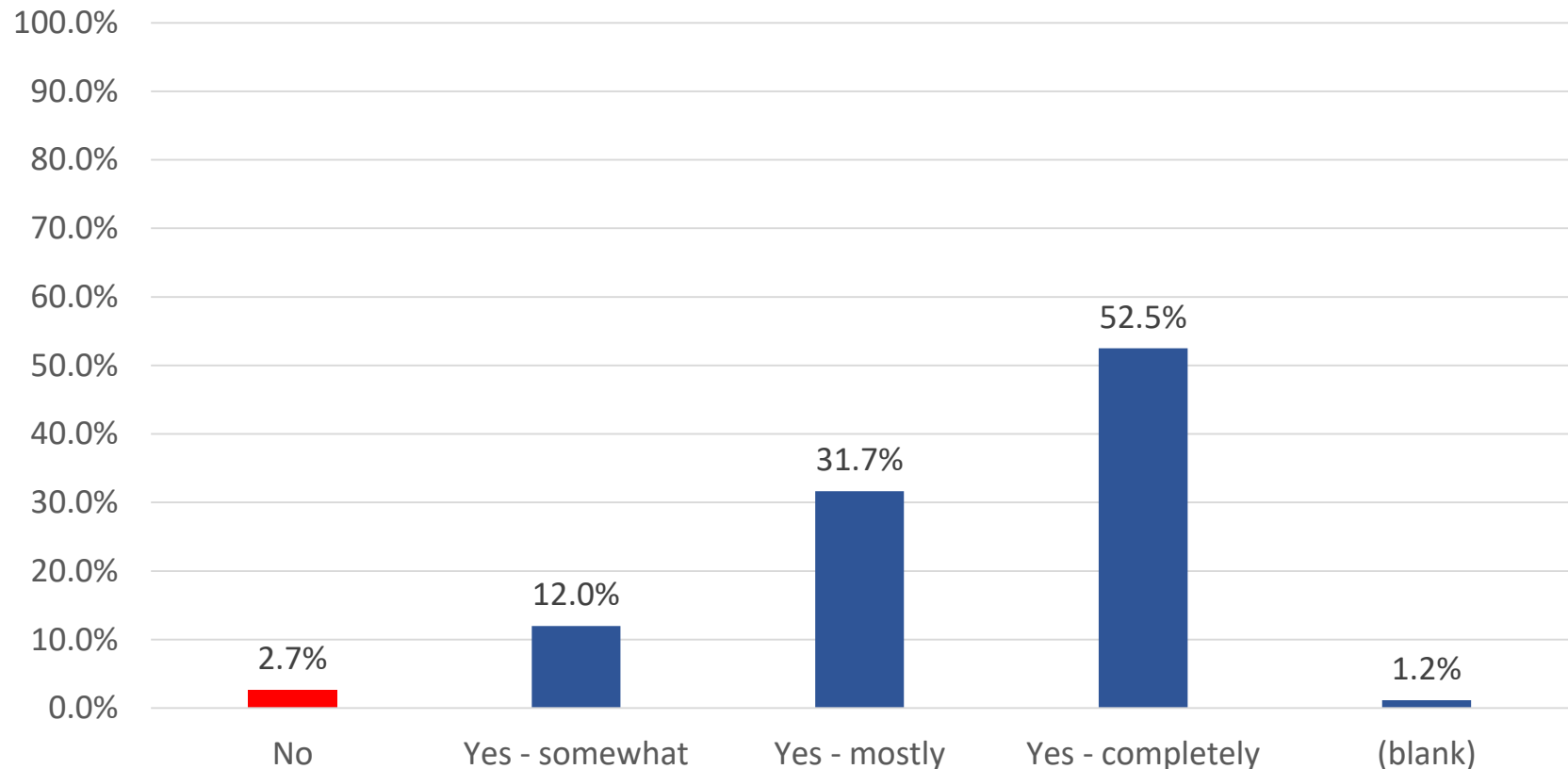
**Please use the scale below to rate your overall experience in the research study, where 0 is the worst possible experience, and 10 is the best possible experience.**



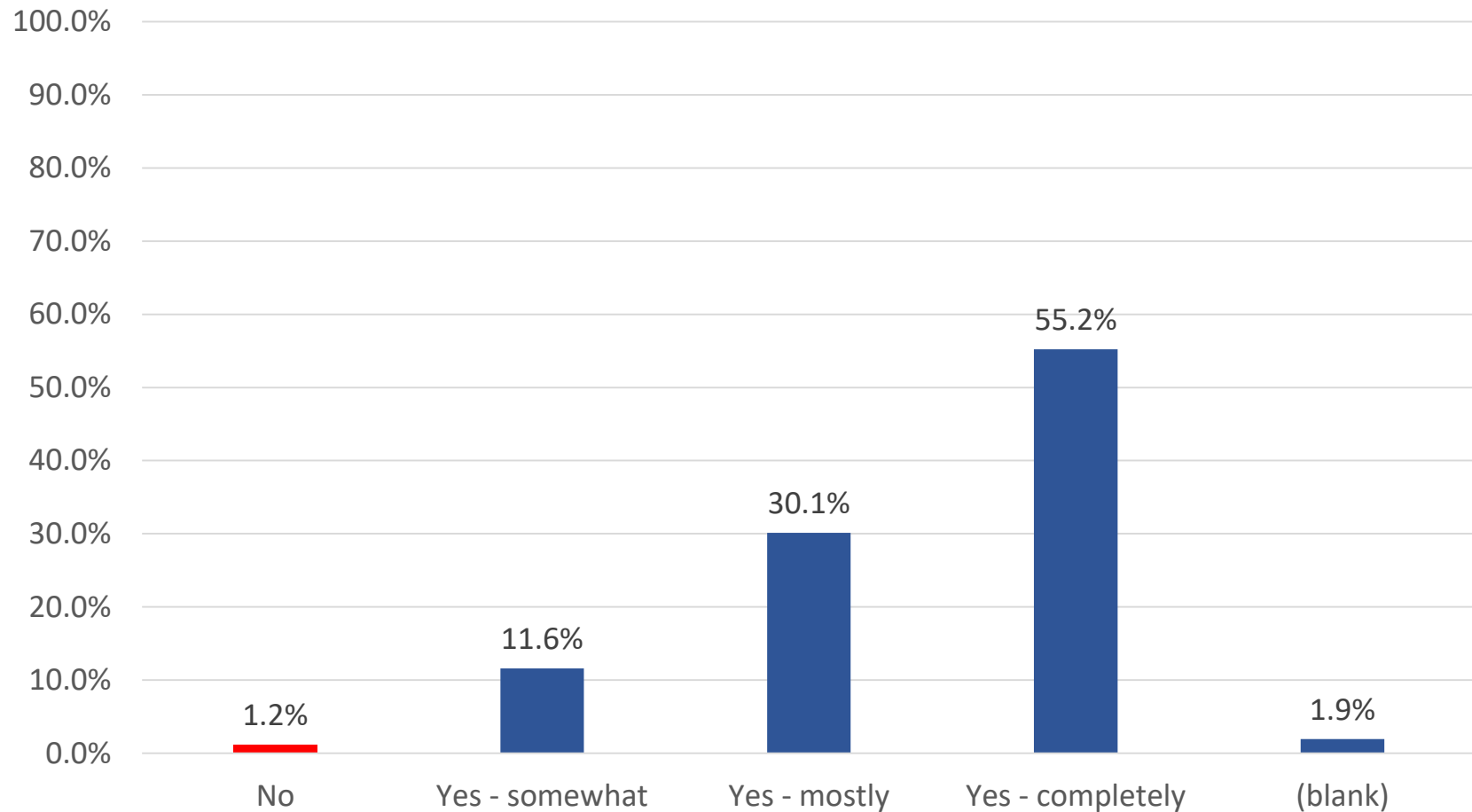
# Before you joined the study, how did the study team discuss the details of the study with you?



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

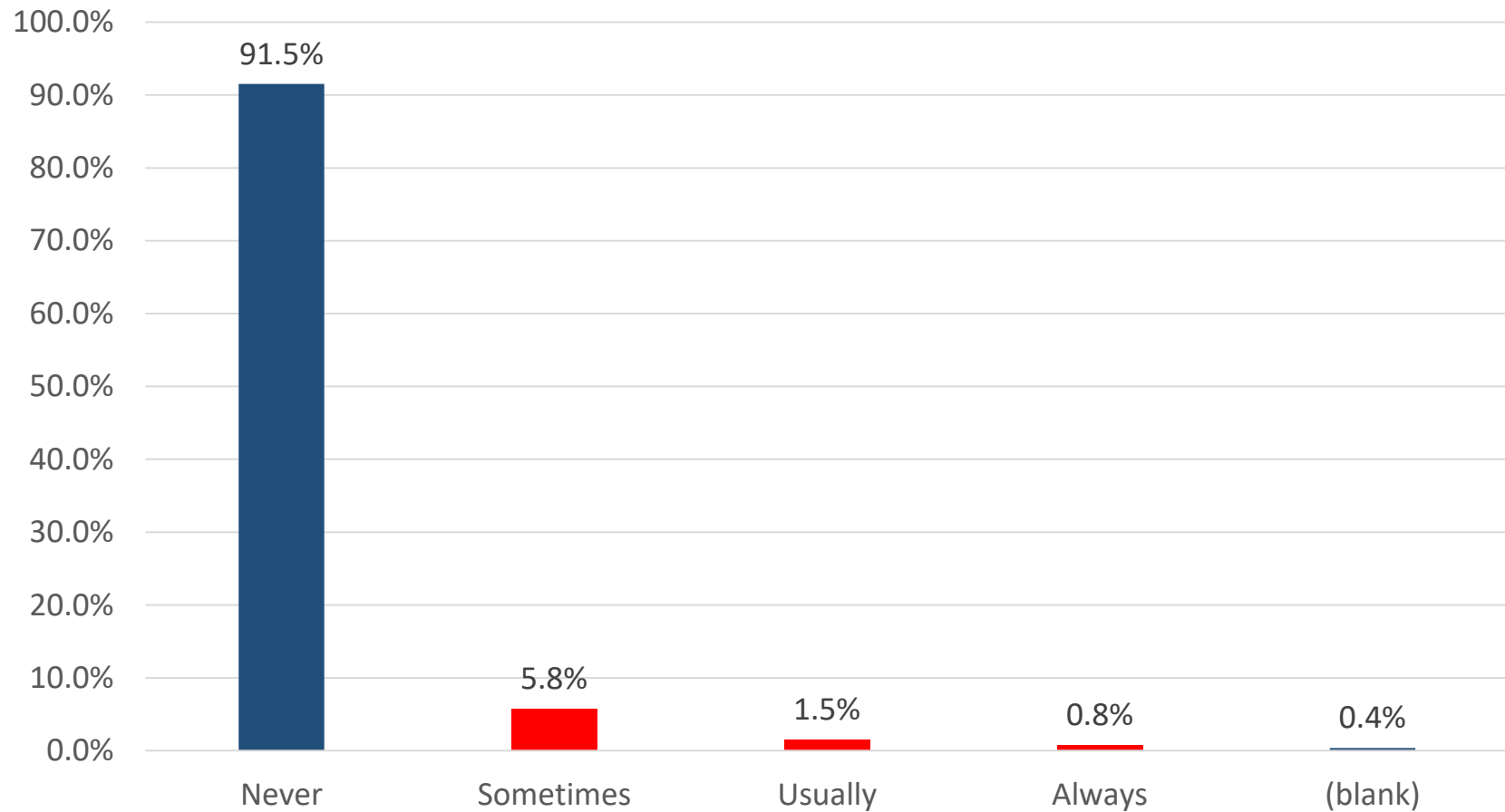


# Did the Informed consent form prepare you for what to expect during the study?

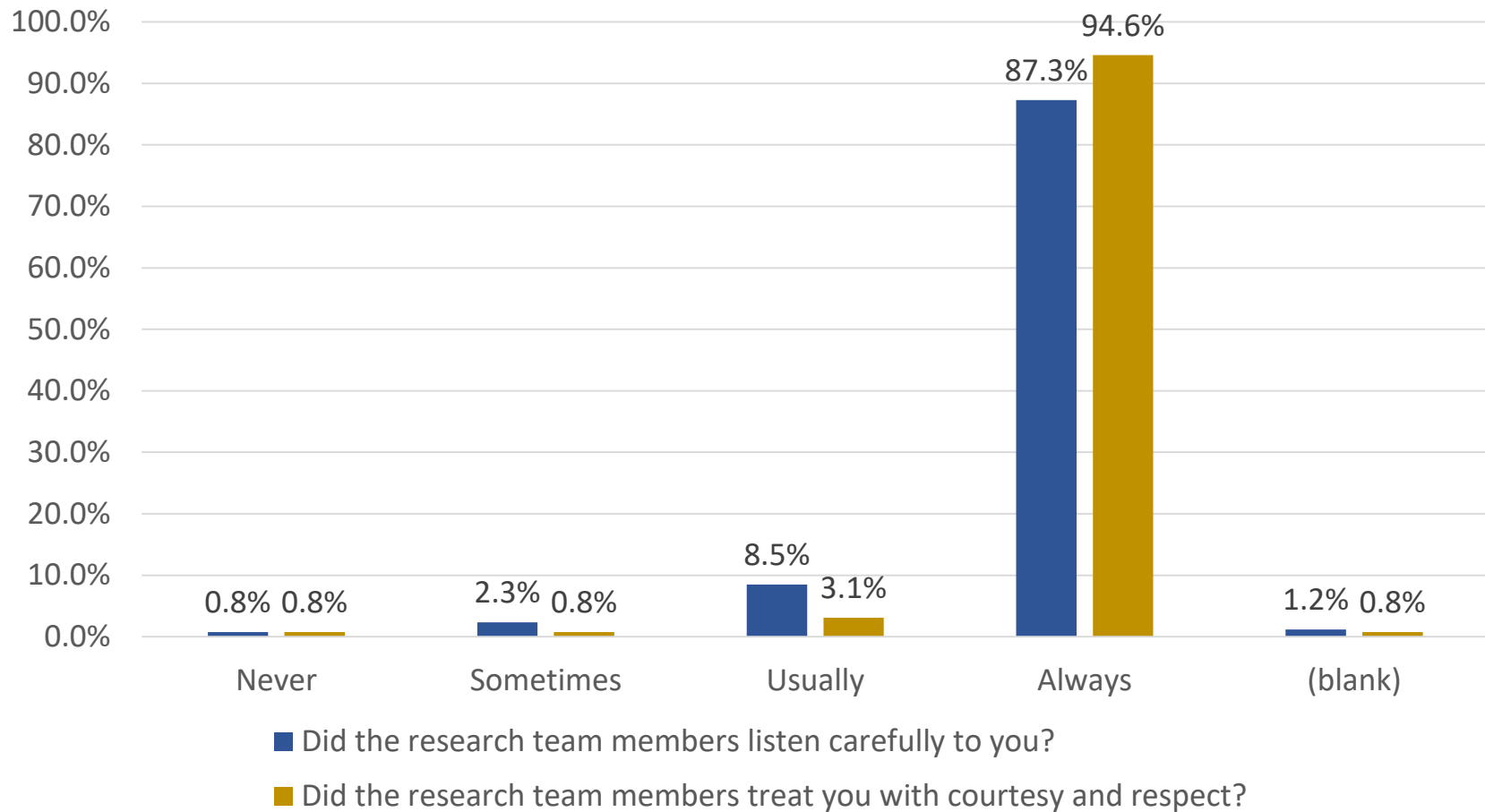




# During your discussion about the study, did you feel pressure from the research staff to join the study?



# 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 leaving the study, did you feel pressure from the Research Team to stay?	87
Did the research staff respect your cultural background (e.g. language, religion, ethnic group)?	96
Did you have enough physical privacy while you were in the study?	90

# Conclusions

- Lower percentage of younger respondents
- Lower percentages of Hispanic and Black respondents
- Overall response rate is good
- Clearly doing well in some areas
  - Courtesy and respect
  - Physical privacy
  - Language accommodations
- Need improvement in others
  - Informed consent
  - Contacting the study team

# 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